A QUEST FOR CLARITY
Reconstructing Standards for the Patent Law Morality Exclusion

Åsa Hellstadius
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Reconstructing Standards for the Patent Law Morality Exclusion

Åsa Hellstadius
To Thea, Carl, Vilhelm
and Christjan
Acknowledgments

It is often said that it takes a village to raise a child, but this proverb is equally true for the writing of a thesis, at least it was for me. The completion of this work and the forming of me as a researcher would never have been possible without the support, input and inspiration from a number of persons – my village.¹

To thank Professor, jur. dr, fil. dr h.c. Marianne Levin for only being my supervisor for this thesis would be to completely reduce her immense importance to me as a researcher and as a person. Not only is she responsible for luring me into the academia in the first place, but over the years I have also had the opportunity of working beside her on a number of research projects and teaching assignments. She is constantly enthusiastic, has a vast knowledge of intellectual property law and all this coupled with a brilliant mind, high work ethic and never-ending energy. Since we share the same sense of humour life is never dull, whether it is discussing the complex field of stem cell patents at a Commission meeting in Brussels, or shopping for make-up at the Brussels Airport when the final boarding call for the flight is announced and one has to run for 10 minutes to get to the gate in time. That is an example of the working life of Marianne, and I thank her for taking me under her wing and making me a part of it. It has been a privilege and I have appreciated every minute of it. But focusing on this thesis, I must also thank Marianne for her constant support and endless faith in me, and for her perceptive guidance when she finally received a manuscript from me. This thesis could not have been completed without her, and I am immensely grateful for her input, especially in this important final year of writing.

I wish that every doctoral candidate could have an assistant supervisor like Professor, jur. dr. Bengt Domeij. When writing your thesis, knowing that Bengt is the one you need to convince with your legal argumentation, creates an awareness of the fact that it has to be of the highest quality or you might as well give up. Apart from this, it is also a privilege to have an assistant supervisor that endures years without the doctoral candidate delivering any texts, and when a manuscript finally arrives it is under a very pressed deadline without much time to read it. Bengt not only gives excellent feedback but also manages to do so

¹ Any mistakes and errors that remain are solely my responsibility. I have probably forgotten to mention some persons in this preface, and I will thank you when we meet.
with enthusiasm. My warm thanks to Bengt for his guidance and also for acting as opponent at my final seminar.

I am very grateful to several persons who have read the manuscript during its final stages. I would like to thank Professor em., jur. dr. HonFSALS Gunnar Karnell, Judge Anders Brinkman, Patent Expert Patrick Andersson and Professor, jur. dr. Per Jonas Nordell for sharing their knowledge and taking the time to read and comment on my text. Many thanks also to Professor, jur. dr. Pål Wrangle, for his insightful remarks on the International and EU law parts of this thesis. Special thanks to Presiding Judge Per Carlson, for his advice on procedural matters and on parts of the text in general, and for his kindness. His comments were not only decisive for my analysis but his offer of help in the pressed final weeks of writing instilled vital courage in me.

My warm thanks to Professor, jur. dr. Antonina Bakardjieva Engelbrekt, who has been an important person and role model to me during my time at Stockholm university. Her academic excellence is a great inspiration and her comments on my manuscript were spot-on.

I am grateful that Jur. dr. Frantzeska Papadopoulou has not only been my colleague over the years at Stockholm university, but also my friend. She is a person dear to me and her support during my writing period has been invaluable. It is rare to find such a special person and I appreciate that we have shared many steps on this crazy journey that being a doctoral candidate has been – at least for us. I also wish to thank her for reading my manuscript and participating at my final seminar.

Writing a thesis in a different language from your native one has been a challenge, and I am immensely grateful for the excellent proofreading by Doctoral candidate Stanley Greenstein. I appreciated not only his efficient work, but also his positive attitude and calm and accommodating demeanour throughout the process.

My thanks go also to Fanny Lundström, student in Business Law, for her tremendous work with the references, footnotes, literature and list of abbreviations.

Special thanks to Librarian Cilla Öhnfeldt at Stockholm University Library, who, in a professional, kind and calm fashion, guided me through the complex process of publishing.

My final seminar also saw the participation of Professor em., jur. dr. Ingrid Arnesdotter, Advokat, Doctoral candidate Pernilla Norman, Doctoral candidate Malki Afram, and Doctoral candidate Sebastian Wärmländer. I thank you all for your contributions.

I wish to express my gratitude to the Faculty of Law at Stockholm University for securing the financing for my research throughout my employment as a doctoral candidate, and for the financing for printing and proofreading of this thesis. I have also had the privilege of receiving financial support in the form of scholarships from Stiftelsen för Åbo Akademi, Institutet för Rättsvetenskaplig Forskning,
During my years at Stockholm University I have appreciated the contact I have had with many inspiring and excellent colleagues, not least at the Institutet för Immaterialrätt och marknadsrätt (IFIM) but also within the Swedish intellectual property society generally. Being part of the Nordic IPR Network has given me the opportunity to build a network of contacts with researchers in the Nordic countries, something which I very much cherish.

I am grateful for having been able to participate in a number of exciting international research projects and establish contacts with many fantastic persons. An important source of knowledge and inspiration in the field of stem cell patents is Professor, Dr. Aurora Plomer, whom I had the privilege of working with in the Stem Cell Patent Project. Her enthusiasm was contagious and I was impressed by her sharp intellect and knowledge within the area of bioethics. I wish to thank Professor, MD, PhD Outi Hovatta for sharing her knowledge of stem cell research (I will never forget the beating heart!) which was an absolute necessity for understanding this advanced and mysterious field of biomedicine. Furthermore, as secretary in the Intellectual Property in Transition Project I especially appreciated the contacts with Professor, Dr. dr. h.c. Annette Kur and Professor Dr. François Curchod.

I am fortunate to have my current employment at the Department of Law and Legal Rights at the Linköping University School of Management. They have not only welcomed me with open arms, but have shown tremendous support in the process of completing this thesis, for which I am grateful. I especially wish to thank Senior Lecturer, jur. dr. Åsa Åslund, whose advice and support has helped me to stay on track for this last part of the journey. Warm thanks also to Lecturer, Rechtsreferendar Johannes Lerm.

The time and attention required for this thesis has made me realise how grateful I am for the support of my family and friends. I wish to thank my parents, Margareta and Jan, for providing me with a peaceful place during the last months of writing, for all the wonderful food and snacks and for the help with the children. I wish to thank my sisters Anna and Ylva and their families, as well as Elisabeth and Jan, Rosmarie, Nanny and Martin, Tove, Linnea and Nils for all the support, help with the children and for a sense of belonging that comes with being a family. My thanks also to Ulrika Öblin and the wonderful pedagogues at Grävlingen preschool for creating a warm, caring and pedagogic environment for my children.

My wonderful and dear friends – Maria, my dearest, I miss you every day and will now start commuting not only to Linköping but also to Tromsø. Cecilia, I am so looking forward to resuming our daily conversations, and special thanks for being my own Wailing Wall. Hans Christian and Pontus, thank you for being part of my chosen family. Anna, lets coordinate our events in life better in the future? Niina and Marcus, I finally have time for Finnish hot dogs! Magnus and Catharina, looking forward to time for actual conversation. Beatrice, I will
forever be grateful to you for teaching me yoga. And Ia, it is immensely reassuring to receive support from a person that understands the way you work. Thank you all for being part of my life.

Writing a thesis is often compared to childbirth, and in my case this has been comparable in the sense of bringing another baby into the household, which in our household has resulted in not only frustrated children but also (quite understandably) sibling jealousy focussed against the intruder. Luckily, this thesis, my fourth child, is now fully grown (although not due to genetic engineering) and hopefully will not need much attention in the future. During this process, my beloved husband Christjan has been the most supportive person that you could wish for. Thank you for taking care of everything during the last year. To my beloved children, Thea, Calle and Ville. You make me proud every day. This thesis is dedicated to the four of you.

Bromma, 30 April 2015

Åsa Hellstadius
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Abbreviations

BPatG Bundespatentgericht
CBD Convention on Biological Diversity
CJEU Court of Justice of the European Union
DNA Deoxyribonucleic acid
DSB Dispute Settlement Body
DSS Dispute Settlement System
DSU Dispute Settlement Understanding
EBA Enlarged Board of Appeal
ECHR European Convention on Human Rights
ECR European Court Reports
EFB European Federation of Biotechnology
EGE European Group on Ethics in Science and New Technologies
EIPR European Intellectual Property Review
EJIL European Journal of International Law
EP European Patent
EPC European Patent Convention
EPO European Patent Office
ESC Embryonic stem cell
EST Expressed Sequence Tag
EU European Union
FTA Free Trade Agreement
GATS General Agreement on Trade in Services
GATT General Agreement on Tariffs and Trade
hESC Human embryonic stem cell
HUGO Human Genome Project
ICT Information and Communication Technology
IIC International Review of Intellectual Property and Competition Law
ILC International Law Commission
IP Intellectual Property
IPR Intellectual Property Rights
IVF In Vitro Fertilization
NGO Non-Governmental Organisation
NIR Nordiskt Immateriellt Rättsskydd
OECD Organisation for Economic Co-operation and Development

2 The abbreviation ‘EPO’ stands for the Office. The European Patent Organisation is not abbreviated in the text.
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I INTRODUCTION

1 Once Upon a Time

March 2008. The European Patent Office (EPO) in Munich is under siege. Over 160 amicus curiae briefs have been filed with the Enlarged Board of Appeal (EBA) in the so-called WARF (Wisconsin Alumni Research Foundation) case, concerning the question of patents for human embryonic stem cells (hESC) and whether the invention should be denied patent protection under the so-called patent morality clause. Following this exclusion, inventions are denied patent protection if their commercial exploitation would be contrary to morality or ordre public. The briefs represented a wide range of opinions, from petitions based on religious convictions for the protection of the sanctity of human life, to pro-patent argumentation about the technical character of stem cells and the necessity of providing stem cell industries with the possibility of patent protection. The EBA denied the invention patent protection.

In 2011, the Court of Justice of the European Union (CJEU) confirmed the non-patentability of hESC in the so-called Brüstle decision, concerning a similar hESC invention. The scope of public engagement in both cases was particularly broad due to the issue under scrutiny – the patentability of human biological material. It signified the culmination of a 15-year long stream of criticism of the patent system on the basis of policy concerns regarding the granting patents to human, animal or plant life, a criticism that is still thriving today, in 2015.

The possibilities of safeguarding ethical aspects of patenting (and intellectual property (IP) in general) have traditionally been dealt with through narrow exclusionary provisions (so-called morality clauses) which have seldom been applied by authorities, apart from in rare national decisions. In Europe, Article 53(a) of the European Patent Convention (EPC) states that ‘European patents shall not be granted in respect of […] inventions the commercial exploitation of which would be contrary to ”ordre public“ or morality’. This morality clause has created counterparts in nearly all European national patent laws. This particular exclusion has a long tradition not only in patent law, but similar exclusions are found also in design and trade mark regulations. Until the 1980s this exclusion was seldom, if ever used, but this ‘patent law fossil’ has actually been vitalized by the advent of genetic engineering.

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3 G 2/06 (Use of embryos/WARF).
4 Case C-34/10, Oliver Brüstle v Greenpeace eV [2011] ECR I-9821.
5 Subject to ‘cold harmonisation’ by the functioning of the EPC.
6 See Karnell, 179-193.
Biotechnology inventions of human, animal or plant origin are both highly technical and highly controversial, and the scientific breakthroughs of the late 1970s laid the foundation for a technological development of enormous potential. Public engagement in patent processes saw a sudden increase during the 1980s, partly due to the new endeavours in biotechnology, and has since continued with unabated strength. The Oncomouse patent application, filed in 1985, was among the first controversial and debated patents and the EPO did not make a final decision in this particular case until 2003. The human gene patent races following the genome screening projects in the late 1990s and early 2000s, and the breast cancer patents awarded to Myriad Genetics (including the controversial enforcement of these patent rights), further fuelled the policy debates. In plant biotechnology, the patenting of transgenic plants and seeds has led to several discussions, e.g. the patentability of essentially biological processes for the production of tomatoes and broccoli. The self-replicating capabilities of biological material have also naturally caused legal problems. The question of whether patent rights to a herbicide-resistant plant gene (used in soy beans) covered also by the soy meal produced by the beans in question was answered in the negative by the CJEU in 2008.

Of the biotechnological advancements during the last 20 years there is no doubt that genetics and proteomics are the ones that have so far caused most controversy. The developments in the field of stem cell research has added to the public concerns regarding the effects of research into the very core of human life, which raises ethical issues such as, notably, concern for the protection of human dignity. But the protection of biological subject matter is nothing new to the patent system. Already decades ago patent authorities and courts had to reassess the limits for patentable subject matter when the first patent applications on biological subject matter emerged. As biotechnological research advances, the patent system has to follow and adapt to these developments. Since the 1980s European states have harboured a number of public and legislative initiatives in response to the challenges posed by the increasing patenting in biotechnology. Of these initiatives, the 1998 Biotech Directive, following the harmonising efforts of the European Union (EU), represents the primary achievement.

After nearly two decades of intense scrutiny of the system, resulting in the enactment of legislative adjustments with the aim of clarifying and consolidat-

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7 See e.g. T 19/90 (Onco-Mouse) and T 315/03 (Transgenic animals/HARVARD).
8 T 1213/05 (Breast and ovarian cancer/UNIVERSITY OF UTAH).
9 T 356/93 (Plant cells/PLANT GENETIC SYSTEMS), G 1/98 (Transgenic plant/NOVARTIS II), G 2/07 (Broccoli/PLANT BIOSCIENCE), G 1/08 (Tomatoes/STATE OF ISRAEL), G 2/12 (Tomatoes II) and G 2/13 (Broccoli II).
ing the European legal framework with regard to the challenges posed by biotechnological inventions, the European patent system is today characterised by a multitude of provisions designed primarily for specific types of biotechnological inventions. While many of the (both perceived and manifested) problems which prompted the legislative actions are based on ethical concerns, notably regarding the effects of granting patents for human material, animals, plants, and diagnostic or surgical methods, the approach chosen by patent legislation is to revert to and adjust the traditional delimitations, which are exclusively technical in character. Although ethical concerns arguably contributed to legislative review, the majority of current provisions require assessments of a purely technical nature.\(^\text{12}\) The only provision in patent law which today enables (or rather requires) an ethical assessment of an invention (as an exclusionary criterion in the examining process) is the morality exclusion, which is regarded by many as a necessary safety-valve in a predominantly technical orientated patent system.

The morality clause is a pre-grant exclusion, the purpose of which is to exclude from patentability, inventions whose commercial exploitation is contrary to morality or *ordre public*. The possibility to apply an ethical assessment in the patent granting process is indispensable for political, social and economic reasons. As necessary as a morality clause may appear, its existence is likewise contested, and a multitude of opinions exist on its optimal scope, interpretation and application.

Another factor in the equation is the institutional framework for European patent law which includes different legal systems on different levels (international, regional and national). The various legal acts and authorities interrelate through an intrinsic web of connections. A corresponding exclusion to the Article 53(a) EPC morality clause is found in Article 6(1) of the Biotech Directive, which in Article 6(2) adds a list of four examples of inventions that should always be excluded from patentability.\(^\text{13}\) In the international arena, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)\(^\text{14}\) contains a similar morality clause in its Article 27.2.\(^\text{15}\) Compliance

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\(^\text{12}\) The main delimitations consists of the concept of invention and the scope of patentable subject matter (Article 52 EPC), the difference between inventions and discoveries in the field of biological material (Article 3 of the Biotech Directive and Rule 26 EPC), the exclusions for essentially biological methods for the production of plant and animal varieties, including the products as such (Article 53(b) EPC and Article 4 of the Biotech Directive), and exclusions for surgical and diagnostic methods (Article 53(c) EPC).

\(^\text{13}\) Processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes. The exemplifying list was introduced in Rule 28 EPC, creating a correspondence between the Biotech Directive and the EPC.

\(^\text{14}\) Annex 1 C of the Agreement Establishing the World Trade Organization.

\(^\text{15}\) ‘Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.’
with TRIPS standards and obligations is necessary for its Members, i.e. the EU and its Member States. The diffusion of patent law rules within different systems (EU, European Patent Organisation, WTO and national systems) further complicates matters. The current legal landscape is in terms of the variety of legal rules and exclusions profoundly different from the situation twenty years ago, which naturally adds an element of institutional complexity to the already complicated legal, (bio)technical and ethical issues present in the question of patent eligibility for inventions captured under the morality clause.

The scope, function and application of the European patent morality clause in the different legal systems is the object of focus in this thesis. The wording of the general patent morality clause is technologically neutral and as mentioned, has seldom been used. Its increased application during the last few decades has definitely been prompted by the increasing protection of biotechnological inventions, which is reflected in the addition of an exemplifying list to the general clause, targeting exclusively biotechnological material. The majority of the decisions in which the morality clause has been raised and applied likewise concerns biotechnological inventions. Despite such a natural relationship, the scope of the thesis focuses on the operation of the morality clause. It is not restricted to biotech inventions and covers the whole range of patent eligible subject matter.

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16 The forthcoming creation of a European patent with unitary effect and a Unified Patent Court will contribute to further harmonising the system.
2 Points of Departure

2.1 Motives for Exclusion

The reasons for excluding socially undesirable inventions from patentability are often held to be of two types: one economic and one political. The primary economic reason is that patents for unethical inventions are a waste of social resources, as expressed by the World Intellectual Property Organization (WIPO) Secretariat at the Roundtable on the Ethical aspects of patenting inventions involving human stem cells:

The very issuance of patents represents a commitment of scarce social resources to the activities of patent offices in handling, processing and examining patent applications. Moreover, the enforcement of patents for socially undesirable, unethical inventions represents an additional engagement of resources that might otherwise be diverted to the enforcement of more useful areas of law. In many countries, on the other hand, patent offices must be subsidized because national inventors cannot afford the fees that patent offices should charge in order to cover the respective administrative costs. In those countries patents, therefore, represent a burden which society carries in exchange of the expectation of gains in inventive activity, creation of new businesses and job opportunities, transfer of technology, etc. Of course, patents for unethical inventions that society, in the first place, did not wish to be developed are not a burden – they are indeed a waste of social resources. For this single reason, patents for unethical inventions should be made unavailable, not so as to discourage their creation – because primarily, patents do not work like that – but in order to avoid the waste of social resources in protecting and enforcing those same unethical inventions.\(^{17}\)

The political reason is related to the public perception of the nature of a patent. Patents are often regarded as rewards for inventive activity, given by society as a sort of certificate, or stamp of approval, to the inventor.\(^{18}\) In extreme cases, issuing patents for inventions contrary to the social beliefs of a society would contribute to public rejection of the patent system and undermine its accountability in the eyes of the public at large.

Scrutinizing the political argument further, an additional function of the denial of protection is the removal of the incentive function of a patent, and thereby discouraging research and development (R&D)\(^ {19}\) in areas regarded as

\(^{17}\) Minutes of the Round Table organised by the European Group on Ethics in Science and New Technologies on 20 November 2001 in Brussels, WIPO Secretariat.

\(^{18}\) Cf. Holtz, 517, 519.

\(^{19}\) See Section 3.5.
unethical where the state should consequently refrain from encouraging efforts. This disincentive effect naturally varies between sectors.

When discussing the purpose and optimal function of the morality clause it is necessary to consider the actual effects achieved by a removal of patentability for certain inventions. The exclusion from patent protection for an invention has no impact on the exploitation of the invention on the market. The actual exploitation can never be prevented by the denial of patentability for the invention, only the incentive for developing the invention in the first place. Such a limitation is inherent in the nature of the exclusive right awarded by a patent, since the only effect of a patent right is to put the holder in an exclusive position on the market. The protection conferred is designed for upholding exclusive control over the invention in relation to third parties, i.e. potential competitors, infringers or licensees. The actual exploitation of the invention on the market is, however, governed by rules external to patent law, for instance, control mechanisms relative to the safety and efficacy of an invention.

Since the grant of a patent only results in an exclusive right to prevent others from using the invention, the denial of protection will only lead to a situation where the invention is free for all to use. It is undoubtedly true that this is the practical result of the removal of patentability, and it is an effect of the purpose of the patent system (granting of exclusive rights) vis-à-vis the function of the so-called regulatory system (monitoring and control of technologies by e.g. authorisation of research, clinical trials, field trials and commercialization). Monitoring and prohibiting unethical or dangerous research or use of technology is not the aim of the patent system, although the use of the morality exclusion will have such effects, albeit limited.

In terms of the wording of the morality clause, the commercial exploitation of an invention with regard to morality or ordre public becomes a central prerequisite in the assessment of excluded subject matter. Already in this formulation the focus of the patentability assessment is directed towards an act (i.e. the exploitation) in relation to which the decision of a patent grant will have a limited effect. In addition, the assessment of whether the act of exploitation of the invention is contrary to morality or ordre public will probably be mirrored by decisions or legislation within the regulatory system. This prompts the question of relation between the respective systems (patent and regulatory) and the purposes of on the one hand, the morality exclusion, and on the other hand, corresponding regulation which may have a bearing on the commercial exploitation of the invention (with or without patent protection). The requirements of the morality clause (for excluding unethical inventions from patentability) must be weighed in relation to the operation of the regulatory system with regard to the commercialisation of the said invention, in order to illustrate the purpose of the morality clause against the effects it is set to achieve. The extent to which external factors should influence the interpretation of the morality exclusion is therefore a decisive issue, and the additional element of excluding the inven-
tions not only from patent protection, but also from commercialization, needs to be considered. However, it is often overlooked not only in public discussions but also by the patent authorities. Therefore, the role of the morality clause must be assessed in light of the function of the system in which it is set to operate.

The relation between the different systems, patent and regulatory, becomes very interesting with regards to the optimal purpose of excluding unethical inventions from patentability. But the argumentation in relation to the removal of the incentive-function of the morality exclusions disregards the role and influence of patent rights on investments in research and product development. Thus, the effects of the patent system in steering developments away from socially undesirable technologies must be scrutinized. If argumentation for incentive-reducing effects has a bearing on the interpretation and function of the morality exclusion, the different roles and purposes of patent and regulatory systems are in fact merging and overlap to a certain extent. The topical question is whether patent authorities and courts should influence the allocation of resources (to the extent that patents can be seen as a resource) and removal of economic incentives for research in terms of ethics. And if this is actually the aim of the morality clause, the question to what extent the patent system is – or should be – detached from or influenced by corresponding legislation within the regulatory system is fundamental.

Against this background the theoretical framework must be identified, namely, what types of patent exclusions are possible with regards to the handling of ethical issues within the patent system, and which regime is currently in force in Europe today? Furthermore, the relevance of moral considerations within the patent system must be assessed in relation to the delimitation between the patent and regulatory systems. The tailoring of the handling of ethical issues within a patent regime is subject to three possible approaches: the facilitative approach, the restrictive approach or a patent regulatory regime that is neither light nor heavy, but deals with each application strictly on its merits. These approaches will be discussed in the following Section 2.2.

2.2 Advocating Patent Ethics’ Regimes

The extent to which patent authorities should regulate ethical issues in the granting of patent rights is subject to three possible approaches: the facilitative approach (favours a light patent-moral regime), the restrictive approach (favours a heavy patent-moral regime) or the approach for a patent-moral regime

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20 Pires de Carvalho, 13.
21 Beyleveld and Brownsword, xv.
that is neither light nor heavy, but deals with each application strictly on its merits.22

The arguments for the facilitative approach, i.e. favouring patentability and keeping moral considerations to a minimum, are based upon the notion that law must keep pace with science, and that the law should include dynamic elements where new developments should be as protection-worthy as those recognised by the legislation at the time of its drafting. The incentive role of the patent system requires that protection should be available for investments in R&D, even though such investments cannot be guaranteed any return. If the European patent system upholds a restrictive or unpredictable application of morality, then the benefits of the new technology will be lost for Europe. The possibilities for Europe to compete on the international arena against opponents such as the US and Japan is often stressed in this regard, and it has been advocated that the European patent system needs to keep in step with those competitors in terms of restrictiveness.23

The arguments in favour of a restrictive approach, i.e. a broad scope for the application of ethical issues as a ground for excluding patentability, are usually more diverse and reflect a variety of concerns, often connected more with the underlying technology than with the patenting of the said technology. Such arguments include the notion that it is intrinsically wrong to interfere with nature, the hazards involved for humans, animals and the environment, the violation of animal rights, the commodification of human beings and the incorrectness of granting private property rights over humans – or human material such as genes.

Rather, the dividing line between opponents and proponents of either regime reflects the view of the proper arena for the regulation of morality in relation to research and commercialization (including inventions), than the preferred level of morality exercised within the patent system. In essence, the main dividing line is more about which system should exercise a moral jurisdiction – the patent system or the regulatory24 system (i.e. society through regulatory laws). Those favouring the regulatory system as the correct arena view the patent system as a system exercising only purely technical criteria for the granting of a patent. The proponents of a moral jurisdiction within the patent system include moral conceptions as a part of patentability, which is in line with the current patent legal systems in Europe.

Beyleveld and Brownsword present two rival views of the inherent jurisdiction of patent authorities and courts, and thus, the relevance of moral considerations within the patent system. These views are the ‘purely technical’ and the

22 Beyleveld and Brownsword, xv.
23 Id., 25.
24 Beyleveld and Brownsword labels this system ‘political’.
‘moral’ conceptions about patentability. The purely technical conception of patentability asserts that an application for a patent should only be granted provided the invention meets the standard criteria of inventiveness etc. According to this theory, morally contentious patent applications should be dealt with under a two-stage procedure: ‘first, the patent system should resolve questions relating to inventiveness; secondly, the political system should resolve the moral (and broader regulatory) questions’. On the other hand, according to the moral conception of patentability, moral objections are an important part of patent determinations within the system as such. The moral conception may be of a weak or strong form. The weak form of the moral conception makes the inclusion of moral considerations in the patentability considerations merely permissible. In the stronger form of the moral conception the patent examiners are required to address the moral issues associated with patent applications.

The purely technical conception of patentability should not be interpreted as having insensitivity towards moral issues. On the other hand, moral issues may well have a place in this system. The difference towards the moral conception of patentability is that where the latter sees moral issues as a matter for the patent system, the former claims that the moral issues should be dealt with by the political system, e.g. the regulatory systems present both pre- and post-patent grant.

Since the EPC incorporates the moral conception in Article 53(a), there is by default an obligation for examiners to address morality, and under the present system the conception in question must be labelled as strong. The possibility to do so is only present under this specific provision, in as much as it is an integral part of the patentability assessment. To follow a purely technical conception of patentability is thus not possible under the limits set by the European Patent Organisation, since the states have delegated their powers of examination and grant of patents to the EPO, in parallel to their national patent systems. In addition the national patent offices and courts are bestowed with the task of supervising the post-grant life of European patents. The main question under the moral conception is the function of the morality clause in the present European system. But from a theoretical point of view, the abstract merits of the different conceptions of patentability are still worthy of assessment, with regard to the division of competences between patent and the regulatory systems in light of the respective purposes of the systems in question. If no moral jurisdiction should be conferred upon patent examiners, no merits can be seen for the existence of Article 53(a) EPC.

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25 See Beyleveld and Brownsword, 33 ff.
26 Id., 34.
27 In this thesis, the term European Patent Organisation is used for the Organisation, including the Administrative Council and the European Patent Office. The abbreviation EPO is used for the European Patent Office.
Many of the moral questions that are topical today are intrinsically tied to the development of biotechnology, gene technology and associated research. The argument can be conveyed that the original mandate given to the EPO did not extend to the kinds of moral dilemmas presented by new technologies. However, this is a weak argument. Biotechnology and especially gene technology was nothing new at the time of drafting of the 1973 EPC. Such dilemmas were arguably not beyond the contemplation of the Contracting States. The adaptive character of the patent system makes it nearly impossible to argue that the mandate given to the examiners of the EPO under Article 53(a) EPC would only cover moral dilemmas conceivable at the time of drafting.28

An important aspect of the European patent system is its capability to adjust to the development of technology. Even though new technologies create difficulties in the application of established patent rules and principles, the system has been able to readjust and settle in the wake of technological challenges. The core patent criterion of inventive step is a perfect example of a patentability criterion that constantly shifts and changes with technological achievements. But the moral aspects of patenting are perhaps something entirely different from the technical aspects, and therefore should be separately judged and interpreted.

Rather, this reasoning brings about a need for a more nuanced view of the functioning of moral issues in the patent or regulatory system. The regulatory system has not disqualified itself from the domain of moral issues involved in patenting by giving competence to the patent system to deal with questions of morality associated with patentability. To the contrary, the regulatory system retains an authority on questions related to morality, specifically such regulatory rules connected to research ethics and authorisation of research, clinical trials, field trials and commercialisation.

2.3 The Efficiency Perspective

As mentioned in Section 2.1, the economic argument for excluding unethical inventions from patentability is the waste of social resources that such inventions represent. The question of morality could therefore also be seen from an efficiency perspective.29 By addressing morality in the patent examining process, the process is undoubtedly delayed for cases involving such considerations, compared with the situation in which morality is assessed outside the patent system. However, if the moral assessment is done outside the patent system, according to the technical conception of patentability, some kind of moral con-

28 Cf. Ekelöf and Edelstam, 74 f.
29 Beyleveld and Brownsword, 39.
sideration must necessarily take place before the patent can be commercially exploited. Thus, the correct way of dealing with the efficiency question is therefore to pose the question whether the most efficient system is one where moral considerations are invoked during the patent examination procedure; or one where the moral scrutiny is done after the technical examination of the invention.

There are several different alternatives for the institutional setting of an efficient treatment of morality in the patent procedure. Beyleveld and Brownsword suggest three models:

1. the Patent Office considers technical and at least some moral issues;

2. the Patent Office considers only technical issues, and the regulatory systems of the individual Contracting States deal with the moral issues;

3. the Patent Office considers only technical issues, and some other delegated courts or committees deal with the moral issues.30

The first model follows the present moral conception, while the two latter demonstrate a technical conception. According to Beyleveld and Brownsword, model no. 2 is the least likely to be efficient. The solution would in this case be to allocate parliamentary subcommittees or similar groupings to assess morality in individual patent applications. From the point of view of the purely technical conception it seems as if no. 3 would be the preferable solution from an efficiency perspective. However, this alternative bears the same efficiency problems as no. 2. The only argument against a no. 1 solution would be that the examiners at the patent authority are not qualified to make moral decisions with regard to patent applications. The argumentation is thus dependent on the view of the moral dilemmas posed by patents. If the point of view is endorsed that moral experts are needed, and that patent examiners could never acquire the expertise needed to make moral assessments, then alternative no. 3 is preferable. But if it can be assured that the patent examiners gain expertise and qualification to deal also with moral assessments, then no. 1 must surely be a preferable option from the efficiency perspective compared to alternative no. 3. The current situation in European patent law follows a technical and a moral conception as expressed in no. 1, following a ‘strong’ moral conception (i.e. required, not merely permissible), which is consequently the natural point of departure for the study at hand.

30 Beyleveld and Brownsword, 40.
2.4 Object and Purpose

The purpose of this study is a comprehensive analysis of the function of morality exclusion under European patent law by Article 53(a) and Rule 28 EPC and Article 6 of the Biotech Directive. Another related purpose is to describe, problematize and analyse the compliance of EU rules with the international framework provided by Article 27.2 of the TRIPS Agreement. The object of this study is the scope, interpretation and application of the morality exclusion in European and international patent law.

The texts of Article 6 of the Biotech Directive and Article 53(a) EPC are nearly identical, while Article 27.2 TRIPS has a slightly different wording. All three versions of the exclusion contain the same fundamental concepts:

- morality and *ordre public*
- inventions,
- commercial exploitation, and
- the so-called proviso/qualification.31

The study of the function, application and interpretation of the morality exclusion necessitates recourse to the prerequisites contained therein. Thus, the function and scope of the morality clause necessitates a study of its requirements and the context in which it operates, and for the purpose of analysis the following five general research questions are considered in the study:

1. What is considered as ‘commercial exploitation of the invention’ in the context of the morality clause assessment?

2. How are the concepts of morality and *ordre public* defined and assessed?

3. Is the interpretation of the morality clause in the EU (and the EPO) compliant with the requirements of Article 27.2 TRIPS?

4. What is the relation between the patent law system and regulatory legislation regarding the operation, function and scope of the morality exclusion?

5. Is there an optimal scope, interpretation and function of the morality clause in the current legal and economic context, especially with regard to biotech patents?

31 Article 6.1 of the Biotech Directive: ‘exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation’. Article 53(a) EPC: ‘such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States’. Article 27.2 TRIPS: ‘provided that such exclusion is not made merely because the exploitation is prohibited by their law’. The terms ‘qualification’ and ‘proviso’ are used in doctrine. The term ‘provisio’ is also sometimes used. In this thesis, the concepts of ‘qualification’ and ‘proviso’ are used in an interchangeable manner.
In the following the five research questions are expanded and problematized.

(1) What is considered as ‘commercial exploitation of the invention’ in the context of the morality clause assessment?

For each of the morality exclusions the commercial exploitation of the invention is crucial for the operation of the clauses because it has an important bearing on the scope of the assessment. According to the literal terms of the exclusions, the object of focus is the commercial exploitation of the invention, not the invention as such, nor the technology or the act of granting a patent. The actual function and content of this qualification has proven difficult to establish, and the legal sources display a range of interpretations of this particular concept. The basic issue is the scope of relevant considerations to be taken into account when considering whether the commercial exploitation of an invention is contrary to ordre public or morality. An important question is, for instance, whether activities during the development of the invention are subsumed under the concept of commercial exploitation of the invention. Of specific interest is the question of prior informed consent to the donation of human biological material, and how this particular research-ethics requirement is dealt with by patent law. The breadth of the commercial exploitation requirement will consequently have a fundamental effect on the operation of the clause. Similar considerations apply to the scope of the concept of invention and the qualification/proviso in the last sentence (targeting prohibitions on exploitation). In order to analyse the aspects of the general research question, the following sub-questions will be considered:

- How is the concept of ‘commercial exploitation’ defined, and what impact has the term ‘commercial’ on the scope of application of the concept?

- Are factors regarding the development of the invention, the technology underlying the invention or the socio-economic effects of the patent included in the concept of commercial exploitation, and consequently in the assessment?

- How is ‘commercial exploitation of the invention’ assessed with regard to the exemplifying list in Rule 28 EPC and Article 6(2) of the Biotech Directive? Is there a difference between the general exclusions in Article 53(a) EPC and Article 6(1) of the Directive and the exemplifying list in this respect?

32 In this context, the concept of invention refers to the scope of the subject matter under scrutiny, i.e. the claims, description and/or the technical teaching.
- How is the scope of the subject matter under scrutiny delimited, i.e. what is considered to fall within the concept of ‘invention’ in this context?

- How is the question of prior informed consent treated by patent law, in connection to the morality clause?

- What impact do the prohibitions on the commercial exploitation of the invention (the qualification/proviso) have on the outcome of the assessment?

(2) How are the concepts of morality and ordre public defined and assessed?

The concepts of morality and ordre public are fundamental to the application of the clause, but their content does not result or stem from the legal sources at hand, namely legal practice, preparatory works or legal doctrine. The influence of non-legal sources is therefore necessary in the interpretation of these concepts, which makes such an assessment difficult, to say the least. Morality and ordre public are adjustable concepts and flexible enough to adapt to the characteristics of different societies and their development. The context in which they are applied necessarily influences their content. Although the core content of ordre public is described as the protection of public security and the physical integrity of individuals and morality is defined as a body of ethical norms, the crucial problem is not the actual description of what constitutes morality or ordre public but rather the method for determining and establishing their content in each decision.

A number of tests are identified in the practice of the EPO. Of interest are also the standards of (especially) morality, or rather, the level of perceived immorality on the part of the public. For instance, the EPO currently uses two alternative standards, unacceptability or abhorrence, which represent different levels of immorality. It is also crucial to describe the limits set by the procedural framework for the EPO, namely the roles of the parties in relation to the Office and to analyse the possibilities for argumentation in different types of processes. More specifically, the treatment of evidence to substantiate the facts is highly relevant to the issue. As identified in the previous section, the role of the commercial exploitation of the invention must be addressed in the assessment.

The morality clause enables an influx of (patent-)external ethical considerations into the patent system, and a fundamental issue is, as mentioned, the pa-
tent system approach towards recognizing and including existing values from the regulatory system in the assessments. Another aspect is the theoretizing of the ethics’ framework, by taking into account the classical schools of ethics and ethical philosophy, and the relation between ethics and law on a general level. To the extent that moral approaches are identifiable as foundations for legal sources (specifically law and legal practice) in the application of the morality clause, these will be described and presented. However, the purpose and aim of this study is the evaluation of the morality clause from a legal point of view, and not the philosophical theories within the field of ethics.

Against this background the following sub-questions relative to the general question of *ordre public* and morality are formulated:

- What tests are used for the assessment of *ordre public* and morality?
- Which standards of *ordre public* and morality should be used, i.e. is there a preferred level (on behalf of society) for when an invention is to be considered contrary to morality or *ordre public*?

(3) Is the interpretation of the morality clause in the EU (and the EPO) compliant with the requirements of Article 27.2 TRIPS?

A study of international law and the principles of e.g. direct effect is conducted with the aim of treating the extent to which (first and foremost) the EU is bound by TRIPS obligations as a WTO member. The influence of TRIPS is further complicated by the fact that it is a so-called mixed agreement to which the EU and the individual EU Member States are parties, in both capacities. To compare and problematize the functioning and effects of the morality clause in the different legal settings requires an understanding of the different legal systems (the EU, the European Patent Organisation and the WTO), their characteristics and interrelations. The operation of the morality clause in the Biotech Directive, within the EU legal system has contributed to an exacerbation of the independency of the morality assessment and the detachment of patent law ethics from traditional norm setting in other fora, even in EU law in general. This development has implications for the internal functioning of the morality clause. For instance, the current CJEU interpretation of Article 6(2)(c) of the Biotech Directive could be criticised as not adhering to the legal framework created by the requirements of the exclusion in Article 6 of the Directive. Furthermore, the compliance of Article 6 with the international framework in terms of Article 27.2 TRIPS is called into question. Thus, it is necessary to assess whether the EU-legislation is compatible with the authorization to exclude inventions on the ground of *ordre public* or morality concerns that Article 27.2
TRIPS allows (but does not mandate). This study is therefore also directed towards the following questions:

- How should the requirements of Article 27.2 TRIPS be interpreted and what effects will the outcome of such an interpretation entail for the treatment of the morality clause in Article 6 of the Biotech Directive by the CJEU?

- If Article 6 of the Biotech Directive is found to be non-compliant with Article 27.2 TRIPS, what are the effects for the EU and the EU Member States, respectively?

- In the case of a norm conflict, is legislative review of the Biotech Directive a possibility?

- What are the effects of the international framework of Article 27.2 TRIPS on the application of Article 53(a) EPC?

(4) What is the relation between the patent law system and regulatory legislation with regard to the operation, function and scope of the morality exclusion?

Since biotechnology is research intense and has ethical connotations, an important aspect is the division of competences between the patent system and the regulatory system and its effects on the application of the patent morality clause. The unique characteristics of patent law ethics are supported by the fact that although the role of ethics and morality is recognised in the patent system in terms of the morality clause, the interpretation of this particular exclusion has been performed by the EPO on an ad hoc basis with little or no recognition of the existing regulatory systems in force in Europe. While the EPO has to a certain extent searched for common European values, the impact of existing legislation on the interpretation of the morality clause is scarce, or non-existent, in EPO case law. Likewise has the CJEU found hESC inventions non-patentable, where the subject matter of the invention was otherwise free to commercialise in, at least, some of the Member States. If the aim of the moral assessment is to protect values which are already expressed in regulatory legislation e.g. the human dignity and welfare of animals, then the question of whether or not the patent legislation and decision-making process needs to be adjusted to the regulatory systems for the protection of such values must be considered. The efficiency of reaching these goals of protection is, however, bound to have a greater impact via the regulatory system, than if a patent examiner excludes a number of inventions from patent protection on the grounds of moral-
ity. The relation between regulatory bodies and the patent system is not exclusionary but complementary. By means of the moral provision in patent law, the system should merely act as a filter against unwanted inventions, which complements the sanctioning role of other bodies. This thesis advocates that the EPO should to a larger degree consider the existing values and norms expressed in the national (non-patent) regulatory legislation in force when interpreting the EPO morality clause. More specifically, the extent to which the regulatory system should have an impact on the interpretation of the patent morality clause, is a fundamental issue and necessitates an analysis of the relation between the patent law system and regulatory legislation with regard to this specific provision.

(5) Is there an optimal scope, interpretation and function of the morality clause in the current technical, legal and economic context?

The European morality clause has been reinvigorated by the advent of biotechnology and the possibilities of patent protection for inventions in this domain. Although the primary focus of this study is the morality clause in general, without any delimitations as to the material subject matter, its function within the specific field of biotechnology patents is nevertheless important to take into consideration. The question of the role of biotechnology patents in the current legal and economic context and its relation to the fundamental functions of the patent system is consequently outlined and described. This study includes the identification of the purposes and the evaluation of the substantive effects of the different provisions. In this respect, systematization of the material, development of concepts, analysis of arguments and possible solutions, creation of principles and theories, and a critical evaluation of de lege lata are necessary components. The aims of the legislators are in this respect compared to the treatment of the rules by authorities and courts. The analysis therefore requires a description of the historical developments and the current legal context of operation of the morality clause. Furthermore, the overarching functions of the patent system in general need to be acknowledged and contrasted against the outcome of the analysis with regard to the current function of the rules.

34 See Warren-Jones 2007, 832.
2.5 Delimitations

The focus of this study is the operation of the patent morality clause in Europe, within the framework created by international and regional agreements. National law is not the object of study and national sources will generally not be used in the thesis. The role of the morality clause in the new system of European patents with unitary effect and within the forthcoming Unified Patent Court will not be studied either.

This study focuses on the prerequisites in the morality clause in Article 53(a), Rule 28 EPC, Article 6 of the Biotech Directive and Article 27.2 TRIPS. In this context, the concept of invention denotes the question of scope of subject matter to be evaluated in the assessment of the exclusion, namely to what extent is material external to the invention/technical teaching (i.e. claims and description) included within a morality evaluation? The traditional question of definition of an invention within patent law, i.e. the delimitation of patentable subject matter under the ‘invention’ concept under Article 52 EPC (and Article 3 of the Biotech Directive) is not treated in this study.

Many provisions are the result of ethical considerations pushing the legislative process, such as Rule 29 EPC and Article 5 of the Biotech Directive on the human body and its elements (notably human genes), Article 53(b) EPC and Article 4 of the Biotech Directive regarding plant and animal varieties and essentially biological processes, and Article 53(c) EPC on medical methods. These provisions are excluded from this study, primarily because their application does not contain any ethical evaluation. The interpretation of these provisions requires a strictly technical assessment of the subject matter under scrutiny.

For the purposes of this thesis, the concepts of ethics and morality will be treated from the point of view of their relation to and relevance for patent legal systems. The aim is to analyse the operation of the European morality clause from a legal dogmatic perspective, and to evaluate the problems associated with the application of this clause within the European patent system. For the completion of this task there is no need to consider a different branch of science, i.e. philosophy, but it suffices to investigate the implications of moral approaches which exist and function as foundations for the application of the patent law morality exclusion. Although there is of course an element of ethics and recognition of values in the morality clause, the approach is a legal practical point of view.

The patenting of biotech inventions is a natural focus of this thesis, because the nature of such inventions creates a complex field of legal, bio(technical) and ethical issues, prompting an interest in the possibilities of the morality clause and an increase in its use as a basis for recourse in patent proceedings. The study is, however, not limited to a particular field of technology, but rather has a technologically neutral departure point in its coverage of the morality clause. Nevertheless, due to the impact that biotechnology has had on the morality
clause and in the development of case law, specific regard is paid to the field of biotechnology innovation and patenting and the effects of limitations on patentability in this domain.

The licensing of biotechnological inventions will not be studied. Neither will topics pertaining to collaborative licensing solutions and liability rules or compulsory licensing schemes. The core patentability criteria of novelty, inventive step and industrial application are not studied either, as these are not considered especially problematic at present, due to, for instance, the successfully stringent application of these criteria conducted by the major patent authorities. The invention/discovery dichotomy has also been elaborated upon in a number of academic publications. Gene technology has already been the object of much scrutiny and the implications of the specific legal exclusions for gene technology will therefore be left aside for the purposes of this study.

2.6 Method and Material

The research for the purposes of this study is conducted with recourse to the normative legal dogmatic method. This method is the primary scientific method for the systematization and interpretation of legal rules. The legal dogmatic perspective includes the systematization of legal provisions and legal concepts as well as interpretation and qualification of the content of the rules. This study is aimed at evaluating the purpose and function of the rules and to critically evaluate the law. The aim of the interpretative part of this study is to identify, problematize and clarify the application of the legal provisions in certain contexts.

The main purpose of legal science is to treat the legal sources of law (in some traditions also preparatory works), practice, doctrine and customary law, with the aim of describing the fiction of ‘the law in force’. The legal sources are used in accordance with the doctrine on the hierarchy of the legal sources. The focus is on the legitimacy and treatment of the legal sources, and their eventual internal hierarchy need not be described or explained. The legal sources doctrine provides a framework for the work of legal science. Legal science is based on the contents of the legal sources, namely the material law. Thus, the legal sources are used to create a unity in the argumentation.

The systematization of law is primarily aimed upon the grouping together of rules and contexts into manageable units. In this study, the interpretation of the legal rules and other norms is based on law, preparatory works and case law (administrative and judicial). The legal provisions must always be interpreted in

harmony with international cooperation which is the basis for the texts in the conventions. Court decisions and other case law is consequently of great importance.

Secondary sources of importance include doctrine and other theories and arguments, e.g. sources contributing to ethical argumentation. This study is directed towards an internationally harmonised domain and includes several countries. The extent of available legal literature is therefore vast. A certain selection is necessary and the choice of sources will be based on formal authority, factual impact, and the language skills of the author. An account of dominant opinions will be given and the lines of argumentation will be analysed.

Other interesting material are the guidelines from the patent authorities and opinions and reports from (international and national) ethical boards, as well as the Opinions from the Advocate General of the CJEU. There are also reports on the implementation of EU legal acts, such as the directives. Material which has an indirect bearing on legal provisions will also be analysed. However, these types of material have in some cases not reached the status of primary legal sources, and their contribution will thus be evaluated accordingly. But in this specific domain of patent law, they may contribute to a greater understanding of the complex legal landscape of the application of the morality clause in a (predominantly biotechnological) sector.

The sectioning of the operation of the morality exclusion in various legal systems and on different levels requires a description of the institutional framework of European patent law, and a comparison of the different legal systems and frameworks. On the one hand, patent law in Europe is to a large extent harmonised through the EPC and the Biotech Directive, as well as through other international instruments such as the Paris Convention on the protection of industrial property, TRIPS and the Patent Cooperation Treaty (PCT). On the other hand, the domain of harmonisation does not, however, stretch further than the criteria for protection; i.e. the examination and granting stages (pre-grant). European patent law is further complicated by the institutional division of competences. The granting of patents may be conducted on the national or on the European level. A joint system for application, registra-

36 The majority of the sources are written in English, but sources from the Nordic states are also used. Sources written in German are not used in the study.
37 The Guidelines give instructions about the practice and procedure to be followed in the various aspects of the examination of European applications and patents in accordance with the European Patent Convention and its Implementing Regulations. These Guidelines are addressed primarily to EPO staff but it is hoped that they will also be of assistance to the parties to the proceedings and patent practitioners, since the success of the European patent system depends on the cooperation between the parties and their representatives on the one hand and the EPO on the other. The Guidelines are intended to cover normal occurrences. They should therefore be considered only as general instructions. The application of the Guidelines on individual European patent applications or patents is the responsibility of the examining staff and they may depart from these instructions in exceptional cases. Nevertheless, as a general rule, parties can expect the EPO to act in accordance with the Guidelines until such time as they - or the relevant legal provisions - are amended. See further the Guidelines for Examination in the European Patent Office (November 2014), General Part, 3.
tion and examination of patents is created through the cooperation within the European Patent Organisation with the EPO as the central authority. The EPO-procedure regulates the creation of patent protection but the afterlife of a patent is subject to the legal systems of each national state in which the patent is valid. When a patent is granted the scope of protection becomes a matter for national law (and EU law in the case of biotechnological inventions through the Biotech Directive).

The fact that the only substantive EU legislation on patents exclusively covers the area of biotech patenting influences the scope of relevant considerations. The Biotech Directive’s provisions are introduced in the EPC, which makes the EPO Appeal Boards and Divisions competent to interpret the rules in question. The legal practice from the Boards of Appeal of the EPO is normative for national patent law in most of the European states. The CJEU is the precedential instance for questions within the Directive’s area of competence within the EU legal order, with impact on national law regarding interpretation of the rules on biotechnological patents. Presently there is an institutional division of competence between two institutions (CJEU and EPO) with normative character, i.e. they are the highest instances regarding cases on biotechnological patents. All EU Member States are also Members of the EPO, which makes them subject to this division of competence. The systems of the EU and EPO are each unique and there is no mechanism that binds the two entities together. This division of competence could give rise to considerable problems in questions where the view of issues is different on the different levels: nationally, EU and EPO. The institutional problems influence the practical effect of the provisions in the national states which are Members of the respective systems and must therefore be considered in this investigation.

The presence of a facultative patent morality clause in Article 27.2 TRIPS necessitates the exploration of the scope, function and effects of this provision in relation to the systems of the EU and EPO respectively. The fact that TRIPS is a so-called mixed agreement in terms of competences of the EU and its Member States adds further complications to the framework, since the obligations of the Agreement exist not only in relation to the EU as a WTO Member, but also in relation to the individual Member States of the EU. Although these legal relationships are not the main focus of this thesis, the effect of such a division of competence is important in relation to one of the research questions, namely to what extent does the EU (and perhaps the EPO) comply with its TRIPS obligations in relation to Article 27.2 and what, if any, are the effects in case of non-compliance? The impact of international law in the specific field of trade law captured under the WTO Agreements must therefore be scrutinized, including its impact on the WTO Members. The possibility of analysis of

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38 At least until the system for a European Patent with Unitary Effect enters into force. See Chapter 11.
the scope of Article 27.2 TRIPS requires a description of the international law system, principles, sources and conflict of norms, with specific focus on the WTO and its Dispute Settlement System (DSS) procedures. A connected issue is whether EU law can be subject to (internal) legislative review if non-compliance with TRIPS is established.

Two of the central prerequisites of the morality exclusion are the concepts of morality and *ordre public*. The understanding of these concepts is arguably not possible to deduce from legal sources, but have to be established by recourse to findings of norms of a different character other than purely legal ones. Procedural aspects are important considering the different stages that a patent application (or patent) may be subject to and consequently, different authorities are considered competent. Pre-grant procedures of examination and decisions of grant or refusal of the application is executed within the administrative system of the patent authority.

For instance, the first-stage interpretation of the morality exclusion takes place within the administrative system of the EPO during the pre-grant examination procedure. It is essentially the Examining Division that investigates whether the (commercial exploitation of the) invention in the patent application is contrary to morality or *ordre public*. Possibilities for post-grant appellate review of the patent exist within the appellate review procedure within the EPO, if notice of opposition is filed within nine months from the notification of the decision of grant. Moreover, a decision of refusal to grant a patent may be appealed within two months from the notification of the decision. The appellate review is performed mainly by the Boards of Appeal, administratively connected to the EPO, but this does not automatically render the procedure purely administrative in character. Depending on the situation, proceedings could be *ex parte* or *inter partes*, which naturally affect the character of the process.

In addition, the granted patent may be subject to post-grant procedures of invalidity (and infringement) in civil courts in the national states of the European Patent Organisation, under the final guidance from the CJEU in cases of patents on biotechnological inventions. In the future, a European Unified Patent Court (UPC) will be competent to judge matters. Consequently, in the future, the interpretation of the morality exclusion may take place under different procedural rules, settings and competent authorities.

The systems investigated are not comparative from a material law aspect, and the analysis of the law must be conducted against the background of the

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39 National patent practice is not included within the scope of this thesis. See Section 2.5.
40 Article 99 EPC.
41 Articles 106-108 EPC. See Chapter 10 for the EPO procedure.
42 Holtz, 64.
43 Id., 74-75.
44 National law is delimited from the scope of this thesis. See Section 2.5.
systems’ functions, organisation and features. In this context it may be appropriate to discuss whether the consequences of the differences in the material application of the legal rules are an effect of the rules as such or the absence of a functioning harmonisation. The results of the institutional division of competences are quite obvious in this respect. The division of the legal rules into different levels – national, EU and international – and the practical aspects of harmonisation will therefore bring an additional dimension to the analysis. Specific aspects regarding the material, sources and procedures applied in the different systems will be described in Part III (the Institutional Framework).

2.7 Research Front

The patent morality clause has been the object of a comprehensive jurisprudential treatment over the years which has resulted in numerous doctrinal sources.45 Those focusing on Article 27.2 TRIPS are naturally characterised by the international context and many treat the issue from the environmental law perspective.46 The division of competences between EPO and national states, and the introduction of an EU patent law morality clause through the Biotech Directive has also gained scholarly attention.47 The CJEU and EBA decisions on patent applications covering hESC, as well as stem cell patents in general, is the focus


of a large amount of the writing. As obvious from the amount of sources, the operation of the patent law morality exclusion covers a vast range of different aspects, of which the totality is difficult to grasp within the scope of a minor study or article. But a study of the total breadth of the exclusion, focusing on the internal relations of its requirements and the effects for its interpretation from a legal scientific point of view, without a specific material focus, has not yet been conducted. More specifically, the legal uncertainty with regard to the role of the notional concept of commercial exploitation in the application of the morality clause, as witnessed by differences in legal practice (as well as various opinions in the doctrine), necessitates attention. The necessity of preventing the commercial exploitation of an invention is also a decisive (and contentious) issue in the context of Article 27.2 TRIPS. The lack of a study which from a legal dogmatic point of departure takes into account the interpretation and effects of the totality of the prerequisites of the morality clause, including the interrelations between the international and regional legal systems in this respect, prompted the launch of the research leading up to this thesis. The handling of the different aspects of the morality clause not only requires but necessitates a treatment as defined by the scope of this study.


2.8 Structure

This study is divided into five parts. In this first part, Introduction, the points of departure are presented in terms of background, problem, object of study, methodological issues and an overview of key concepts.

Part II, Patents, (Bio)Technology and Ethics describes in Chapter 4 the development and challenges posed by the advent of biotechnology in the patent law domain. The various theories of justification for patent protection are presented and related to the practical effects of biotech patenting, including the role and status of patents in the knowledge based economy. This part also contains Chapter 5 with an overview of the current theoretical framework of the relation between law and ethics, including a presentation of the dominating moral approaches in the field of biotechnology in general, which are predominantly used to justify exclusions from patentability on ethical grounds. In Chapter 6 the justifications and critiques are summarized.

The following Part III presents the Institutional Framework. Chapter 7 contains a description of international law and the relation between international conventions and EU-law and national law respectively. The purpose of this part is to create a framework for an analysis of TRIPS-compliance especially on behalf of the EU-legislation with regard to the morality exclusion. Chapter 8 treats the international patent law. The remaining Chapters 9 and 10 describe the characteristics of the EU and the European Patent Organisation respectively, with regard to issues of legitimacy and principles for interpretation, including the interrelation of the respective legal acts. In Chapter 11 the future perspectives for the European patent system are discussed, especially with a view to the forthcoming unitary patent system.

Part IV is devoted to the Patent Law Morality Exclusions with a view to their respective legal context, scope, requirements and approaches to interpretation. Chapter 12 treats Article 27.2 TRIPS, Chapter 13 covers Article 53(a) and Rule 28(c) EPC and Chapter 15 focuses on Article 6 of the Biotech Directive. Chapter 14 contains a background consisting of the treatment of morality and *ordre public* in the case law of free movement as well as an overview of the drafting process of the Biotech Directive.

Part V contains the Final Remarks in the form of an analysis of the functioning of the patent law morality clauses in accordance with the research questions as identified in Section 2.4. The aim of this part is to analyse the conclusions with regard to the concepts as well as the relation of the three respective systems (WTO, EU and European Patent Organisation). Chapter 16 focuses on the concept of commercial exploitation, Chapter 17 treats the concepts of morality and *ordre public* and Chapter 18 contains an analysis of TRIPS-compliance. Chapter 19 discusses the findings of the relation between patent and regulatory systems, and in Chapter 20 the conclusions and recommendations of this thesis are presented.
3 Key concepts

Throughout this thesis a number of specific concepts are used to explain and build the framework. These terms require explanations and definitions. The aim of this chapter is to provide short descriptions of such commonly used concepts, and consequently focuses on the following terms: biotechnology and life sciences, stem cells, the regulatory system, ethics, morality and values, and innovation and R&D.

3.1 Biotechnology and Life Sciences

Karl Ereky, a Hungarian scientist, is often quoted as being the founder of the biotechnology concept. He introduced the term biotechnology in 1917 and defined it as ‘all lines of work by which products are produced from raw materials by the aid of living things.’ The latest OECD definition is somewhat more detailed: ‘the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.’ The European Federation of Biotechnology (EFB) defines it as ‘the integration of natural sciences and engineering in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services.’ The EFB applies separate definitions for ‘traditional’ and ‘modern’ biotechnology. Traditional biotechnology refers to ‘the conventional techniques which have been used for many centuries to produce beer, wine, cheese, bread and other foods.’ Modern biotechnology embraces ‘all methods of genetic modification by recombinant DNA and cell fusion techniques together with the modern developments of traditional biotechnological processes.’ In general, the term biotechnology as used in this study refers to modern biotechnology.

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30 From a patent legal perspective, Article 2 of the Biotech Directive uses the term ‘biological material’ as ‘any material containing genetic information and capable of reproducing itself or being reproduced in a biological system’, whereas ‘microbiological process’ means ‘any process involving or performed upon or resulting in microbiological material.’ The concept of biotechnology is not defined in the Biotech Directive.
31 Glick, 5.
33 See the European Federation of Biotechnology at www.efb-central.org/ (9 April 2015).
34 DNA stands for deoxyribonucleic acid. The concept of biotechnology may also be defined by different generations of technology. The first generation included the ancient traditional technologies like the use of yeast in beer brewing and the making of bread. The second generation began with the work of Louis Pasteur on microbiological applications and continued with the mass fermentation of antibiotics. Also included in the second generation are tissue culture and plant and animal breeding. The third generation started after the Second World War and the advancements in molecular biology, introducing techniques such as recombinant DNA, monoclonal antibodies, PCR and cloning. The science of today is generally viewed as belonging to the third generation, including the innovations related to human cells and cell therapies.
The term *life sciences* is broader but often used in connection to biotechnology. Life sciences stands for ‘the sciences concerned with the study of living organisms, including biology, botany, zoology, microbiology, physiology, biochemistry, and related subjects.’ Life sciences is often contrasted to physical sciences, concerned with the study of inanimate natural objects, including physics, chemistry, astronomy, and related subjects.

From a practical perspective, biotechnology is often used to as an umbrella term for the use of molecular biology, cell- and tissue culture biology and microbiology in technical processes. The molecular biological processes are mostly processes conducted with or on genes and proteins. Cell biological processes relate to different procedures directed on the cellular level, e.g. processes regarding human stem cells. In general, microbiological processes are directed towards the use of microorganisms such as bacteria, fungi and viruses. Biotechnology has a very broad area of application. Healthcare biotechnology (or biomedicine) is the main area of activity of the biotech industry. This particular domain includes many applications with considerable economic and public health significance. Biotech-based products have mainly therapeutic uses (i.e. biopharmaceutical), but also diagnostics and preventives (i.e. vaccines). Most sectors that concern biology and medicine are or will be affected by biotechnology. Organisms used in biotechnological processes may consist of bacteria, fungi, yeast-, plant- or animal cells.

3.2 Stem cells

Stem cells are able to regenerate tissues and organs and act as building blocks for all tissues in the body. Stem cell research therefore offers the prospect of developing new methods to repair or replace tissues or cells damaged by injuries or diseases and to treat serious chronic diseases by cell-based therapies such as diabetes, Parkinson’s, chronic heart failure, stroke and spinal cord injuries. In basic research, stem cells are important for the understanding of the processes of cell differentiation and cell growth. Stem cells are also used in specific medical applications to gain an understanding of disease development and the development of safer and more effective drugs.

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55 Definition by the Oxford Dictionaries, at oxforddictionaries.com (9 April 2015).
57 Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the mid term review of the Strategy on Life Sciences and Biotechnology, COM(2007) 175 final, 4.
A stem cell is basically a non-differentiated (unspecialized) cell with the ability to give rise to specialized cells. Stem cells also have the ability to divide and multiply for indefinite periods in culture in their unspecialized state. Under certain conditions, they are also able to give rise to more specialized cell types, e.g. blood cells, muscle cells and nerve cells. There are various types of stem cells with different properties. The various stem cell types are derived from different sources. Stem cells are often defined by their source of origin, or their potential for development.

For the source-definition, stem cells may broadly be divided into two groups, (1) embryonic stem cells (ESC), and (2) somatic stem cells (adult or tissue stem cells). The sources of ESC are pre-implanted early human embryos (donated surplus In Vitro Fertilization (IVF)-embryos). Somatic cells are long-lived tissue stem cells that are responsible for replacement of old or dying cells in body tissues and upon injury repair the tissue in which they are found. Another more specialized way of defining stem cells is their division into three main groups: (1) Adult stem cells are derived from adult individuals, (2) foetal stem cells are taken from foetal tissue, and (3) embryonic stem cells are isolated from a preimplantation embryo at the blastocyst stage (5-7 days after fertilization).

The concept of human embryo is difficult to define from a common European perspective. The legal and moral status of the human embryo is also something that differs between countries, and many legal systems lack embryo definitions. Where such definitions exist, they may differ between legal, medical or social contexts. The CJEU has created an embryo definition for the purposes of biotechnology patents, which focuses on the potential of the material to develop into a human being:

Accordingly, any human ovum must, as soon as fertilised, be regarded as a ‘human embryo’ within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive, since that fertilisation is such as to commence the process of development of a human being. [...] That classification must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis. Although those organisms have not, strictly speaking, been the object of fertilisation, due to the effect of the technique used to obtain them they are, as is apparent from the written observations presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so.59

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59 Case C-34/10, Oliver Brüstle v Greenpeace eV [2011] ECR I-09821, paras 35-36. Parthenogenesis, i.e. the growth and development of a human ovum without fertilization, is not regarded as a human embryo by the CJEU because such subject matter lacks the potential to develop into a human being. See Case C-364/13,
Stem cells have different potentials. A fertilized egg is one type of stem cell. After the time of conception the fertilized egg starts to divide. During the first stages of the cell division (the blastocyst stage) each of the cells have the potential to develop into a complete human being, and those cells are therefore labelled as totipotent. After the first early stages of cell division, the cells of the blastocyst start to specialize into different cell layers generally consisting of an inner cell mass (subsequently becoming the foetus) and an outer cell mass. The stem cells extracted from the inner cell mass resulting from such specialization are referred to as pluripotent, which means that they may specialize into all cell types in the human body, except that they may not form a complete human being. Multipotent cells exist in different parts of the adult human body, where they develop and replace organs and tissue of a specific type, e.g. blood stem cells.

Permission for clinical trials using hESC was initiated in 2007 in the US for the treatment of spinal cord injuries with nerve cells, developed from hESC lines. The trials, conducted by the California-based company Geron, are the first trials using hESC on humans. Adult stem cells are already widely used for instance in the culturing of skin tissue, for the treatment of e.g. leukaemia and for burns.60

3.3 The Regulatory System

The literal meaning of the concept of ‘regulatory’ is ‘serving or intended to regulate something’. Regulation is a rule ‘made and maintained by an authority’.61 Traditionally, the regulation system is described as a bipartite process involving government and business, where the former acts as regulator and the latter as regulated, but research shows that mechanisms of informal social control are today equally, if not more, important.62 The most important element of the regulatory regime is the creation of a normative structure of standards, principles and rules for achieving policy objectives formulated (most often) by the political system. Additional system elements are processes for monitoring and mechanisms of behavioural modification.63

For biotechnology, the focus of regulation is usually the technical applications on human health and food production which are manifested in a number

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60 In 2007, the European Commission agreed to fund a European registry for hESC lines. The main objective is to provide comprehensive information about all hESC lines available in Europe. 81 different lines are currently used in EU projects. www.hescreg.eu/ (21 July 2014).
62 Gunningham, 5.
63 Scott, 19.
of issues. The main fields are the safety of new technological applications, the protection of the environment from irreversible change, the protection of consumers’ economic interests (e.g. disclosure and labelling), the protection of IP rights and the ethical issues involved in research and applications, e.g. genetic testing, cloning and therapeutic applications of recombinant DNA.  

From this point of view, patents (as included in the field of general IP rights) are but a part of the general regulatory structure of technology. The main difference between the field of patent law and the specific regulatory issues is the different functions and purposes of the respective systems. Whilst patents are mainly justified by the function as an incentive for technological development, the main purpose of the presented issues is the regulation of safety for the protection of human health and environment, and protection of ethical issues in research and medical applications.

In regulatory systems, law is used in a number of situations. It is used to impose total bans, or prohibitions, for instance on human cloning or the planting of genetically modified crops. It is also used to permit activities within certain limits, for instance the use of data from genetic testing by insurance companies. The granting of licenses for permitted activities is another function, and likewise, imposing certain conditions for the marketing of products, for instance pharmaceuticals.  

The concept of regulatory system in its broadest sense covers regulatory legislation, authorization procedures as implemented by relevant authorities and monitoring and authorization duties. In this sense, regulatory law could be equated to public law. The research on or exploitation of products or processes may be regulated entirely by legislation, in the sense that certain acts or uses are prohibited or allowed as such. In addition, the acts or subject matter may be subject to a process of authorization resulting in a permission or prohibition by decision of relevant authority, or court by process of appeal. A third alternative is where the acts in question are permitted by notification, but subject to monitoring, where misuse or misconduct could lead to the acts being prohibited retroactively.

The purpose of the legislation and monitoring consequently vary from regulating ethics in the R&D of medicinal products, to protection of environment, health, security etc. It depends on the type of subject matter, aim of the acts and nature of the protection system. The R&D of certain products or processes is subject to regulation and monitoring. For instance, research on human beings or animals must conform to regulation safeguarding ethics and safety. Thus, the framework covers the work of research ethics committees (of various scope
and authority, i.e. multidisciplinary or covering a single discipline, consultative or decisive, local and regional etc.), funding councils, marketing authorization authorities, and other types of monitoring bodies.

In this study, the concept of regulatory law is used to denote legislation and the connected authorisation processes with the aim of protecting the safety of humans, animals, plants and the environment, as well as the protection of ethical issues in research on and applications of biotechnology.

3.4 Ethics, Morality and Values

*Ethics* is a concept with different significations, different schools of thought and overlapping and sometimes confusing distinctions between different terms such as ethics, morality and norms. The basic notion of ethics is the science of values. Ethics’ (usually treated as plural) is defined as ‘moral principles that govern a person’s behaviour or the conducting of an activity’. In singular, ‘ethics’ denotes ‘the branch of knowledge that deals with moral principles’. The traditional task of ethical philosophy is the evaluating, normative reflection about the foundations upon which, as a system of values, individual persons or group of persons should base their behaviour. There are different kinds of ethics; individual, personal, and social ethics to mention a few.

From a descriptive point of view, *morality* refers to values of different kinds (personal, cultural etc.) that distinguish between right and wrong in a society. Morality is usually considered as the actual choices that people make, and the concept of ethics is then the theory of morality. *Value* is a difficult concept, relating to principles or standards of behaviour; the regard that something is held to deserve. It is held that values are disclosed by feelings which would make them subjective and arbitrary (emotional). As a useful distinction, Hermerén refers to the empirical and normative concepts of value, which can be studied in particular by surveys and document studies:

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67 See e.g. Hermerén, 5, 10.
69 Id.
70 Moufang 1994, 495. The schools of ethics originating in Western philosophy could be roughly divided into three directions. The first is founded in the work of Aristotle, holds that the virtues (such as justice, charity, and generosity) are dispositions to act in ways that benefit both the person possessing them and that person’s society. The second school is represented particularly by Kant, and makes the concept of duty central to morality in the sense that humans are bound, from a knowledge of their duty as rational beings, to obey the categorical imperative to respect other rational beings. Thirdly, utilitarianism asserts that the guiding principle of conduct should be the greatest happiness or benefit of the greatest number, where interests are balanced against each other. (Oxford Dictionary 2014.)
71 See e.g. SOU 2008:20, 133.
Empirical concepts are defined in terms of the extent to which certain events, characteristics, states of affairs, and so forth, as a matter of fact are desired, wanted, or highly appreciated, by certain individuals, groups or majorities in society. This may be indicated by the choices they make in specific situations. Normative concepts are defined in terms of the extent to which certain events, characteristics, states of affairs, and so forth, are desirable, ought to be pursued or to be highly appreciated, by certain individuals, groups or majorities in society, given other values adopted and the desire to have a consistent set of value premises.\textsuperscript{73}

Values are always values related to something, or values of something, which gives every description of values a cognitive content in addition to the emotional element. It is essential for every society to create room for critical reflection on values and on the consequences of using them to guide different decisions.\textsuperscript{74}

3.5 Innovation and R&D

The two terms R&D and innovation are frequently used throughout the study. A practical definition of R\&D is ‘a term covering three activities: basic research, applied research, and experimental development.’\textsuperscript{75}

Innovation is a term that could be described as simply ‘the bringing a product to the market’. In this sense, it has been stated that ‘innovation goes far beyond R&D. It goes far beyond the confines of research labs to users, suppliers and consumers everywhere – in government, business and non-profit organisations, across borders, across sectors, and across institutions.’\textsuperscript{76} Innovation is thus used to describe the introduction of something new to the market or to the world.\textsuperscript{77}

\textsuperscript{73} Hermerén, 9.
\textsuperscript{74} Id., 8.
\textsuperscript{77} See further the definitions provided in OECD and Eurostat (2005), Oslo Manual – Guidelines for Collecting and Interpreting Innovation Data, OECD, Paris 2005: ‘There is growing recognition that innovation encompasses a wide range of activities in addition to R&D, such as organisational changes, training, testing, marketing and design. The latest (third) edition of the Oslo Manual defines innovation as the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, work-place organisation or external relations. By definition, all innovation must contain a degree of novelty. The Oslo Manual distinguishes three types of novelty: an innovation can be new to the firm, new to the market or new to the world. The first concept covers the diffusion of an existing innovation to a firm – the innovation may have already been implemented by other firms, but it is new to the firm. Innovations are new to the market when the firm is the first to introduce the innovation to its market. An innovation is new to the world when the firm is the first to introduce the innovation to all markets and industries. Innovation, thus defined, is clearly a much broader notion than R&D and is therefore influenced by a wide range of factors, some of which can be influenced by policy. Innovation can occur in any sector of the economy, including government services such as health or education. However, the current measurement framework applies to business innovation, even though innovation is also important for the
3.6 Exclusion or Exception?

In European patent law, a number of concepts are used to denote different types of limitations. The first limitation of relevance is the definition of patentable subject matter of a technical character, as opposed to abstract or other kinds of phenomena. Hence, such non-technical subject matter can never be regarded as inventions, as Article 52 EPC and Article 3 of the Biotech Directive provides for, and which is often referred to as ‘excluded subject matter’.\(^7\)

The delimitation in focus of this thesis is the exclusion of subject matter in Article 53(a) EPC and Article 6 of the Biotech Directive. Furthermore, non-patentable inventions are treated by Articles 53(b) and (c) EPC and Articles 4 and 5 of the Biotech Directive. These are usually labelled as ‘exceptions’. Other types of limitations consist of post-grant exceptions from the exclusive right, for instance with regard to experimental use. Such limitations are often referred to as ‘exceptions’, ‘exemptions’ or ‘limitations’, but no coherent terminology exists.\(^7\)

With regard to terminology, Article 27.2 TRIPS uses the term ‘exclude’, whereas Article 53(a) and Rule 28 EPC simply state that patents ‘shall not be granted’ and in Article 6 of the Biotech Directive the term ‘inventions shall be considered unpatentable’ is used. Although many use the term ‘exception’ to denote the morality clause, the term ‘exclusion’ is, however, applied not only in TRIPS but also in the four main recitals connected to Article 6 in the Biotech Directive.\(^8\) Against this background, the term ‘exclusion’ is used throughout this thesis to denote the limitation expressed in the morality clauses.\(^9\)

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7 Bently and Sherman 2014, 459 f.
8 See Kur, 210 ff.
9 See Recitals 38, 40, 42 and 45 of the Biotech Directive.
10 See further Kur, 210 ff.
The relation between law and ethics or law and morality is a fundamental theme in legal philosophy. The patent law morality clause is consequently placed within a field fraught with tensions. The understanding of the morality clause necessitates a background perspective of the legal and philosophical context of the law and ethics’ relation. In addition, the analysis requires an overview over the justifications of the patent law system and a description of the function of biotech patents in the current economic and political climate. This Part II begins in Chapter 4, which contains a historical background of the emergence of biotech patents, and provides for a theoretical framework of the conceptualization of theories of justification for patent protection, including the practical effects of biotech patents in a market setting. The purpose of the following Chapter 5 is to provide an overview of the relation between law and ethics from a broader perspective, as well as the moral approaches which exist within the patent legal sphere. Conclusions are drawn in Chapter 6.
4 A Theoretical Framework

4.1 The Historical Developments

Patent law stands at the crossroads of technology, science, law and economics. The primary aim of the patent system is the protection of technical inventions, achieved by the granting of exclusive rights to patent applicants fulfilling the formal as well as substantive patentability criteria.

In Europe, the motives for an IP system are generally traced back to natural law and natural rights while the basis in Anglo-American jurisdictions is mainly utilitarian. Suggestions of both motives are, however, found in most countries. At the international level, the mixture of IP regulation with trade policies through TRIPS has resulted in utilitarian motives for the evaluation of the IP system. The utilitarian rationale for IP protection has influenced the traditional rationales, and focuses on the contribution of IP law to overall utility. In Europe, despite the fact that the European patent systems traces its lineage back to the natural theories of the 18th century (the idea that a natural property right exists in inventions was adopted as a principle by the French Constitutional Assembly in 1791), the general framework adopted in most legal systems should be labelled utilitarian.

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82 It is of interest to note that the theorizing of IP has increased as IP has become more economically important. Gordon, 624.
83 The beginnings of patent law may be traced back to the prerogative-based privilege system of medieval England, where the sovereign could make grants of various kinds. The purpose of patents was seen as encouraging the transfer of valuable trades and technologies to England. The instrumentalist attitude dominating the approach of the common law courts to monopolies is visible in the *Statute of Monopolies* (1623), where all monopolies except for patents were declared void as not promoting ‘publique good’. However, the patents were granted by virtue of a privilege and not a natural right of some kind, even though this instrumentalist justification worked out in the context of a natural law tradition. See Drahos, 29. From a philosophy perspective it is the theories developed from John Locke that have had most influence on IP and have been used to explain the justification of exclusive rights. There are several difficulties with Locke’s argument, which focuses on a person’s labour mixed with an object from the common, which would entail a property right. Locke’s argumentation focuses on labour and in IP, many doctrines distinguish between physical work and mental work, as well as creative mental work and merely arduous mental work. That the type of labour should matter for justification of the right is not explained by Locke. See Gordon, 624. Josef Kohler built upon the work of Locke when arguing that the idea of founding property on work must also apply to immaterial goods. Winter, 167.
84 The consequentialist reasoning in the U.S is visible in the language of the Constitution: ‘To promote the Progress of Science and the useful Arts’ (Article 1, cl. 8, para 8).
85 A third philosophy, the public rights view, was found in socialist systems and still underlies conceptions of information in some developing countries. Maskus, 27-28. From a historical perspective, the connection between IP, science and economic development is not generally universal, but rather contingent and local. Also, leaving the Eurocentric perspective aside, the concept of incorporeal property was developed already amongst the Andaman Islanders, the Kái, the Koryak and the Plains Indians. The main concerns of these societies were, however, the restriction of transfer of the rights. Drahos, 13, with further reference to Lowie.
86 Levin 2011:2, 4 ff.
87 Machlup and Penrose, 11-17, Maskus, 28.
During the 18th and 19th centuries discussions were concerned with whether patents would stimulate progress, or, to the contrary, hinder it by monopolizing know-how. Numerous patent law theories were developed in order to justify the protection of inventions, based on various lines of argumentation.88 The intense public debates of the 18th and 19th centuries were silenced after the adoption of patent legislation in Europe and North America, and the further development of patent law became depoliticized.89 The 20th century European patent system has to a large extent continued in this vein up until the advocating of product protection for chemical compounds, and later the biotechnology patenting debates.90

In Germany, Josef Kohler developed a doctrine which provided patent rights with a moral basis and thereby immunized it against political review. The starting point for Kohler’s argumentation was in many aspects pre-societal, a matter of natural order. Kohler’s theories were criticized on the basis that patent law should be understood as public, not private law, but Kohler’s view of the system as a natural order expresses itself much more in the stable private law than in public law.91 The criticism remained unobserved. Kohler’s conception remained authoritative, in the more flexible notion that the ground for a patent is investment of labour or money, not labour alone.92

Kohler’s doctrine on the foundations of patent law moved the focus away from economic policy discussions, and new technologies were therefore discussed merely as doctrinal problems. The patent law criteria were regularly developed and adjusted with regard to the demands of new technologies, in order to provide them with the possibility of patent protection. The discourse was more scholarly than political.93

During the latest years of development, including significant research achievements in ethically sensitive areas, the patent system has increasingly been regarded as a system of regulation, in other words as a regime that modifies behaviour. The economic approach to patent protection has gained strength, due to the increased influence of the Anglo-American legal tradition and the shift in the use of patents to strategic instruments for market power. With the introduction of the law and economics movement, economic justifications for patent protection such as wealth maximization and social welfare have gained ground also in legal discussion.94 Such a view of the system, as a tool for promoting economic ends, regards non-economic factors such as health, hu-

88 They were systemized in 1958 by Fritz Machlup. See e.g. Machlup and Penrose, 11-17.
89 Winter, 167.
90 Dutfield, 49 ff.
91 Kohler’s major opponents were the public law scholars Paul Laband and Otto Mayer.
92 Winter, 166 f.
93 Id., 168.
94 See Wechsler, 68.
man rights, the environment, or ethics as external constraints upon the core activities of the patent system.\footnote{Bently and Sherman 2014, 380. Cf. Ghafele, 31.}

Against the background of the emerging knowledge based economy\footnote{The term ‘knowledge based economy’ is often used synonymously with the term ‘knowledge economy’, although the former seems to be more frequently used. The knowledge based economy is an expression coined to describe trends in advanced economies towards greater dependence on knowledge, information and high skill levels, and the increasing need for ready access to all of these by the business and public sectors. OECD, The Knowledge-based Economy, OCDE/GD(96)102, Paris 1996, 7 ff. and OECD, The Measurement of Scientific and Technological Activities: Guidelines for Collecting and Interpreting Innovation Data: Oslo Manual, 3rd ed., prepared by the Working Party of National Experts on Scientific and Technology Indicators, OECD, Paris 2005, para 71.}, the main reason today for having a patent system is to solve a market failure problems associated with publicly available knowledge, and to allow market participants to engage in entrepreneurial activities.\footnote{See e.g. Burk and Lemley, 4, Ghafele, 1, and Olson 2009, 182.} In the Western hemisphere the – short and simplistic – motives for a patent system are several: the encouragement of the establishment of new forms of industry and commerce, a reward for inventors and investors for their time, work and investment risks, dissemination of technical ideas through publication and the promotion of the individual’s right to property in their own ideas as innovations.

Economic arguments, trade interests and trade politics characterize the IP system in the 21st century. IP assets have not only gained a growing economic importance, but the exclusive rights connected to them have increased in strength.\footnote{See e.g. Merges 2000, 2234 and Stenvik 2007, 111 ff, on the favouring of strong patent protection of behalf of the CJEU. Cf. Domeij, 12 ff.} The last two decades have witnessed an expansion of the IP system, not only in general importance but also in terms of objects of protection, scope of protection and period of protection.\footnote{See e.g. Lemley, 14, Levin 2011:2, 3, Boyle 2004, 1-2 and Barton, 114-115.} The global market competition has created a demand for patents, as national markets to a greater extent are susceptible to international competition. The increased competition also forces companies into specialization, which requires a higher degree of IP protection for a clear delineation of property to share and under which conditions access is allowed.\footnote{Guellec and van Pottelsberghe de la Potterie, 9.} The system has grown stronger in the sense that commentators view patents (and perhaps this is true for IP in general) as something that has developed from a limited exception to the principle of market competition, to more or less absolute protection that has only been reinforced. This development is possible since the system is technologically neutral, and has been able to adjust to new technologies, albeit with more difficulties in some fields than others.\footnote{Lemley critizes the growing tendencies to treat IP just as real property from a systematic approach. Lemley, 15.}
The transition into the knowledge based economy has entailed a shift in focus for the system as a whole. Today patents are primarily regarded and used as a form of protection for investments with the purpose of promoting innovation and thereby economic development. In philosophical discussions, the focus was (and is) mainly on the principles behind the creation of patent protection and the balance of the system, but the main point has shifted to terms of investment and innovation, a development mirroring technological achievements, e.g. the growth of global sectors of information and communication technology (ICT) and biotechnology.

This development is visible in patent statistics, as patent filing generally has increased. The strong tendency to patent inventions during the past 20 years has been due to technological change, economic transformations and patent policy shifts. Knowledge and competence are today important foundations of competitive advantage. The alleged impact of patents on the creation of value and wealth is something that needs to be considered. The emerging of new technologies, e.g. electronics, ICT and biotechnology has resulted in the founding of many new technology-based firms as well as in an increasing pace of technological change and accumulation of intellectual capital.

In this new business climate, the role of patents has been affected. The IP system has had an impact on the way firms behave and interact with each other, witnessed on an international level by the way in which countries behave for

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102 For an illustrative list of economic, IP legal and technological/R&D changes from the end of the 20th century, see Granstrand 2003, 13-14.


104 2013 World Intellectual Property Indicators, WIPO Economics & Statistic Series, WIPO 2013, 5. The increase saw a dip following the 2008 global financial crisis, whereas patent filings grew by 9.2% in 2012, representing the fastest growth in the past 18 years.

105 The ‘propensity to patent’ (the number of patents taken per dollar or euro of R&D, assuming the productivity of R&D constant) has increased by 20 percent in less than 20 years in the OECD (following a long-term decline in the US). (Guellec and van Pottelsbergh de la Poterie, 9). Where the US still accounts for the largest share of triadic patent families (a triadic patent family is patents filed in the United States, Japan and the EU to protect the same invention.), the US and EU shares have fallen whilst the share of patent families from Asian economies has increased rapidly between 1995 and 2005 (beginning at a low level). (OECD Science, Technology and Industry Outlook 2008, 12). The Chinese Intellectual Property Office saw the largest increase of patent filings in 2012. (2013 World Intellectual Property Indicators, WIPO Economics & Statistic Series, WIPO 2013, 5).

106 In addition to the dynamic capabilities, i.e. a firm’s entrepreneurial and strategic asset orchestration capabilities. Teece, 3. Many new theoretical concepts have emerged – e.g. ‘knowledge strategy’, or ‘knowledge creating company’. See Tietze, Granstrand and Herstatt, 520, with further references.

107 Tietze, Granstrand and Herstatt, 520. On the concept of ‘intellectual capital’, see e.g. Petrusson, 58 note 165 with further references to e.g. Choo and Wei or Catasús and Chaminade.

108 ‘The experienced importance of IPRs becomes an evolutionary process, generating a constantly increasing pressure to use IPRs in business constructions. […] The more the focus is on IPRs, among competitors, the greater the incentive to develop skills and tools for IPR management. The increased claiming of IPRs put a pressure on the administrative and judicial institutions, e.g. patent offices and courts, to reconstruct IPR regimes in order to adapt to the changing business situations. Academic scholars, business lawyers and management consultants develop new concepts, models, strategies, etc. […] that can be used as tools.’ Petrusson, 15.
the purpose of safeguarding their IP portfolios. This behaviour is described by Granstrand as ‘intellectual capitalism’, and denotes a trend as described by Levin:

IP tends to be appreciated as a tool for protecting investments rather than as the incentive to cultural, including innovative, developments. When providing the basis for investors to place their resources at risk, IP rights are evaluated as (any other) commodity objects, or even regarded as ‘currency’. This can be seen especially when a growing body of intellectual capitalists build up IP portfolios that will enable them to do research and development (R&D) in a certain direction, or integrate themselves into certain research networks or markets. Thus, behind the increased propensity of individual firms to patent is the fear of costs that might be incurred if they fail to take out patents while their competitors do. The expected ‘insurance value’ in IP has been claimed to explain the ever increasing trends to patenting. Additional effects of such intellectual capitalism are the expansionist developments of IP legislation that tend to replace a pro-competitive IP system with a more ‘proprietary’ system, protecting those who already own IP against new entrants in technology and knowledge-based markets.

The creation of patent portfolios is a common practice and is a must for many companies today, mostly due to the increase in patent applications during the past decades. The development has been described in terms such as ‘patent race’ or even ‘patent battles’, denoting the many common disputes arising. The interest of patents is also visible in strategic management, where patent portfolios are designed with the purpose of e.g. circumventing a key invention, blocking a specific competitor’s behaviour or generating a bargaining position.

Despite this focus on patents, empirical evidence as to the role of patent protection in promoting innovation and growth remains inconclusive. The complex relations between economic growth, R&D, innovation and patents have been the object of a number of studies, both empirical and theoretical. On a macro-level, technical and organizational development has a vital part to play in economic growth in the form of innovations of different kinds. The patent system has traditionally had a secondary role. On a micro-level, the connections are more varied and vague. The state of knowledge of the impact of patenting

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109 Levin 2011:2, 7-8.
110 An economic system with basic capitalist institutions (private property rights, private profit motives, competitive markets and free enterprises) in which productive assets and processes, as well as commercial transactions and products, are predominantly intellectual or non-material rather than physical in nature for instance, corporate know-how, consumer loyalty, distribution networks, IP, and so on. Granstrand 2000, 10.
111 Levin 2011:2, 8-9, with further references to Cardullo, Ghafele, Granstrand, Ullrich and Drexl.
112 Petrusson, 17.
113 Id., 18.
114 Meléndez-Ortiz, vi.
115 SOU 2006:80, 149.
on R&D and economic growth is characteristically weak. Studies of the economic aspects of patents show positive but rather weak average connections between patents and the degree of innovation. Likewise the relationship between patenting and R&D is difficult to ascertain.

The conclusion is that growth generates R&D which in turn generates patents, but the reverse is not necessarily established. This has been labelled the ‘patenting paradox’. In addition, variations between industry sectors do exist. Despite the difficulties in establishing empirical evidence concerning the relationship between patents, R&D and innovation (between various sectors), it remains a well-established fact that patents are regarded as an extremely important factor for enterprises seeking to secure (especially) high-risk investments.

4.2 The Conceptualisation of Patent System Theories

The justifications for the patent system are conceptualized in different theories. When such aspects of the patent system are discussed, some types of

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116 This is relative to an earlier weak patent system and low interest among economists for patent issues, which has been handled by lawyers and engineers. The variations between sectors in terms of (economic) impact of patents are still very large, which makes it impossible to measure the statistical relationship or other kinds of evidence. SOU 2006:80, 162.
117 SOU 2006:80, 151.
118 Since the 1990s the number of patent applications has increased faster than R&D. The question is whether this reflects a genuine increase in the productivity of R&D, or a higher propensity to patent for reasons other than increases in the productivity of the innovation process. A study of German companies suggests that the productivity of R&D may increase due to factors other than patents, such as the advances in some basic disciplines, e.g. life sciences or engineering sciences, or better tools for conducting or managing research (ICT, software, etc.). Gambardella, Giuri and Marianiet, IV, Mazzoleni and Nelson, 1038 with further references to Manfield, Levin et. al, and Cohen, Nelson and Walsh.
119 SOU 2006:80, 162.
120 Id., 151.
121 Justifications for time-limited exclusive rights have evolved to categories of interwoven arguments from the property theory (respect for the intellectual creations of inventors), the reward theory (rewarding inventors for their achievements that benefit society), the incentive theory (encouraging the inventive, investment and innovative activities of industry), to the disclosure or contract theory (promoting the disclosure and dissemination of technical component). Mazzoleni and Nelson have proposed at least four different, broad theories about the principal purposes that patent law serve: The invention motivation theory (the anticipation of patents provides motivation for useful invention), the invention dissemination theory (patents induce inventors to disclose their inventions when otherwise they would rely on secrecy, and in this and other ways facilitate wide knowledge about and use of inventions), the induce commercialization theory (patents on inventions induce the needed investments to develop and commercialize them) and the exploration control theory (patents enable the orderly exploration of broad prospects). (Mazzoleni and Nelson, 1033.) Certain versions of the theories are sometimes at odds with each other, e.g. one version of the invention dissemination theory assumes that inventions will occur without patents and that the presence of patents mainly serves to widen use. This is opposite to the common version of the invention motivation theory. Cf. Machlup and Penrose, who also distinguishes four arguments for justification of the creation of patent rights: the property argument, the reward argument, the incentive argument and the disclosure argument. Their arguments correspond to a certain extent with the theories proposed by Mazzoleni and Nelson. See Machlup and Penrose, 10 ff. Cf. also the categorization in the contract theory, the reward theory, the incentive theory and the prospect theory in Wechsler, 68, with further references to Bainbridge, Waltersheid, Meshbesher, Mossoff and Hes-
justifications (e.g. natural rights, property) are not as readily used compared to the more popular public interest rationales and the public benefits resulting from the granting of patent monopolies. For instance, the law and economics movement tends to take a property position of analysis for patents (and copyright), but economic theories on the virtue of common ownership of IP (including patents) have increased in strength during the last decade.

From an economic perspective, the patent system is often described in terms of a spiral of growth. The patent system creates incentives to invest, and growth is generated by the dissemination of innovation created by investment, which provides resources for further investments in R&D, etc. These aims are fulfilled by a number of functions, some being more articulated than others. The different functions of the patent system correlate to some extent, but in other ways collide.

The prevailing and commonly accepted motivation behind the patent system is the function as incentive to invent, expressed in the invention motivation theory. This basic core of the patent system is often coupled with the theory of rewarding the inventor, which has an almost ethical aspect. The reward argument has frequently been called into question with regard to the patenting of biotechnological material, especially human genes, as unfairly rewarding discoveries instead of inventions. The common basis of different versions of the incentive theory is the presumption that no invention would occur without patent
protection. It is also assumed that the stronger the patent protection, the more inventions will occur.\textsuperscript{128} Patent legislation gives the inventor the possibility to control his or her inventions, and creates a private right of economic value. The incentive is mainly focused upon the individual inventor/company.

A different aspect of the invention motivation theory is the \textit{incentive to commercialize}, i.e. the practical application of inventions in commercial activities.\textsuperscript{129} This aspect focuses almost entirely on the investors: the developers, producers, marketers and distributors of the invention, and not the inventor as such (even though the roles may overlap). Traditionally, the first aspect (incentive to invent) has been the one focused upon. From a modern socioeconomic perspective, however, the second aspect (incentive to commercialize) is as important as the first one.\textsuperscript{130} The encouragement of improvements and innovation serves as a link between R&D and the commercial sphere. Arguments of encouraging R&D are especially important in situations where an invention can be readily ascertained, or reverse-engineered, from the marketed product.\textsuperscript{131}

The incentive to invent theory is often coupled with the theory that extensive patenting as a basis for the national system of innovation is necessary for development and success in the global system of competition.\textsuperscript{132} A powerful politic for innovation and growth is often synonymous with pro-active patent policies. In this regard, the patent system \textit{protects investments} in R&D through the possibility of patent protection to recoup high investment costs. Also, the existence of patent protection is held to increase product development and competition. The main criticism against this view is the lack of a statistically significant connection between patents and technical development. Patents do not signify anything more than basically a tendency of companies to seek protection for their investments. To substantiate the connection between patents and innovation, more parameters need to be taken into consideration.

The function of the \textit{invention dissemination theory} is fulfilled through the disclosure requirement. By the disclosure of sufficient information of the invention the patent contributes to technical knowledge and generates R&D through the use of such information. The history of patent law shows that the dissemination of patent information contributes to the total amount of technical knowledge in the world. The rate of innovative technology is dependent on the rate of technical knowledge that exists in a specific domain.\textsuperscript{133} Technical

\begin{thebibliography}{133}
\bibitem{Mazzoleni and Nelson, with further references to Arrow, Nordhaus and Scherer.} Mazzoleni and Nelson, with further references to Arrow, Nordhaus and Scherer.
\bibitem{Stenvik 2013, 24.} Stenvik 2013, 24.
\bibitem{Id., 25.} Id., 25.
\bibitem{The main objection against the incentive theory is that the incentive may be too great, thus resulting in an inefficiently high level or pre-inventive activity or an unnecessary deadweight loss during the patent grant. See Gordon, 632 and Mazzoleni and Nelson, 1036 ff.} The main objection against the incentive theory is that the incentive may be too great, thus resulting in an inefficiently high level or pre-inventive activity or an unnecessary deadweight loss during the patent grant. See Gordon, 632 and Mazzoleni and Nelson, 1036 ff.
\bibitem{Andreasonsson, 121, with further reference to SOU 2006:80, 108, 261, where the economic growth in Asia is described as an example of the relation between innovation, growth and patents and the transition from weaker to stronger national IP regimes.} Andreasonsson, 121, with further reference to SOU 2006:80, 108, 261, where the economic growth in Asia is described as an example of the relation between innovation, growth and patents and the transition from weaker to stronger national IP regimes.
\bibitem{Domeij labels this effect as 'technology-push', see Domeij, 27.} Domeij labels this effect as ‘technology-push’, see Domeij, 27.
\end{thebibliography}
knowledge as such has a so-called generic character, meaning that it may be applied in different areas or be combined with known technology to create new innovations. Moreover, technology development is a cumulative process; the technology needs to reach a certain level before innovations may take place. This has been theoretically labelled as incentive to disclose theory. The results of this are that others are able to use the invention after the patent term has expired, and that the dissemination of technological information may in itself work as a catalyst for new innovations.\(^{134}\) However, the theory rests on the assumption that the disclosure teaches the public – which in some instances is actually not true. Also, the disclosure theory is related to the notion of the patent as part of a bargain: The disclosure is given to the public/government in exchange for the possibility of exclusivity.\(^{135}\)

The patent system may also coordinate or push the production of knowledge.\(^{136}\) One aspect of this statement is the ‘incentive to design around theory’ – that the patent right functions as an incentive for others to develop substitutes for the patented technology. This will be beneficial to society, i.e. the consumers, in that it results in more products being available on the market, provided that the products are truly new inventions and not too close to the original.\(^{137}\) On the other hand, patent law may also act as a disincentive to R&D from the point of view of competitors. This is the starting point of the so-called prospect theory, which is based on the notion that the patent system may increase the exchange of resources used for R&D, through patents’ coordinating effects.\(^{138}\) The function of the patent is seen as a prospect, which allows the inventor to centralize the exploitation and development of the prospect.\(^{139}\) When a patent is granted in a certain area, competitors will steer away from that area and thereby resources are freed for R&D in other domains. The prospect theory focuses on the organization of post-inventive activity, and is related to theories on the incentive to invest, incentive to innovate and incentive to commercialize.

According to the prospect theory, granting a patent early in the development process will allow the inventor to invest in development without the threat that someone may steal the work. Also, the inventor is encouraged to commercially coordinate with others regarding the search for technological and market enhancement of the patent’s value in a way that significantly lowers the transaction costs, since duplicate investments are not made and information is exchanged.\(^{140}\) This prospect function necessarily implies a broad patent scope, something encouraged by many features of the system. For example, it has

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\(^{134}\) Stenvik 2013, 25.
\(^{135}\) Gordon, 632.
\(^{137}\) Stenvik 2013, 26.
\(^{139}\) Gordon, 633. See also Domeij.
\(^{140}\) Kitch, 276.
been argued that the scope of patents is usually broader than the reward function would require, something which also serves as an indication of the existence of prospect elements in the system. The system as such (e.g. the priority rules), also forces early filing of patent applications, before the technology is refined to a commercial product (before the reward has been found).

When discussing the incentive or informative aspects of the patent system, some important factors must be considered. First, the pros and cons of the system vary according to levels and actors (nation, company, individual). It may also vary between different actors, depending on industry sector. Patents are of major importance for R&D investments, innovations and economic growth in chemical-based and pharmaceutical industries. A large part of findings with regard to the biotechnology domain consists of pharmaceuticals, for which the prospect theory is the primary theory of justification. For gene technology, on the other hand, the main focus has been the anticommons theory. Second, there are alternatives to patents as policy measures for the stimulation of R&D. For instance, monopolies or monopolistic conditions may arise without patents, if such measures are desirable. Third, the patent system may be fine-tuned in numerous ways through possibilities of amendments to law and practice, where each such modification has the ability to influence the effects of the patent system.
system. The resulting effect is to a large extent dependent on the details of the particular system in question.

Patent protection often serves as a selling argument to gain competitive advantage, not only regarding the technical superiority of the product but also in the sense of public sanction that a patent lends; a ‘stamp of approval’ of the invention on behalf of the state.148 But naturally, with the expansion of IP follows criticism of the system. The entering of IP into the international trade arena, the increased interaction between IP policies and other economic policies and the emergence of new technological systems has led to reflections towards the policy aims and rationales of the system, and questions regarding the future of the system.149 Two major problems resulting from the increased protection are the position of IP in relation to the needs of developing nations, and public domain.150 The claiming of patent rights take place in the public domain, where universities and other public research institutions operate in a commercial climate characterised by increased university patenting and private funding of university research increase.151 The discussions tend to centre on the question of balance between private property rights and public domain.152 The opponents of the expansion of IP rights often stress the fact that more property rights actually slow down innovation and that the public domain is threatened by privatization.153

On the other hand, the transfer of knowledge from the public domain to the private good has entailed a development where creative minds and innovative firms have clear incentives to become involved in inventive activities. Through patents, they are guaranteed a recoup of investment in capital and labour in the creation of new knowledge and are provided with the chance to make a profit. The use of patents as a mechanism for hedging against risk provides creators with the opportunity to engage in commercial interactions, where the clear

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148 Bently and Sherman 2014, 380. The public sanction argument is also interesting from the point of view of ethically sensitive patents, and the function of the morality clause.
149 See e.g. Boyle 2004, 9, and Boyle 2003. In the latter article, Boyle labels the contemporary expansion of IP as ‘the second enclosure movement’ and draws an analogy to the environmental movement, arguing for more importance of the concept of public domain. Cf. Merges 2000, in which a quite positive vision of the capacity of the system to adapt to technological challenges is presented.
150 See among others Maskus and Reichman, 4 ff., Nelson, 121 ff. and Maskin, 139 ff.
151 The amount of patenting activities and exploitation of research results in Europe is, however, far behind the US, where policies adopted by the US lawmaker already in 1980 (e.g. the Bayh-Dole Act and the Stevenson-Wyder Act) have served as a means for US universities to successfully exploit research results commercially, something also visible in patent statistics. See Straus 2004, 19 ff. for a discussion of the facilitation of commercialization of research results at higher education institutions in Sweden and the rest of the Nordic countries, see SOU 2005:95 Nyttiggorande av högskoleuppfinningar, Stockholm 2005, 22 ff., 142. See Guellec and van Pottelsberge de la Potterie, 183 ff. on the rise of academic patenting, and Pamp, 40 ff. on the changes of university conduct and the need for legal access to research results.
152 Nelson, 121 ff. and Maskin, 139 ff.
153 See e.g. Boyle 2003, 44. Cf. Merges, who argue that private initiatives actually broaden the public domain and this is partially a result of the strengthening of IP rights, i.e. public resources emerge against the background of private entitlements. Merges 2004, 184 ff., 202.
societal objective is economic growth. This need of IP is seldom disputed and serves as a motor for welfare distribution.\textsuperscript{154} The general tendency in the global development is the experience of competitive pressure on managers and entrepreneurs to adopt an intellectual property rights (IPR) focus:\textsuperscript{155} ‘Patents are no longer simply a defensive shield, but a key weapon of corporate strategy.’\textsuperscript{156}

4.3 Policy Reactions to Biotechnology Patents

4.3.1 The First Wave

The foundations of modern day biotechnology rest on discoveries and innovations made more than a century ago. The findings of the basic rules of heredity by Gregor Mendel in the 1860s developed into scientific breakthroughs such as the discovery of DNA as the carrier of genetic information in 1944 by Oswald Avery, Colin McLeod and Maclyn McCarthy at the Rockefeller Institute in New York, and the subsequent elucidation of the double helix structure of the DNA macromolecule by different groups of researchers both in the US and in Europe. This advance made it possible to discover the function of DNA: the expression of the genetic information for the production of amino acids and proteins.

Although these scientific breakthroughs were of immense significance for molecular biological research, no commercial applications were derived from the findings. It was not until the development of the recombinant DNA technique by Stanley Cohen and Herbert Boyer in 1973 and the subsequent patenting of the method by Stanford University that the biotechnological sector experienced a commercial breakthrough.\textsuperscript{157} The technology was widely licensed in the US and it is estimated that it generated over $200 million in royalties between 1975 and 1997, when the patent expired.\textsuperscript{158} European researchers could benefit from the fact that results were published as early as 2002, which prevented European patents on the technology.\textsuperscript{159}

The next major scientific and commercial innovation was the development of the hybridoma technology by Georges Köhler, Cesar Milstein and Niels Kaj Jerne in 1975. A hybridoma is a hybrid cell formed by the fusion of a myeloma

\textsuperscript{154} Levin 2011:2, 6.
\textsuperscript{155} Petrusson, 15.
\textsuperscript{156} EPO, Scenarios for the Future: How might IP regimes evolve by 2025? What global legitimacy might such regimes have?, Munich 2007, 20.
\textsuperscript{157} Recombinant DNA technique allows for the introduction of foreign genes into microorganisms and their multiplication through cell division.
\textsuperscript{158} Dutfield, 138.
\textsuperscript{159} Even export to the US of products produced by the technology was possible, since no indirect product protection applied. Yanchinski, 642.
(a type of cancer) cell and an antibody-producing cell. Hybridomas are used to produce monoclonal antibodies, i.e. multiple antibodies of a highly specific type. The basic hybridoma technology was not patented, a decision which caused heavy criticism at the time, not least from leading politicians. Despite the controversies surrounding the lack of patent protection, it took nearly twenty years for the first monoclonal antibody drugs to reach the market. Most of these are, however, patented and have proven to be commercial successes.

The polymerase chain reaction (PCR), another fundamental innovation, was discovered by a corporate researcher: Karl Mullis, working for the California-based company Cetus Corporation. Mullis was awarded the Nobel Prize in 1993 for the findings. The PCR technique is a very valuable research tool, enabling rapid production of large quantities of selected DNA in a laboratory, and has applications in both genome sequencing and diagnostics.

At the start of the 1990s, gene patents were already well integrated in the field of biochemistry and cell biology. The patents usually consisted of specific and well-described applications, ranging from receptor proteins for drug entry to sweetening proteins to replace sugar. During the 1990s the advancements in genetic research peaked with the mapping of the human genome and the publication of the human genetic code on a global scale in e.g. the Human Genome (HUGO) project, but also in cooperation with projects from Iceland, UK, France, Japan, Germany and China. The large-scale, high-throughput automated sequencing prompted a rapid identification of the human genes.

The findings led to a large increase in biotechnology patent applications globally at a pace never before seen. The surge in biotechnology patents in the late 1990s was partly due to patent applications pertaining to the human genome. HUGO had organised an expert workshop as early as 1991 on IP issues associated with the identification of our genetic heritage. When the US National Institutes of Health (NIH) filed patent applications for over 2,000 gene fragments also known as expressed sequence tags (ESTs), major policy groups became concerned with the rapid privatization of genetic material. According to the critics, the developments forebode the hampering of the free exchange of pre-competitive knowledge. Ironically, it was the public research institution of the NIH which was the forerunner in the early gene patenting race, while one of the first initiatives to put IP matter into the public domain was industry-

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160 i.e. Margaret Thatcher, the then Prime Minister of the UK.
161 Dutfield, 138.
162 Id., 138.
163 Matthijs and Van Ommen, 311.
164 Matthijs and Van Ommen, 311.
165 Humans have approximately 20,000 genes, which make up ca 5% of the entire DNA. The rest of the genetic information has no known function.
166 The first initiative came from J. Craig Venter, then a NIH-employee, in 1992. The NIH applications were eventually not maintained. J. Craig Venter later established the Human Genome Sciences (HGS) company, which targeted 100,000 ESTs and licensed them further to the pharma company SmithKlineBeecham.
founded. The privatization of EST information came to a halt when a consortium of academic institutions funded by Merck&Co pledged to rapidly generate 300,000 ESTs in one year and to make them publicly available.\textsuperscript{167}

4.3.1.1 Legal Reactions

April 1994 saw the conclusion of TRIPS in the Uruguay Round trade negotiations under the General Agreement on Tariffs and Trade (GATT) and the establishment of the World Trade Organization (WTO). The conclusion of TRIPS not only strengthened IP rights on an international level, by requiring e.g. minimum protection standards, but also established IP as a brick in the worldwide trade system with possibilities of trade sanctions in case of non-compliance. The consolidation not only fuelled the tension between developing and industrialized states, but also highlighted and solidified already existing controversies regarding the interrelations between a strengthened international IP system and societal, environmental and health objectives. These conflicts are still prevalent today.

In addition, a number of provisions in international legal instruments were formulated at the time, which especially enshrine major ethical principles applicable to the research on humans, of which the non-commodification of the human body is the most prevalent.\textsuperscript{168} Against this background, the slogan \textit{no patents on life} had begun to appear as a term for all kinds of concerns associated with the increased pace of biotechnological research and the patent rights associated with many of the scientific breakthroughs. The controversies were furthered by the turbulent situation in the EPO, which had difficulties handling the lengthy and sometimes very public oppositions associated with high profile biotechnological patents.\textsuperscript{169} Some of these objections were not even associated with patent law but rather concerned biotechnological research in general.

\textsuperscript{167} Matthijs and Van Ommen, 312.

\textsuperscript{168} Article 21 of the Convention on Human Rights and Biomedicine states that ‘the human body and its parts shall not, as such, give rise to financial gain.’ The UNESCO Declaration on the Human Genome and Human Rights stipulates in its Article 4 that the ‘human genome in its natural state shall not give rise to financial gains (UNESCO Universal Declaration on the Human Genome and Human Rights, signed in Paris, 11 November 1997).

\textsuperscript{169} The protracted processing of the so-called \textit{Oncomouse} patent application, which concerned questions of patentability as well as morality issues pertaining to the creation of transgenic animals, fuelled the public awareness and triggered negative commentary from many civil society groups. European Patent Application No. 85304490.7 was filed in 1985. See V 4/89 (Harvard), V 6/92 (Harvard), T 19/90 (Oncomouse/HARVARD) and T 315/03 (Transgenic animals/HARVARD). After nearly 20 years of processing, including numerous appeals, the patent was granted in 2004 in a narrower version compared to the original claims. The \textit{Relaxin} case was another public EPO decision, concerning a patent on the human hormone relaxin. The patent covered not only the relevant DNA sequence and the substance as such, but also the use of recombinant DNA for the cloning of the gene that was used to produce the synthetic version of relaxin. A patent was issued in Europe in 1991, but opposed in 1992 by members of the Green Party in the European Parliament. See V 8/94 (Howard Florey/Relaxin) and T 272/95 (Relaxin/HOWARD FLOREY INSTITUTE). Some high profile cases concerning transgenic plants were also decided by the EPO during the 1990s.
The full expansion of the biotechnology sector in the late 1980s exacted measures from the European legislator not to hamper the speeding development. The Commission had identified the fragmentation of European patent laws and differences in existing laws as a potential problem as early as 1985, which resulted in the enactment of the Biotech Directive in 1998.170 The Directive was negotiated in a turbulent time for both biotech research and patenting, and the adoption followed a nearly ten-year long period of difficult negotiations, controversy and lobbying.171 This stretched the European democratic process to its utmost, fuelled by widespread concerns about the core question on no patents on life debates in the Council, the European Parliament as well as in the Member States of the EU. The protection of human dignity and the integrity of the human body were strongly advocated by lobbying groups during the Directive’s negotiations, while the promises of the biotechnology industry for the EU economic expansion, especially in relation to the US and Japan, was a major concern.172 But the political battles were not solved by the adoption of the Directive.

4.3.1.2 Public Reactions

Not least in view of the public debates on no patents on life, the national implementation of the Biotech Directive proved to be a cumbersome process in many of the Member States. The national implementation processes were marked by intense debates as to social and ethical arguments concerning patenting biotech inventions, and the completion date of 30 July 2000 proved to be too early in many instances.173 In fact, only four of the Member States completed the implementation process on time.174 It was not until November 2006 that every EU Member State had notified the European Commission of the instruments of implementation.175

Public concerns grew rapidly when the Utah-based company Myriad Genetics was first granted patent rights in 1998 over the breast cancer genes commonly known as BRCA1 and BRCA2. The focus of criticism was – perhaps

(see e.g. G 1/98 (Transgenic plant/NOVARTIS II) and T 356/93 (Plant cells/PLANT GENETIC SYSTEMS).
171 See further Section 14.3.
172 Porter 2009:1, 11-12.
surprisingly – not so much on the patenting of the genes as such, but rather the company’s strong enforcement of their rights through the use of what many labelled as excessive licensing terms, targeting not only commercial use of the patents but also preventing health care personnel from testing patients for the presence of the genes. The number of patent applications as well as the manner of exploitation was widely condemned from the research community.

Even though the major concerns of this first wave of patent controversy were focused on gene patenting, the discussion had a spill-over effect on biotechnology patenting in general. An important strand of criticism centred around the distinction between (natural) discoveries and inventions, thus sparking the ‘product of nature’-debate. Ethical concerns were also voiced. A prominent concern of academic and policy groups to biotechnology patenting, especially patents claiming human DNA sequences, had been the so-called ‘tragedy of the anti-commons’, i.e. the possibility that the large number of patents and patent owners would block the possibilities for research, as the acquiring of the necessary rights would be such a burdensome task, and the feared result was the non-use of valuable technologies. Another important apprehension concerned the restriction on access to technology and material that patent rights may entail. The possible prevention of developments in research and health care caused by these rights, that were also labelled as too broad or excessive in terms, were the core of this second concern, no doubt fuelled by e.g. Myriad’s aggressive patent policy. A third concern, closely connected to the second, was the detrimental effect that biotechnological patents may have on the open science environment in universities and public research institutions, preventing free access to material and also early publication and sharing of research results. It was feared that these developments would hamper the progress of science and technology.

4.3.1.3 Patent Offices’ Reactions

The early 2000s saw a multitude of proposals from e.g. public inquiries, NGOs, ethics councils and other authorities to counter the alleged negative effects of biotechnology patenting. The most common suggestions centred on the following:

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176 See Walsh et al., 1091 and Van Overwalle 2007, 244 on the two different ways blocking effects may occur.
177 In Europe, the Myriad originally filed 3 patent applications, for a method of diagnosis (EP699754), the gene (EP705902), and mutations (EP705903) which have been amended to include only few of the original claims and thus being very limited in application compared to the original breadth of claims. The reasons for amending the applications were purely technical, no ethical considerations were applicable and the EPO could not take economic factors into consideration. See T 80/05 (Method of diagnosis/UNIVERSITY OF UTAH), T 666/05 (Mutation/UNIVERSITY OF UTAH) and T 1213/05 (Breast and ovarian cancer/UNIVERSITY OF UTAH).
178 See e.g. Heller and Eisenberg, 699.
179 Walsh et al., 1091.
180 Non-Governmental Organisation.
- no broad patents on human gene sequences or stem cells;
- clear criteria for patentability that must be applied in a stringent fashion;
- safeguarding of human dignity in the patenting process;
- a proper compulsory licensing system;
- clarification of the research/experimental use exemption; and
- enhancing the non-exclusive licensing or for research tools, or include them under a research exemption.\textsuperscript{181}

A prominent concern was the granting of patents on inventions of human material and the extension of rights to the human body in its natural state. Likewise, (broad) patents covering natural products such as human genes were regarded as excessively rewarding the patent holder for something he or she did not invent, but merely used. The fear of broad patents may seem surprising in a historic perspective, where scientific breakthroughs have been patented in an extensive manner.

The controversies caused the patent offices and authorities to take action to meet the growing concerns and challenges, which in many instances led to projects for the enhancement of patent quality in general, not only with regard to biotechnological inventions.\textsuperscript{182} The policy reactions resulted partly in a strengthening of the application of the basic patentability requirements, especially the industrial application and inventive step criteria, and partly in an overall assessment of the quality of patent applications and patents. The debates also resulted in narrower legislation in some states.\textsuperscript{183}

After a steady growth in the 1990s, the number of biotechnology patent applications filed under the PCT decreased from more than 11,500 applications in 2000 to 8,700 in 2006 (-4.6% per year). Conversely, the total number of PCT patent applications increased by an average of 5.7% per year from 2000 to 2006. On average, biotechnology patents represented 6.5% of countries’ patent portfolios over 2004-06, compared to 10.3% in the mid-1990s.\textsuperscript{184} Thus, the decrease is often explained by the introduction of more stringent criteria for the granting of patents on genetic material. Consequently, the relative weight of


\textsuperscript{182} See e.g. the EPO project ‘Raising the bar on patent quality’, www.epo.org/about-us/office/annual-reports/2007/focus.html (5 May 2010).

\textsuperscript{183} Some states narrowed the scope of the patents by introducing different types of purpose-bound product protection for human genes. See Minssen 2008, 214.

\textsuperscript{184} OECD Biotechnology Statistics – 2009, 70.
biotechnology in all international patent filings decreased in many countries between the mid-1990s and the early 2000s.

With the passage of time and subsequent decrease in the number of gene patent applications, another technology was brought to the forefront of controversy in the late 2000s, which became as much the object of public and political concern as gene patents had ten years earlier.

4.3.2 The Second Wave

In 1998, James A Thomson and his research team at the University of Wisconsin succeeded in deriving and establishing the first hESC line from a (surplus) human embryo. This advance was made possible only because of the building blocks of earlier discoveries that preceded this evolution: from small molecule antimicrobials (e.g. penicillin), antibodies and monoclonal antibodies, to modern genetics, genomics and cell therapy.185

Thomson’s method of derivation of hESCs as well as the resulting products, the cells, was the object of three US patent applications, which were granted to the WARF by the United States Patent and Trademark Office (USPTO).186 The patents claim hESCs per se as well as their preparation and isolation – a very broad protection covering almost every possible way of establishing hESCs in the US.187 The corresponding European WARF-applications were rejected by the EBA at the EPO in 2008,188 on the ground that the inventions involved the destruction of human embryos, thereby falling within the scope of the exclusion for ‘uses of human embryos for industrial or commercial purposes’ in European patent law.189 The CJEU came to a similar conclusion in 2011, confirming the non-patentability of hESC derived from human embryos.190

The rejection of the applications was a relief for many European stem cell researchers as they had feared that the grant of the patents might lead to problems of access to and control of material in a similar fashion encountered in the US.191 Other types of hESC patents have been granted in Europe, but their scope of protection is quite limited compared to the US patents, and there are -

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187 The US patents are currently in force but have been challenged recently on the grounds that they overreach and are not novel – that the methods described in the patent constituted prior art. The patents were held invalid by the USPTO in a preliminary ruling. However, there are numerous possibilities for appeal and the resolution time for a final decision is probably lengthy.
189 Article 53(a) and Rule 28(c) EPC, Article 6(2) of the Biotech Directive.
191 The United Kingdom Intellectual Property Office (UKIPO) has granted a broad range of hESC patents, both foundational patents and follow-on inventions, including claims on differentiated cells made from embryonic lines. See also Plomer 2009:2, 195 ff., for a description of UK policy on hESC inventions, and also Plomer, Taymor and Scott, 16.
so far - no current indications of a negative impact on R&D in this particular field in Europe. Others reacted with concern over the broad interpretation applied by the EPO and CJEU especially with regard to inventions derived from hESC, and the decisions have been heavily criticised not only with regard to the legal interpretation but also with regard to the effects entailed for hESC research and applications in Europe. The opposing positions pro or con patent protection in this particular domain are not only locked, but involve a broad range of issues.

In the US, the presence of WARF’s broad patent rights was – and still is – regarded as a threat to the progress of hESC research. The patents’ claims to hESC cells provide WARF with ownership rights over all hESCs and downstream products in the US, regardless of how the cells are derived. However, such broad patents are not unusual for break-through inventions in new areas of science and technology, and they are arguably an appropriate reward (and incentive) for entering into uncharted territory. The WARF patents were issued at an early-stage of stem cell research and their commercial potential was at that stage uncertain. As a result, in principle, every way to a commercial product derived from hESCs in the US is covered by the rights of WARF. The development of downstream inventions and derivatives thus requires permission, and the patents are heavily licensed.

Stem cell research is still to a large extent an academic occupation, but private investment is seen as crucial for the bringing of applied products to the market, for instance in stem cell based therapies. For the development of the vast potential stem cells offer, e.g. into therapeutic products, industrial and commercial inputs are required. Such input is necessary for the production and manufacturing of cell lines on a large scale, for the support of multicentre clinical trials as well as for marketing, distribution etc. But for the time being, the uncertain therapeutic possibilities and the development of regulatory environments, which vary considerably between the European countries, makes the research prospects uncertain.

It has been argued that patent protection is necessary in particular for stem cell product development, where the road towards finalized therapies is expensive and time consuming. Commercialization of stem cell research is therefore

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192 Plomer, Taymor and Scott, 15.
193 Rabin, 818.
194 Johnston and Wasuna, 12.
195 See Rabin, 818.
196 Taymor, Scott and Greely, 411.
deemed necessary for the step from basic to applied research. It is unlikely that current public funding will provide enough financial support to gather the data needed for full marketing licenses for new treatments. Future needs may require partnerships between publicly funded research groups and commercial companies, whereas funding by the private commercial sector is definitely required.\textsuperscript{200} For such endeavours, patent protection is seen as an absolute necessity.\textsuperscript{201} Consequently, the requirements for patent protection need to be clear, stringently applied and foreseeable.

In this context, a clear legal framework is regarded as important and something that the field would benefit from, regarding both moral and commercial aspects of this type of research and product development.\textsuperscript{202} From a commercial perspective, the broad interpretations awarded to the exclusions from patentability on moral grounds are regarded as a ‘serious impediment to obtaining full benefit from stem cell R&D.’\textsuperscript{203}

On the other hand, stem cell research is quite different from other areas of biomedicine. The stem cell technologies, and particularly hESC, are part of the post-genomic technology ‘for delivering on the promises of the human genome sequencing project’.\textsuperscript{204} The use of genomics for the derivation of hESC lines is already used by commercial companies in the US.\textsuperscript{205} Although the concept of stem cell research is presented as a revolutionary technology with therapeutic promises, it has many things in common with conventional methods of organ transplantation. With stem cells, it is a population of cells that is introduced in a patient rather than a whole organ. By means of techniques such as therapeutic cloning, the cells introduced could originate from the patient him or herself, and the problem of immune rejection is avoided.

Many of the problems that manifested themselves with regard to human gene patenting are also present in the context of stem cell patents (e.g. blocking effects of Thomson’s breakthrough method). Hence, the questions and problems in the field of gene patents also apply, where appropriate, to stem cell patents. However, due partly to the origin of the raw material used in stem cell research (i.e. derivation of hESCs from human embryos), and partly due to the sensitive nature of stem cell research in general, stem cell patents raise more

\textsuperscript{200} Kemp, 1.
\textsuperscript{204} European Molecular Biology Organization, Stem Cell Research – status, prospects, prerequisites, EMBO 2006, 11.
\textsuperscript{205} Id.
far-reaching types of ethical concerns than gene patents, notably the status of the human embryo and the protection of human dignity in that specific context.

The relationship between patent law and (biotechnological) research regulations is manifestly put to the test in the field of hESC patenting. This is due to the express exclusion from patentability of uses of human embryos for industrial or commercial purposes, found in Article 6.2 of the Biotech Directive and transposed into Rule 28 EPC as well as in national laws. Even though specific morality exclusions have always been present in European patent law, the Directive contributed to an enforced application by providing an exemplifying list of non-patentable subject matter, including several methods of exploitation of human biological material.

4.4 Practical Effects

4.4.1 The Importance of the Biotechnology Industry

Biotechnology is regarded as crucial for industrial development, not only in Europe, but in most industrialized countries in the world, and is considered as the next wave of the knowledge-based economy, after ICT. Its importance is of major significance not only in healthcare and pharmaceuticals, but also in the fields of industrial processing and primary production/agro-food. Politically, effective patent protection is regarded as a crucial incentive to R&D and innovation and an essential means of guaranteeing return on investment. The dissemination of information by the disclosure of patent publications is also important as a contribution to the overall development of biotechnology. In the view of the EU Commission, biotechnology is probably the most promising of the frontier technologies and life sciences and biotechnology can provide a major contribution to achieve the EU Lisbon Summit’s objective of becoming a leading knowledge-based economy. Life sciences and biotechnology is thus an area of key importance, not least considering current challenges such as the consequences of an ageing population or the threats posed by possible pandemics. However, the Lisbon standards have not been met by most of the

207 Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the mid-term review of the Strategy on Life Sciences and Biotechnology, COM(2007) 175 final, 3.
208 Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of Regions, Life sciences and biotechnology – A Strategy for Europe, COM(2002) 27 final, 3.
209 Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the mid-term review of the Strategy on Life Sciences and Biotechnology, COM(2007) 175 final, 4.
EU countries. The reasons for this failure are several – the lack of structural reform in general and a weak European scientific and technological policy have been cited as main problems.210

Most of the commercial biotechnology so far has been developed in the US, Japan, and Europe with the UK, France and Germany being the most successful countries.211 The beginning of the 21st century witnessed an increase in biotech patent applications from countries such as China, South Korea, India and New Zealand.212 Up until 2010, the patenting of biotechnological inventions was more politically and publicly controversial in Europe compared with Japan or the US, with more organized opposition.213 The developments in the US regarding gene patents and the challenging of the ‘product of nature’ doctrine by the US Supreme Court have entailed a shift in attitude mirroring the European debates.214

4.4.2 In Search of Empirical Evidence

From a general perspective, the biotechnology sector makes extensive use of IPRs, especially patents.215 It appears as if the existence of patent protection is a prerequisite for technological development in the biotechnological domain, perhaps even more so than in other areas of technology, but this has not been substantiated.216 Perhaps the necessity of patent protection in the pharmaceuti-
cal domain has a spill-over effect on biotechnology in general. Innovation in the pharmaceutical sector is characterized by extremely long development periods and high development costs. In part, these delays are caused by lengthy administrative systems for regulatory overview of safety and efficacy of drugs and agrochemicals.217

Biotechnology at large encompasses a multitude of scientific branches. As a processing technology, biotechnology end products may not only be biotechnological but also chemical, of which the results are used in the pharmaceutical sector. From a structural point of view, there is basically no crucial difference between the patenting of chemical and biotechnological inventions. When inventions consisting of genes, e.g., are patented the claims are directed to DNA as a chemical compound. Cell technology-based research, however, usually differs from organic chemistry in that the situation is more often so that multiple patents are involved in the creation of a biotechnological drug compared with traditional pharmaceuticals.218

As mentioned, patent authorities have formed special groups and procedures for the patenting of biotechnological inventions.219 Also, the enactment of special legislation such as the Biotech Directive indicates that biotechnological patent issues deserve special attention. From a historical viewpoint, chemistry is the discipline that is the most analogous to biotechnology, even overlapping to a certain extent. The patent authorities have therefore consequently applied principles from chemistry on biotechnological patent applications.220 However, the main difference between patenting in biotechnology and organic chemistry is that patent claims in the former discipline generally cover final products, intermediaries leading to final products, processes of making intermediaries and final products, and methods of using final products.221 In organic chemistry, basic laboratory instruments and materials for research are not usually patented, but free for all to use or at least commercially available under implied licenses protecting from patent infringement.222

Many of the fundamental or pioneering inventions in biotechnology were and are protected by patents, and not only the products as such but basic (laboratory) methods.223 The development of follow-on products leads to ques-

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217 The discovery, development and registration of a pharmaceutical is an extremely expensive activity, with unique challenges. For every 9000 to 10,000 compounds specifically synthesized or isolated as potential therapeutics, only one (on average) will actually reach the market. See Cox Gad, 1.

218 Bostyn 2003, 118.

219 See Section 4.3.1.3.

220 Feit, 819.

221 Id.

222 Id.

223 The most famous examples include the Cohen-Boyer enabling technology for cloning heterologous DNA in bacteria, covering the basic method and plasmids, the transgenic Oncomouse and its method for produc-
tions of infringement of the basic methods and the scope of the basic patent rights. The main solution for dissemination of these technologies is thus licensing agreements; however, important aspects are the terms of such agreements, and the availability and use of sublicenses. Much of the biotechnological research is furthermore labelled as early-stage or basic research, in which increased patenting is held to jeopardize the natural progress of science and technology.\textsuperscript{224}

From a survey conducted by the Swiss Federal Institute of Intellectual Property, participants confirmed that the patent system is an important incentive for investment in R\&D in the field of biotechnology, and that patents and licenses for biotechnological inventions are considered an important incentive to stimulate research, knowledge flows and the entry of new technologies into markets. Whilst the number of patent applications rises with firm size, small companies nevertheless consider patents to be highly important for acquiring venture capital.\textsuperscript{225} In a similar vein, research institutes place more value than companies on patents for the financing of R\&D.\textsuperscript{226}

As biotechnology is an activity which is both research-intensive and also of a high-risk nature, biotechnology companies rely heavily on patent portfolios for the attraction of investors, and the larger the portfolio the greater the interest. The size of the portfolio is often related to the quantity of patents, not necessarily their quality.\textsuperscript{227} In the pharmaceutical industry today, there is heavy dependence on research tool improvement and platform technologies that are provided by small start-up biotech firms. Their patent portfolios are essential for attracting funding.\textsuperscript{228}

\subsection*{4.4.3 SMEs and Start-up Companies}

The effects of the patent race and increased awareness of IP and intellectual capital has had a somewhat different impact on small and medium-sized enterprises (SMEs) and start-up companies.\textsuperscript{229} Patent races are more common in

\textsuperscript{224} Gilat, 77.
\textsuperscript{225} Thumm 2003, VII ff.
\textsuperscript{226} Id., 22 ff.
\textsuperscript{227} See e.g. Dutfield, 153.
\textsuperscript{228} Yu, 308.
\textsuperscript{229} SMEs may be defined either according to number of employees, or according to financial assets. The number of employees varies between countries. According to the EU definition SMEs employ fewer than 250 persons and have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. See Article 2 of the Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, OJ L 124, 20.5.2003, 36. In the US,
science-based industries such as biotechnology. The reason for this is that multiple inventors see the same broad unmet needs, and pick up knowledge of research advances that suggest particular routes to follow.\textsuperscript{230} The creation of transaction costs is an effect of patents and the systems of control and remuneration. Negotiations for accessing technology are nowadays necessary, especially in the worlds of ICT or biotechnology, due to e.g. the complexity of the products and existence of patent thickets. It has been held that the transaction costs have increased, also because of the lowering standards for the inventive step. All in all, the increased transaction costs mainly affect SMEs, while larger actors are rather favoured by the developments.\textsuperscript{231}

It has been held that in high-technology sectors, such as semiconductors and biotechnology, innovative SMEs are a key to growth and dynamism.\textsuperscript{232} In general, the approach to patents is very ambiguous in this sector.\textsuperscript{233} In the biotechnology sector, large firms, in general, make more use of patenting as a means of protecting inventions than smaller firms. However, the patent density (patents per employee) of small firms is much higher than that of large firms.\textsuperscript{234}

Although SMEs are a heterogeneous group, the main asset that such companies possess is their technology, and (often) the only protection of this technology is by means of patents.\textsuperscript{235} A well established, multinational firm may want certain research tools, such as receptors or genes, to be placed in the public domain. By contrast, smaller companies may wish for protection, to be able to attract venture capital, or to create the conditions for it to be bought out by a larger firm.\textsuperscript{236}

For SMEs, the increased focus on IPR could be more of an indication of a harsher market climate, where the protection and control over competitive advantages, such as IPR, are subject to strategic aims. One reason for the problematic situation for SMEs is the strong position, not least financially, of multinational firms. A small biotech firm often operates on an international arena, and thus has a similar need for patent protection in several countries just as a
larger enterprise does. But the financial means necessary to build up a patent portfolio or even only to protect one invention internationally can prove difficult for a start-up venture with a limited budget. Small firms may be deterred from trying to invent in the areas where large firms hold patents.237 SMEs usually have difficulties with access to financing of investments in innovation.238 The large IP portfolios found in multinational companies create an environment of multiple and often overlapping IPR claims, in which smaller businesses need to navigate and avoid getting stuck.239

The risk for IP-related conflicts with larger companies is also present. Such conflicts are complex and therefore require financial means for litigation or negotiations. It is nearly impossible for SMEs to take on such conflicts without external support.240 The main reason could be fear of high litigation costs. Other reasons may be a reluctance to pursue innovations where competitors have a significant lead due to strategic reasoning, specifically in patent race situations, or a reluctance to compete with established firms with large budgets for marketing. From this point of view, the increased IPR focus may constitute a hindrance for small ventures, because it creates problems and obstacles to growth.241

Today, patents are used to raise capital. They signal quality and technical advance to capital markets or to venture capitalists and serve as collateral for bank loans. Such new uses have made patents more attractive. In a nutshell, the economic transformations of the last few decades have increased the demand for patents, and the need for patent protection is perhaps more evident in the biotechnology domain than in others.242

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237 Lerner, 471.
238 SOU 2006:80, 120.
239 Petrusson, 21.
240 Id., 22.
241 Id.
242 Guellec and van Pottelsberghe de la Potterie, 10.
The Role of Ethics in Law

A General Perspective

Laws are specific concepts, but ethics is an abstract phenomenon. If ethics is regarded as having an idealistic goal, namely the search for the well-being of the person and humanity, then law can also be seen as having a quest for the ideal, namely the endeavour of social stability. The standpoints with regard to law and ethics range from a total emancipation of the law from morality (legal positivism) to advocating the closest possible harmony between both normative structures.

The main dividing line is found in the essential question of whether law is a reflection of morality or whether it can be separated from morality. The positivist school of law would argue that law has to be divorced from morality and instead be based on the rules of logic and reason. The school of natural law on the other hand would argue that the law necessarily reflects the morals of society and that it cannot be based solely on rules of reason and logic.

Whereas ethical philosophy aims to be universal in content and transcendent in viewpoint, the nature of the legal system is concrete and specific. However, the role of ethics in legal systems is often referred to as the search for ‘justice’ or the ‘truth’ and in that respect, the modern legal systems in the developed world resemble each other in important aspects: constitutional government, individual rights, private property, and extensive freedom of contract. Legal institutions define the normative context and seek to reconcile general ethical norms with actual ethical problems. The Rule of law, the legal maxim which provides that no one is above the law, in legal terms corresponds to constitutional government. A corollary of this principle is that a constitutional regime must have an independent judiciary, and a legal profession sufficiently autonomous to be able to invoke the authority of the independent judiciary.

A much-debated issue in the philosophy of law is whether morality is recognised as a source of law. From a legal positivist point of view, the question of the validity of a law is distinguished from its morality. According to the theory of the Rule of Recognition, every legal system necessarily contains one, and only one, rule which sets out the test of validity for that system:

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243 Petit, 306.
245 See e.g. Fitzgerald.
246 Hazard and Dondi, 7.
247 Hazard and Dondi, 1.
248 Singer, 214.
249 Originally developed by Herbert Hart.
The systemic test of validity specifies those properties the possession of which by a rule renders it binding in that system. Any norm that bears one of the marks of authority set out in the rule of recognition is a law of that system and officials are required to recognize it when carrying out their official duties.251

The Rule of recognition specifically states what the legal sources are in the legal system in question:

The statement that a particular rule is valid means that it satisfies the criteria provided by the rule of recognition. The criteria so provided may take any one or more of a variety of forms: these include reference to an authoritative text; to legislative enactment; to customary practice; to general declarations of specified persons, or to past judicial decisions in particular cases.252

The Rule of recognition also specifies orders of precedence among the sources of law. Hart recognised ‘supreme’ criteria of legal validity, which specify those legal rules which are not trumped by any other possible rule. An important aspect of the rule of recognition is that its content is determined by what officials (jurists) consider to be legal sources. Thus, the rule of recognition is the product of interplay between the officials that form and maintain the present legal system. It is the opinions of those officials that form the view of the content and validity of legal sources. If morality is considered a legal source by the officials in a specific legal system, it automatically earns the status as a legal source, albeit of a subjective character.

Kohler, on the other hand, attempting to enforce the teachings of Hegel, puts his faith in the law rather than the executive, the law-maker or the judge. He is of the view that the standards in the laws should be ethical rather than material. The perception of morality may consequently diverge from person to person and from system to system. In support of such reasoning, Raz has argued that the validity of a law can never depend on its morality.253

If the relation between ethics and law is recognised at a more practical level, apart from the legal philosophical discussions, it is imperative to admit that such relations are not necessarily the same in all countries. If law, values and ethics are considered against the background of complex and changing social, economic and political systems, of which they are a part, it is only natural that such relations change over time. They are dynamic, not static.254 It can also be generally assumed that the areas of law and ethics intersect, despite the vast spectrum of standpoints on this particular topic. Furthermore, it is also assumed that not everything can, and should, be regulated by law, and that the

251 Shapiro, 4.
252 Hart 1965, 97.
253 Carter, xxxiii.
254 Hermerén, 31.
overlapping area between ethics and law should not be too small. Moufang describes this relation as two intersecting circles, which only leaves outside the overlapping area legal rules of a purely technical nature, i.e. those that are neutral from a moral viewpoint, and legally irrelevant moral norms.

The nature of the relationship between ethics and law is often described as one in which ethics precedes law, and that ethical considerations may influence the wording of the law as well as the interpretations of legal provisions. This is especially true concerning the relationship between ethics and law in the discipline of bioethics, with the codification of a number of important ethical principles. The assumption that ethics precede legislation is however not entirely true, since the picture is more complex. For instance, it is clear from the wording and argumentation in some treaties and in the attempts by ethics councils to advise on the patentability of certain subject matter that some aspects of the work take place neither in law nor in ethics. It would be correct to presume that a grey area exists in which neither law nor ethics prevails, but a certain kind of mixture between them, in which legal concepts are misinterpreted when put outside the legal context in which they are set to operate.

5.2 Ethics and Patent Law

The contribution of patents to scientific and technical development can be ethically justified, regardless of its effects. The same consideration is true for the guarantee of a ‘socially cushioned’ free market economy. The justification for the protection of inventions clearly displays either a direct moral element, or at least relies upon a balancing of interests, which is influenced by ethical judgments.

When discussing the terms ethics and morality in relation to patent law, the terms ethics, morality and values are seldom defined and often used in an interchangeable manner. The terms morality and ordre public are, by their use as exclusionary grounds in various legal contexts on international, regional and national levels, given the status of quasi-legal concepts. Their interpretation and function necessitates recourse to non-legal sources in terms of their function in a societal context.

The specific relation between ethics and patent law is aptly described by Van Overwalle, in that ‘[t]he confrontation of ethics and patent law is difficult, to

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255 Hermerén, 31.
256 Moufang 1994, 497.
257 See e.g. The EGE Opinion No 16 on ethical aspects of patenting inventions involving human stem cells, Luxembourg 2002, Danish Council of Ethics, Patenting Human Genes and Stem Cells, 2004.
258 See Article 7 of the TRIPS Agreement.
259 See Moufang 1994, 498.
260 Id., 499, with further references to Johan Stuart Mill, Säger and Beier.
say the least, and usually ethics are seen in this context as a disturbance, as “die grosse Störung”.\textsuperscript{261} The statement is reflected in the position of the patent authorities, which traditionally are negative towards involving moral issues in the patenting process. The difficulties with such a mixture of law and ethics have already been recognized by the EPO in relation to the patenting of stem cells. In the Edinburgh decision, the Opposition Division consulted the European Group on Ethics in Science and New Technologies (EGE) Opinion No 16 as a further source for arguments in assessing the patentability criteria of morality with regard to the contested patent, in line with Article 7 of the Biotech Directive.\textsuperscript{262}

After considering the Opinion, the Opposition Division concluded that the Opinion (for several reasons) could not be taken into consideration, but instead should be disregarded in toto, due to ‘its many inconsistencies, logical flaws, and incompatibility with existing patent law and the EU Directive’.\textsuperscript{263} The Opposition Division held that ‘the Opinion creates new patentability criteria which do not exist in the EPC and therefore cannot be taken into account. Moreover, classical concepts of patent law are misinterpreted and confused.’\textsuperscript{264} For instance, the Opinion contained recommendations for the non-patentability of subject matter due to ‘closeness to the human body, to the foetus or to the human embryo’, and the distinction between the concepts of discovery and invention was, according to the Opposition Division, ‘wrongly associated with inventive step, and moreover, an ethical dimension is accorded to it when the field of biotechnology is concerned.’\textsuperscript{265}

These statements are interesting, because they are indicative of the difficulties encountered in the assessment of ethics in patent law. However, developments in the biotechnological field, coupled with the opportunities for public influence inherent in the patent system, especially in terms of the morality clause, have entailed a shift in attitude. Historically, considerations of an external nature have had a limited influence on the patent system. The lack of public reaction in relation to the early biotech patent rights confirms this approach.\textsuperscript{266} But this is not an entirely correct observation. Patent proceedings represent an arena for participation, e.g. in terms of opposition procedures.\textsuperscript{267} The advent of broader commercialization prospects in biotechnology actually prompted public protests against patents beginning as early as in the 1980s, but the discussions were intensified through time.

\textsuperscript{261} Van Overwalle 1997, 147.
\textsuperscript{262} Article 7 of the Biotech Directive states that ‘the Commission’s European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology’.
\textsuperscript{263} Opposition Division decision of 21.07.03 (Edinburgh), Reasons for the Decision, paras 2.5.4-2.5.5.
\textsuperscript{264} Id., para 2.5.4.
\textsuperscript{265} Id., para 2.5.4(a).
\textsuperscript{266} See e.g. Cornish, 150.
\textsuperscript{267} See e.g. Article 99 EPC.
Today, stakeholders do not always participate solely because of their conviction for or against patent rights. Rather, it may be due to the fact that, for some reason, they have failed to achieve their influence from within the regulatory framework. Depending on the type of technology and application such participation may exist upstream or downstream. The possibility to express values and to participate in the policy making processes that result in law being created is an important characteristic of a democratic system. Upstream public engagement may influence priority settings such as e.g. research financing. Downstream engagement may consist of influence being exerted after innovation processes are already set.

The current arena for the expression of values in patent law ethics in the EPO unfortunately operates in its own sphere, without guidance from regulatory law incorporating ethical considerations. Existing regulatory legislation is currently not used by the patent offices and courts in the application of the morality exclusion. When an ethical evaluation of patentability takes place, an understanding of the patent system and the criteria for patentability is an absolutely necessity. This does not mean that ethical considerations should always be subordinate to patent concerns. On the contrary, they seem to have an overriding function in the sense that the application of the morality clause cannot be trumped by any technical criteria being fulfilled. But it is imperative that the legal prerequisites are clear and upheld, and that the assessment of ethical considerations is performed with due regard for the legal framework put in place by the morality exclusion. The alternative is a legal and ethical quagmire.

5.3 Ethical Theories

Classical ethical theory is usually based on the premises of universality and transparency. The universality premise means that an ethical analysis undertakes to address all ethical problems, regardless of the context in which they appear. By means of transparency, the ethical analysis proceeds from a principle that the actor has access to all the facts of the situation being confronted. The classical ethical philosophers sought to create propositions that would hold for all ethically problematic decisions. A prominent example is the critical moral philosophy of Kant, in which the fundamental principle of our moral duties is a categorical imperative: a moral law that is unconditional or absolute for all agents, the validity or claim of which does not depend on any ulterior motive or

268 Harmon 2006:1, 642.
269 Id., 644-645.
270 On the other hand, such tie is reinforced in some of the Contracting states of the EPC, where by direct references in the legislation the morality clause related to existing research regulation. See Hellstadius 2009, 119 ff.
According to Kant, an act can be justified only if it conforms to a universally applicable norm. Kant’s ethics approach is deontological, judging the morality of an action based on that action’s adherence to a rule or rules, regardless of its consequences. Deontological ethics is commonly contrasted with consequentialist or teleological ethical theories, according to which the rightness of an action is justified by its consequences, represented by, e.g., Bentham. Bentham represents the utilitarianism concept that the consequences should be assessed in terms of ‘the greatest good for the greatest number’. In contrast to Kant and Bentham, earlier philosophers such as Hobbes, Hume, Descartes and Montesquieu also presented insights into legal ethics. Later philosophical theories of morality tended to take utilitarianism as its starting point, but philosophers such as Hegel, Gewirth and Rawls, to mention a few, have formulated specific moral theories, often influenced by the classical philosophers. Rawls, for instance, in his formulation of the Theory of Justice, worked toward a model of justice and theory that is drawn from Kant, through a constructivist framework.

In modern debates, the principal conflict tends to centre around on the one hand utilitarian theories and non-utilitarian rights theories, and on the other hand rights theories that are limited to negative rights and rights theories that include positive rights. The influence of Kant’s reasoning on our modern society cannot be underestimated. But the possibilities of ethics are limited by its problem-oriented character, and it is not to be expected of the discipline to produce mandatory normative deductions for codes of conduct for each individual case.

The increased technological possibilities available to humans represent a vital theme in current philosophical reflections. The pace of scientific advances in the application of biotechnologies involving humans and human material has caused the formulation of applicable ethical and legal principles to lag behind science. A virtual dissolution of traditional ethics as a result of technology is sometimes advanced, due to the fast developing fields of research involving the application of new biotechnologies such as stem cell research or research on human tissue. The increased globalization of medical research is also heightening the tension between the aspiration to universality of ethics-driven regulation and the diversity of moral cultures in democratic societies and the need to respect plurality and ethical diversity. The demands under which ethics is put in terms of the technological pace, in addition to the global scope in both space

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272 See e.g. Hazard and Dondi, 12 ff. and Beyleveld and Brownsword, 56 ff.

273 Moufang 1994, 495.
and time, has created a new sub-discipline of ethics, frequently described as bioethics.

5.3.1 Bioethics

Bioethics or biomedical ethics is the ethics of medical and biological research. The challenges posed by modern biotechnology merge together several different disciplines – medicine, ethics and biotechnology. Bioethics’ main characteristic is the ethical analysis of a range of moral questions posed to medical practice by the advances in biomedical sciences and technologies. Its origin is traced back to the brutal abuse of human lives during the Holocaust, and in the resulting Nuremberg Trials where medical researchers were convicted of ‘crimes against humanity’ on the basis of 10 ethical principles, said to be fundamental and universally applicable to all eras and cultures. Following these trials, bioethics’ has formalized and codified such ethical principles. Related issues, such as the question of proprietary interests in human biological material, have consequently arisen, especially concerning how such interests are to be regulated. These discussions often tend to be centred on the fundamental question of whether the concept of property is applicable in relation to human beings.

The main ethical principles embraced by bioethics are not universally recognized or subject to universal consent. In relation to the codified ethical principles, a number of principles remain just principles, and their influence on the legislation and the decision-making process is treated e.g. by institutional means, such as the setting up of research ethics committees. Outside the realm of legislation, the influence and status of e.g. agencies and authorities set to interpret general and vague legislation on the basis of case-by-case examinations and decision, international declarations without legal status, and codes of conduct by professional organizations, is interesting because they have an impact on the legislation and the decision-making processes in parliaments. Modern bioethics displays different moral approaches based on either deontological or consequentialist theories, as recognized in classical ethical theories.

276 Cf. Hoppe, 4 ff.
5.3.2 Utilitarianism

The utilitarian approach consists of a weighing of probable benefits against harms in reaching a result where one set of factors outweighs the other in relation to the total set of consequences.\textsuperscript{277} It is a consequentialist theory, focusing on the effects of acts and not the value of the act itself. The decisions as to what constitutes ‘good’ and ‘harm’ respectively depends on the ideology underlining the definition of the factors. The approach is detached from the assessment of values on the part of the general public, and is inherently pragmatic.\textsuperscript{278} Well-being is the only thing that is a good in itself or valuable for its own sake. The good attaches only to individuals (human beings or other sentient creatures), and the assessment of the good or harm of a particular matter is judged only in relation to its effect on (particular) individuals. The good is additive and the right course of action is the one that brings about the greatest expected net well-being. The theory of utilitarianism is universal because it focuses on the well-being of all individuals, but this particular characteristic has been subject to criticism.\textsuperscript{279}

5.3.3 Deontology

According to the deontological approach, certain things are morally impermissible, even when producing more benefits than disadvantages.\textsuperscript{280} Focused on the principle of human dignity, it is established upon a number of ethical principles. From a religious viewpoint the concept of human dignity is represented by the principle of sanctity or intrinsic value of human life at all stages.\textsuperscript{281} This principle is however not particularly present in the discussions concerning the morality clause in patent law, where focus has instead fallen on the tenets of non-instrumentalisation and non-commodification of human beings; non-commercialisation of the human body; and respect for human rights.\textsuperscript{282} However, this perspective may be changing with developments within bioethics which also has had a spill-over effect on patent decisions.

Brownsword describes the original two approaches with general application in modern bioethical debates as one utilitarian and one ‘reflecting a sense of justice, rights, or human decency’ (deontological approach).\textsuperscript{283} These approaches

\textsuperscript{277} See e.g. Bently and Sherman 1998, 113, Sterckx and Cockbain, 296 and Harmon 2006:1, 648.
\textsuperscript{278} Sterckx and Cockbain, 296 and Brownsword 2005, 222.
\textsuperscript{279} Slote, 661.
\textsuperscript{280} Harmon labels this approach as ‘human rights approach’. Harmon 2006:1, 653 f.
\textsuperscript{281} Sterckx and Cockbain, 307, with further reference to Singer (fn. 30).
\textsuperscript{282} Id.
\textsuperscript{283} Brownsword 2005, 221. See also Brownsword 2012, 17, where he argues that such bifurcation of bioethics may be too straightforward and that there are important differences within the two approaches as well as theoretical approaches for blending the utilitarian and deontological perspectives.
yield, according to Brownsword, three different perspectives: the first utilitarian pragmatic, the second defending human rights based on respect for human dignity (with emphasis on the importance of autonomy and informed consent) and the third demanding that human dignity should never be compromised.284 This third perspective is represented by a movement labelled by Brownsword as the ‘dignitarian alliance’, representing a range of philosophical and religious views of which the protection of human dignity is the unifying value.285 The primary concern of this alliance and what constitutes this dignitarian approach is the notion that human dignity is a good which must not be compromised by our actions or practices. Any action or practice that compromises this good is unethical ‘irrespective of welfare-maximising consequences (contrary to utilitarianism) and regardless of the informed consent of the participants (contrary to human rights thinking)’.286

5.3.4 Human Rights and Human Dignity

Human dignity as a concept can be sorted into two approaches: human dignity as empowerment and human dignity as constraint.287 The first approach is closely linked to human rights thinking and sees every human being as possessing an inherent dignity which is the foundation of inalienable human rights; including autonomy which protects the capacity to make one’s own decisions and necessitates respect for the decision-making capacity of others.288 The second approach rests on the notion that human dignity and fundamental human rights must be safeguarded and therefore science (particularly in biology and medicine) should develop with respect for these seminal values and consequently constraints should be put upon development.

Whereas the first approach (human dignity as empowerment) is one of the foundational ideas in the Universal Declaration of Human Rights (1948) as well as the Covenants on Economic, Social and Cultural Rights (1966) and on Civil and Political Rights (1966), the second approach (human dignity as constraint) has evolved in modern bioethics and its influence is visible not only in the Biomedicine Convention (1997), the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) but is also explicitly recognized in e.g. Recital 16 of the Biotech Directive (1998).289 The foundations of human dignity as a constraint are drawn especially from Kant’s notion of dignity, mixed with Catholicism, especially the idea that persons have unconditioned

286 Brownsword 2012, 18.
and incomparable dignity and deserve respect as entities who belong to a moral community in which dignity and autonomy is ascribed to every member who is a rational person with a will. Kantian morality from this perspective claims that commodification (commercialization, objectification and/or exploitation) of the human body, i.e. to treat persons as a means to an end only, would compromise human dignity. From the perspective of human dignity as a constraint, human dignity is ascribed to every entity which is a living thing and a member of the human species. In this context, the question of subjects of dignity becomes especially relevant when discussing material derived from the human body as well as the human embryo.

It is recognized that from the moral and philosophical foundations of human dignity that a subject of dignity and bearer of human rights can only be ‘an individual human being with a separate body, consciousness and the capacity for self-determination’. To ascribe human dignity to human biological material that does not pass this articulated test of being an individual (and therefore also lacking moral status) based in classical philosophical traditions would therefore require a different foundation. Such an alternative paradigm is found in religiously, particularly Catholic, inspired articulation of human dignity, which has influenced the instruments on bioethics in the last decades whereby human dignity as a constraint has evolved in the form of the ethical regulation of science. Such an interpretation of the human dignity concept is frequently criticized for its religious foundations and the guarding of the ‘sanctity’ of human life at any stage in its development, an ideal not universally shared.

But it is argued, albeit not without opposition, that a number of principles are part of the concept of human dignity which are in fact independent from the perceived religious influence: the principle of non-commodification of human beings, the principle of non-commercialisation of the human body, and the principle of respect for human rights. For instance, Sterckx states that the concept of human dignity cannot be reduced to the perspective of ‘human rights’ alone in the narrow sense. An action is contrary to human dignity if it violates a person’s basic human rights (e.g. the right to autonomy). But the possession of moral status does not depend on the possession of human rights,
but even in the absence of human rights (e.g. a human corpse or a human embryo, which are not the possessor of rights from this point of view) the requirement to not instrumentalise such human material or treat it as a commercial commodity applies.297 Although these principles are contained in a number of international and European human rights instruments, their scopes are not entirely clear and depending on context the content of these principles takes on different meanings. Their relation to the human dignity and human rights concept(s) is also, as seen from the discussions, elusive.

As mentioned, international and European human rights instruments seem to apply different meanings to the concept of human dignity. A topical issue is whether human dignity may be attached as an attribute to human persons already born or whether the scope of application of the concept applies equally to pre-borns or even the human species as a whole. A tentative conclusion is that the instruments, both international and European, permit a scope of moral perspectives (which in some instances are even contradictory) on the concept of human dignity which accommodates broader as well as narrower interpretations, depending ultimately on a background of overarching moral, religious and cultural factors.298

An example of such contradictory interpretation is Article 3 of the Charter of Fundamental Rights of the European Union, entitled ‘Right to the integrity of the person’, which states in section (2) that: ‘In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law, the prohibition of eugenic practices, in particular those aiming at the selection of persons, the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive cloning of human beings.’ Such a prohibition does not only concern the selling of a human body and its parts, but more specifically makes them ‘a source of financial gain’. It is argued that the act of commercialization would thus not be necessary to make the handling of subject matter contrary to Article 3(2); it would suffice with the patenting of the subject matter, because the exclusionary position awarded is regarded as strongly linked to the commercial exploitation. On the other hand, EU law specifically regulates the marketing and commercialization of e.g. human embryonic tissue in the industrial production of therapeutic products (applied to the human body) by the so-called Human Tissue Directive.299 Even though the donation of such material should be voluntary and unpaid, there is still a discrepancy between the permissive framework provided

297 Sterckx 2008, 491 ff.
298 See the overview by Plomer 2009:2, 209 ff.
by the Directive and the argued effects of Article 3(2) of the EU Charter of Fundamental Rights.
6 Justifications and Critiques

6.1 Biotechnology and Life Sciences

Biotechnology is distinct from many other technologies, because it is characterised by the use of material whose origins or applications have ethical connotations, and is often self-replicating. The general public expects the innovation in this particular sphere to serve particular goals, often related to fundamental human needs such as health, nutrition, and protection of the environment. From this perspective there is also an – explicit or implicit – expectation that the results of this labour in the form of safe and efficient technologies should be equally distributed as widely as possible. The expectations for dissemination of these technologies are more insistent than in other fields, perhaps because the issues at stake relate to human well-being, even human life itself. The inputs of research material, e.g. tissue, blood, embryos are donated from humans and pose additional ethical and legal questions.300

In the context of life sciences and biotechnology it is assumed that patent rights are typically viewed – and justified – as an essentially utilitarian means towards public policy ends. Its worth is assessed from a consequentialist and empirical perspective.301 In the policy areas of life sciences, any attempt to justify patents from natural law or argue for any inherent sense of entitlement is difficult from a public policy perspective, because what counts are the outcomes – the production and effective dissemination of certain concrete public goods, e.g. new pharmaceuticals, diagnostic tests or plant material.302 In this context, the question of access to technologies is of importance, both from an international perspective (scarcity of knowledge resources and research capacity, as well as inequities of access to research outputs), but also nationally.303

The main critique against allowing patent in biotechnology and life sciences seems to be grounded on the fact that the rights are perceived as being a hindrance to further R&D and healthcare. The manner in which companies and individuals assert and execute their rights has been labelled as being contrary to the policies of the patent system, thus creating outcomes at odds with the policy goals of the system, or in conflict with society’s social expectations, e.g. diagnostic testing which becomes too expensive for regular healthcare to licence, or profiting from publicly funded research by patenting the results and making private wealth possible, funded by taxpayer’s money. To justify patents in this context by referring to natural law justification becomes impossible for public

300 Related to e.g. informed consent and distribution of profits.
301 Taubman, 219 f.
302 In addition, there are demands for higher level public goods such as health, nutrition and global equity.
303 See e.g. Thomas, Hopkins and Brady, 1185-1188.
policy reasons. The main way – the only way – to justify patent rights is by referring to the public policy motives of the system – the cost of private entitlements are being balanced against the benefits to society in the form of incentives for innovation and dissemination of technology. If the system is perceived as unbalanced, if failings and shortcomings are detected, calls for legal reforms, increased public access or other remedies are frequent, because the utilitarian motives are no longer upheld. Major problems in this respect are the difficulties connected with the ways of empirically measuring the effect of exclusive rights.

The relation between new technologies, such as e.g. ICT and biotechnology, and patents has been said to contribute to a reshaping of business in a drastic fashion.\(^\text{304}\) The developments naturally challenge the prevailing justifications and the current balance within the system. The debate on exclusions from patentability has in general been focused on the understanding that patentability should be excluded whenever technology puts protectable values at risk, for instance health, or offends a society’s morals. By excluding socially undesirable inventions from patentability, the patent system acts as a guardian of the line over which human research should never cross. In essence, this function rests upon the rationale that patents promote research, and by denying patentability research is equally discouraged.\(^\text{305}\)

The extensive use of patent protection for biotechnology products does not imply that the patenting activity is socially beneficial; it is simply because claiming patents is seen as profitable by the firms involved in this particular industry sector. The desired link between strong patents and the promotion of innovation and commercialization is not necessarily evident.\(^\text{306}\) Increasing the economic reward of innovation by limiting the free access of competitors and the spreading of knowledge diffusion are two of the main justifications for the patent system. From an economic viewpoint, these justifications are correct but only in as far as they relate to pioneering enterprises that are easily copied. For innovations whose commercialization requires small costs to achieve, without a high degree of novelty and whose production will occur even in the absence of patents, then such justifications are no longer applicable and the patent protection may work against the public purpose it is set to serve.\(^\text{307}\)

A number of commentators have suggested that there are fundamental differences between earlier technologies and biotechnology, and even some subdivisions of biotechnology, e.g. genes and stem cells, where the nature of the inventions raise fears of absolute control by a few individual patent holders over an entire field of science and technology, thus resulting in a distortion of

\(^{304}\) Petrusson, 15.
\(^{305}\) See e.g. Pires de Carvalho, 294.
\(^{306}\) Isaac and Park, 230.
\(^{307}\) Id., 231, with further reference to Polanvyi.
the system and its functions. There are also opposing views of the interests of the system – the incentives to invest are perhaps as necessary in biotechnological as in other fields, or even more so, especially for SMEs, while the interest of society in the access to protected material is equally important, so that research and healthcare is not impeded by patents.

In the matter of biotechnological patents, the patent system has been stretched further than ever before, incorporating not only technology specific legislation but also creating difficulties and unpredictability for patent authorities, courts and the public at large. The view of biotechnology as a key factor to economic growth and technological development was however strongly furthered in Europe, the major reason for the enactment of the Biotech Directive in 1998. The Directive has led not only to technology-specific national legislation which deviates between the EU states (principally in relation to the scope of protection of human gene sequences and stem cell inventions), but also to questions of interpretation of the provisions which shows a high degree of difference between national approaches. Thus, the Directive has not only highlighted the lack of genuine harmonisation among European states in the matter of biotech patents but has also contributed to a growing legal crevice between them, perhaps adding to the weakening of the structural setting in Europe with regard to biotechnology patenting.

6.2 An Appropriate Balance of Interests

The discussion on patents and morality from a wider perspective includes fears of strong blocking rights and the potential for dominant positions on the market which may lead to market abuse. Expressions of alarm regarding too broad patent rights as well as so-called reach-through patents may stifle downstream research and product development. Such claims strike at the heart of the patent system, namely to uphold a balanced and justified allocation of public and private interests. Unjust and unworthy patents are most often the result of a failure to correctly apply the patentability criteria, leading to too low thresholds for protection where the gatekeeper function of the patent authorities is compromised.
The transition into a knowledge based society has resulted in a new type of economy dominated by knowledge and intellectual capital. Intellectual resources, or patent dependent technology resources, which nowadays, in the knowledge based economy, constitute a high proportion of the total amount of resources, are also regarded as the most valuable assets within every sector of society.\textsuperscript{311} The relevance of such resources has increased considerably during the past few years.\textsuperscript{312} This transition has not, however, altered the structural framework and the institutions of the capitalist economic system. Those structures prevail but are influenced by the shift of dominance into non-physical non-financial capital.\textsuperscript{313}

The new regime can be traced back to the beginning of the 1980s, where the development particularly in the US laid the foundation for a strong system for the acquisition and use of IPR, including the expansion of boundaries of patentable subject matter, resulting in possibilities for the patenting of living organisms and software. The patent regime of today is criticized for mainly being a tool for global corporations, where the system as such is counterproductive and threatens technological and economic development.\textsuperscript{314}

The morality clause is centred in this complex field of law, economics and ethics. The influx of moral approaches to the application of the provision necessitates knowledge of the systematic relation of law and ethics, a consideration of its effects from a patent justification point of view, and an understanding of the function of (biotechnology) patents in the knowledge based economy.

\textsuperscript{311} Andreasson, 29.
\textsuperscript{312} Id., 32, with further discussion in note 7 regarding the theoretical foundations of the knowledge economy and the importance of the idea of intellectual resources.
\textsuperscript{313} SOU 2006:80, 102-103.
\textsuperscript{314} Id., 104-105.
The purpose of Part III is to describe the institutional framework, which is a necessary condition for the analysis of the operation of the morality clause in European patent law and the effects and possibilities for interactions between these systems, especially in cases of norm conflict. Chapter 7 outlines the general international law principles regarding sources and conflict of norms, with the main aim being to place the WTO system in a proper context and to understand the influence of international law on national (and regional) legal systems. Chapter 8 provides an overview of international patent law contained in TRIPS within the WTO legal system and the DSS. In Chapter 9 the EU legal system is addressed, both with regard to its competences within the specific field of patent law, but also with regard to the relation between international law and EU law. The latter description is necessary for understanding the influence of TRIPS on the EU legal system and the possibilities for legislative review of EU legal acts in case of non-compliance. The characteristics of the European Patent Organisation are explored in Chapter 10, including the specific relation between the legal acts of the EU Biotech Directive. A summary and tentative outlook is provided in Chapter 11.
Modern international law is held to govern the relations between states in their mutual intercourse, between states and international organisations, between international organisations *inter se* and to a certain extent even individuals.\(^{315}\) International law is a legal system, in which its rules and principles (i.e. its norms) ‘act in relation to and should be interpreted against the background of other rules and principles.’\(^{316}\) As a legal system, international law is not a random collection of such norms. The norms are set in relation to each other, and in the application of international law, the relevant relationships need to be determined in order to apply valid norms to a specific situation.\(^{317}\)

From Article 38 of the Statute of the International Court of Justice, the sources of international law are identified as:

- a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
- b. international custom, as evidence of a general practice accepted as law;
- c. the general principles of law recognized by civilized nations;
- d. [...] judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.\(^{318}\)

Drawing parallels to the nature and hierarchy of legal sources in domestic systems is not appropriate with regard to sources of international law.\(^{319}\) Nevertheless, some rules of international law are accepted and respected as being more important than others, and by their status are elevated to a superior position in the international legal system. For instance, *jus cogens* as ‘peremptory norms of international law’ in accordance with the definition in Article 53 Vienna Con-

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\(^{315}\) The perception of modern international law as a phenomenon of medieval Western European origin is the dominating view, but not unchallenged. See Hillier, 3 ff. The branch of private international law deals with the act of individuals and is essentially a part of domestic law governing e.g. conflict of laws in cases involving foreign elements.


\(^{317}\) The ILC Report states that: ‘That two norms are valid in regard to a situation means that they each cover the facts of which the situation consists. That two norms are applicable in a situation means that they have binding force in respect to the legal subjects finding themselves in the relevant situation.’ ILC Report, para 1, fn. 1.

\(^{318}\) Regarding the discussion on the concept of ‘sources of international law’, and the different notions of legal positivism or law of nature regarding the basis of obligations of international law, see Verma, 22 ff.

\(^{319}\) See regarding the continuing uncertainty as to the sources of international law e.g. Pauwelyn, 89 ff.
vention on the Law of Treaties (VCLT) enjoys such status, at least with regard to the most frequently cited examples of such norms, i.e. ‘the prohibition of aggression, slavery and the slave trade, genocide, racial discrimination apartheid and torture’. Likewise, the status of the United Nations Charter as well as rules specifying obligations owed to the international community as a whole (obligations *erga omnes*) also enjoy a special status in the international legal system.

The scope of international law has increased during recent decades, and regulates a multitude of international activities and institutions, both regional and universal. The issues regulated range from trade to environmental protection, from human rights to scientific and technological cooperation, and involve a number of institutions. The globalization of societies has, perhaps not surprisingly, led to a so-called ‘functional differentiation’ in terms of an increasing specialization of parts of society, leading to autonomy. Such autonomy has legal significance as the development gives rise to specialized and relatively autonomous rules or ‘rule-complexes, legal institutions and spheres of legal practice’.

Due to the fast pace of development witnessed in the era of increased globalization and resulting fragmentation of law, the use of treaties is imperative for the creation of international relations, instead of the process of custom, which is by comparison much slower. Thus, general international law has diversified into sub-systems such as ‘trade law’, ‘human rights law’ and ‘environmental law’, to mention but a few, each with its own unique principles and institutions. Such developments may be designed to meet the needs of a pluralistic world, but a major substantive effect of this fragmentation is an increased risk of incompatible rules of different international legal regimes in turn resulting in conflicts of rules of international agreements, principles, rule-systems and international practices. Even though normative conflicts within the system of international law are not new, their increased relevance must be addressed and dealt with, as will the means with which to resolve them.

Also intra-regime conflicts are increasing, of which WTO is a prime example. The WTO treaty, although representing a ‘single package’ binding on all Members, is actually composed of more than sixty different legal instruments.

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323 ILC Report, para 4.
324 Id., para 6.
325 Verma, 33.
326 ILC Report, para 9.
During the Uruguay Round many of the legal instruments were negotiated with the aim of them operating as autonomous instruments, not necessarily in total conformity with the parent GATT provisions of 1947. The subsequent decision to create an umbrella agreement had as an unintended effect, a bundle of agreements with repetitions, omissions and possible conflicts.327

7.2 Conflict of Norms

Conflict of norms is inherent in any system of law; a system intended to cover a multitude of factual situations by means of a limited number of general rules. The system of international law is particularly sensitive to norm conflicts due to a number of specific characteristics of the system. Pauwelyn identifies four fundamental factors in this respect: A large number of law-makers (essentially as many as there are states, plus a growing number of international institutions), the time factor (states may change their mind at any point in time), a multitude of law-makers at the domestic level and no centralized adjudicator.328 In addition to these inherent factors the end of the cold war era shifted the position of international law from one of ‘co-existence’ to a law of ‘co-operation’, witnessing a dramatic increase not only in the number of international treaties but also in the character of the treaties negotiated.

The shift of paradigm moved conflicts originating from bilateral treaties to conflicts of multilateral treaties related to different common goals. Contradictory norms stemming from different sub-systems of norms (e.g. trade law versus environmental law) became more frequent. But the norm conflicts may also exist within the same sub-system (e.g. two norms of WTO law329). The functional differentiation of international law in different regulatory areas has also prompted the growth of potential conflicts between norms of international law in different sectors. This problem is particularly manifest regarding WTO rules. As norms regulating trade relations between states, they have a potential impact on a large amount of domestic legislation in the interdependent world of today. Trade rules create an intricate web in relation to almost all other rules of international (and national) law.330

International treaties are horizontal instruments without internal priority. They are normative expressions of rights and obligations that states accept and promise to honour not only in respect of other contracting states but also towards the citizens of these states. Their internal relation may give rise not only

328 Id., 13-17.
329 The term ‘WTO law’ includes the WTO Agreement, its annexes, as well as the adjudicated recommendations of panels and the Appellate Body upon adoption by the Dispute Settlement Body.
330 Pauwelyn, 17 ff.
to overlaps but also to conflicts. The United Nations International Law Commission (ILC) identifies the relationship between two or more rules or principles that are both valid and applicable in respect of a particular situation as being either (1) relationships of interpretation, or (2) relationships of conflict.331 Relationship of interpretation covers situations in which one norm may assist the interpretation of another norm as e.g. clarification or updating, and both norms are applied in conjunction.332 Where a relationship of conflict emerges, two norms are both valid and applicable but give incompatible results. States cannot simultaneously fulfil both obligations without violating one of the two and therefore a choice must be made between them.

Regarding relationships of conflict, the VCLT is the instrument to apply when considering the resolution of such normative conflicts.333 For relationships of norm interpretation, the principle of *harmonisation*, or harmonious interpretation, is highly relevant.334 There is a strong presumption against norm conflict in international law. Formal statements confirming incompatibility are ferociously avoided, not least in respect of the political element strongly present in international law. Likewise the principle of *systemic integration* codified in Article 31(3)(c) VCLT requires the interpreter of a treaty to take into account ‘any relevant rules of international law applicable in relations between the parties’. This principle is fundamental in determining the relationship between a treaty provision and material sources external to the treaty, such as other treaties, customary international law or general principles of international law. In addition, Article 31(3)(c) VCLT requires the interpreter to consider ‘other treaty-based rules so as to arrive at a mutually consistent meaning between two or more distinct treaties’.335

The generally accepted maxim *lex specialis derogate legi generali* is an important principle of conflict resolution and interpretation technique in international law. It specifies that, with regard to norms dealing with the same subject matter, priority should be given to the norm that is more specific.336 In addition, certain

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331 Validity entails that the norms each covers the facts of a particular situation. Applicability means that two (or more) norms have binding force in respect to the legal subjects in a relevant situation. ILC Report, para 7 note 6.
332 ILC Report, para 14.1(2).
333 Id.
334 Id., para 1(4).
335 See also Grosse Ruse-Khan 2011:2, 11.
336 Although the ILC devotes special attention to the application of the maxim (subject to a number of interpretative principles), it is nevertheless subject to certain criticism. Ghouri, 252 ff.
types of general law, most notably *jus cogens*, may not be derogated from by special law.\(^{338}\)

A particular form of *lex specialis* is the so-called *special (self-contained) regimes*, denoting a group of rules and principles concerned with a particular subject matter, often coupled with specific institutions to administer the relevant rules.\(^{339}\) The effects of the special character of such a regime are that the interpretation of the norms should often relate to the specific purpose and object of the regime in question and that general international law is subordinate to the special regime and is applied rather as a gap-filler.\(^{340}\)

### 7.3 International Conventions and National Law

#### 7.3.1 Theories of Incorporation

The conclusion of an international agreement gives rise to two specific questions – the adherence to the obligations by one party in relation to the other parties (external issues), as well as the effect of the agreement within the internal legal order of the parties (internal issues). Responsibility to uphold the obligations *vis-à-vis* other parties is an external question. The failure of a state to give effect to its obligations under a treaty on grounds of domestic law does not release the state from liability due to such breach, as stated in e.g. Article 27 of the VCLT. The function and effect of such an instrument in a domestic legal order is an internal issue, subject to various modes of incorporation.

In general, public international law is silent on the validity and effects of international law in national legal orders, but provisions governing these matters could naturally follow from the treaty in question. There is no principle stemming from international law stating that national courts should construe their

\(^{337}\) According to the definition provided in Article 53 VCLT, *jus cogens* is ‘a peremptory norm of general international law. For the purposes of the present Convention, a peremptory norm of general international law is a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.’

\(^{338}\) In the same vein, conflicts between successive norms are subject to the principle of *lex posterior derogat legi priori* (see Article 30 VCLT) according to which ‘later law supersedes earlier law’. In such a situation, the subject matter of the norms, their chronology as well as the contracting parties need to be established. See ILC Report, para 5(24) ff. and Ghouri, 247-280, 250 ff.

\(^{339}\) The Report of the Study Group of the International Law Commission distinguishes three types of special regimes: (1) Violation of a particular group of (primary) rules is accompanied by a special set of (secondary) rules concerning breach and reactions to breach, e.g. Article 55 of the ILC’s Draft Articles on State Responsibility, (2) A set of special rules relating to a special subject matter, e.g. a geographical area (a particular river) or some substantive matter (uses of a particular weapon), (3) All rules and principles regulating a specific problem area are collected together to express a ‘special regime’, e.g. ‘law of the sea’, ‘human rights law’, ‘environmental law’ and ‘trade law’. Such a regime may, for interpretative purposes, be considered in its entirety. See ILC Report, para 3(12).

\(^{340}\) See ILC Report, para 3.
domestic law in conformity with international law, perhaps with the exception for the application of the principle of consistent interpretation. 341 This decision does not, however, stem from international law but from national law. Therefore, the internal role of international law in domestic legal systems is a matter for states to construct, and there are a number of specific approaches in this respect.

In modern societies, the position of domestic law in relation to international law obligations is subject to a plurality of solutions that rarely fits into the dichotomy of the traditional notions of monism and dualism. 342 Today, although commentators generally prefer the notion of ‘pluralism’ 343 to signify the vast spectrum of approaches towards the inclusion and effect of internationally agreed obligations in domestic law, the discussion nevertheless requires a brief repetition of the original points of departure in monism and dualism in order to explain some of the relationships between treaty law and domestic law.

The monist approach views domestic law and international law as parts of a single legal structure. International law needs no procedure to be effective within the national legislation, but is automatically part of domestic law as a result of the doctrine of incorporation. 344 In cases of conflict, international law is supreme over national law, even if no formal steps have been taken by domestic legal actors to introduce international legal norms into the domestic legal order.

The dualist notion completely separates international and national law; it regards them as two entities and individual systems each operating in its particular sphere. Their respective validity is drawn from different sources and they address different subjects. For instance, international law is addressed to states and governs their relations, whilst national law governs individuals. In case of a conflict, national law is still valid within its particular sphere – the national state in which it operates, and this notion, driven to its extreme gives the effect that no conflicts can arise because of the parallel dimensions that do not overlap. Consequently, international obligations need a process of transformation into the norms of the domestic system to gain validity and legality. 345

The picture is further complicated by the fact that monism and dualism can vary according to the type of obligation. For instance, some states are monist with regard to treaty law but dualist with regard to customary international

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341 Betlem and Nollkaemper, 574.
342 In recent years, the academic discourse has shifted to rather describe the relationship in terms of constitutionalism or pluralism. See e.g. Wessel, 10, Boas, 120 ff. and Jackson, 313 ff.
343 See e.g. von Bogdandy, 399-400.
344 The monist school of thought is highly influenced by the works of Hans Kelsen. The full legality and validity of international law confers validity of national law, and national law is merely a 'partial system' in relation to the universality of international law. See Kelsen 1945.
345 Usually such an act consists of a statute duly enacted by the parliament, but other legal instruments can also serve as an act of transformation, perhaps including regulations of administrative bodies or even court decisions. See e.g. Boas, 136 and Jackson, 315.
The variation of approaches shown in national states displays a palette of solutions rather than strict adherence to monism or dualism – frequently referred to as pluralism. A fundamental point is however, that regardless of the choice of approach, there is always the domestic legal system – even in true monist states – that decides on the application of international law via either the operation of domestic law (international conventions) or national court decisions (customary international law), subject to certain policies.

In addition, so-called self-executing treaties represent a group of agreements which are sufficiently clear and precise so as to confer rights or obligations on individuals in domestic law without requiring implementing legislation. Two conditions must be satisfied: one personal (the individuals entitled to the right or subject to the obligation must be specifically targeted by the international treaty) and one material (the rule must be sufficiently precise and clear so as not to require national implementing measures, and there should be minimal scope for different interpretations of the implementation of the international rule). Still, the national constitution or even the constitutional system of the state in question must permit provisions or treaties to be self-executing (regardless of approach in general).

The question of the superiority of international law must be strictly separated from the broad notions of dualism and monism, as the latter only allots the mode of transformation of international rights (and obligations) into domestic law. Modern constitutions often refer to the binding force of international law within domestic law, including the recognition of primacy of international law over national law, but such primacy is usually not accepted over domestic constitutions. A notion of the convergence of international law with national constitutional law is also evident, not least during the recent decades. Such development stems inter alia from political motives prompted by membership of certain international organizations. It is particularly pronounced as regards international standards of human rights protection or even democracy. Constitutional practices are highly responsive to international law but at the same time safeguard (at the least) domestic constitutional principles against international intrusion. The organic relation between international, constitutional and domestic law is difficult to properly characterise as one particular notion, and hierarchies are nearly impossible to establish with regard to national law.

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346 See the examples provided in Ginsburg, Chernyk and Elkins, 204.
347 Jackson, 312.
349 Peters, 171.
350 See Ginsburg, Chernyk and Elkins, 202 f.
351 The current trend has been described as the ‘horizontal’ convergence of constitutional and international law, ‘a globalization of state constitutions and a constitutionalization of international law’. Peters, 174.
352 Peters, 195.
and global levels, political entities and legal orders, which has also given rise to a variety of scholarly proposals. Peters labels the development as one of pluralism, denoting a plurality of perspectives, legal orders, legal actors, and rules in conflict. Against such a background, the conflicts cannot be solved by legal arguments, only by political decisions.353 The solution to conflict of norms, according to Peters, lies in disregarding the formal hierarchy and focusing on the subject matter of the norm in question. The relation between international and national (constitutional) law is therefore not necessarily regarded as existing on different levels, but instead as existing in a state of interaction and reciprocal influence, based on discourse and mutual adaption.354

As established in this Section, there are different theories governing the effect an international treaty exercises on the domestic legal system of a signatory state and the requirements for such influence. A specific question is the extent to which self-executing treaties have the capability of conferring rights or obligations on individuals in domestic law without an act of transposition, i.e. the principle of direct effect. The principle of direct effect is not only important for the execution of rights established under international treaties, but in the EU legal order this principle has impacted on the possibilities for legality review. In addition, the principle of consistent interpretation may also have an indirect influence on the relation between international and national law, especially in the context of EU law.355 These principles are scrutinized in the following Section.

7.3.2 Direct Effect and Consistent Interpretation

Under the premise that the current global legal landscape denotes a pluralistic dimension where international norms and constitutional/domestic norms gradually interflow, subject to increased mediation, an important question is to what extent international norms are directly applicable in domestic legal systems, i.e. to what extent do they have so-called direct effect. The extent to which interna-

353 See the following statement from Peters: ‘The new label given to these judicial practices and scholarly proposals is the label of pluralism. Pluralism here refers first of all to perspectives and denies the existence of an absolute external observation standpoint (‘God’s eye-view’). The consequence is that there is no absolute vantage point from which to decide where the rule for deciding a conflict sits and what its content is. The plurality of perspectives is accompanied by a plurality of legal orders, a plurality of legal actors claiming ultimate authority, and a plurality of rules of conflict. In this intellectual framework, there is no legal rule to decide which norm should prevail, in other words there is no supremacy. There is also no legal rule to resolve the competing claims to authority raised by the international and the domestic constitutional actors. Different legal actors, e.g. courts, usually belong to one of the various orders and therefore necessarily speak from their own perspective, and can only apply a rule of priority residing in their own legal system. In the absence of an overarching, institutionalized power which could decide a conflict, the different actors’ perspectives are – in legal terms – equally valid and consistent. Conflicts can therefore not be decided by legal argument, but must be solved politically.’ Peters, 196.
354 See Peters, 197 and von Bogdandy, 400-401.
355 The EU legal order is treated in Chapter 9.
tional treaties are given direct effect (or are so-called self-executing) in domestic legal systems is a highly relevant question, even though it is only one in a series of issues relating to the relationship of international treaties and national systems. In this constantly fluctuating environment the domestic effect of international norms is usually dependent on the doctrine of direct effect as well as the doctrine of consistent interpretation.356

7.3.2.1 Direct Effect

The notion of direct effect signals an approach where a rule of international law is applied by a national court as an independent rule of decision in the national legal order when that rule is not transposed (or not adequately so) in domestic law.357 The concept of direct effect is broad and covers within its limits a multitude of phenomena.358 The setting in which direct effect is traditionally considered is where courts rely on international law to protect the rights of individuals, thereby securing performance of international obligations.359

The capability of an international agreement to create rights for individuals (for instance in the case of self-executing treaties) is often treated as a question of character of the international instrument in question. Many commentators argue that direct effect is dependent on the quality and character of the international provision, which of course is true as far as the rule in question is capable of actually creating direct effect.360 Usually, such capacity is tied to the creation of subjective rights of individuals. On the other hand, the focus on the international agreement as such has been criticised on the basis of constitutional issues (separation of powers between domestic institutions, the role of the political institutions as gatekeepers and their relationship to administrative bodies and the judiciary) that influence the function of the doctrine of direct effect, and it is argued that the concepts of subjective rights and direct effect are to be kept separate.361 The determination of the principle of direct effect would from such a perspective depend more on the actual constitutional and domestic setting of the national state in question than any characteristic of the international agree-

356 von Bogdandy, 402.
357 Betlem and Nollkaemper, 571.
358 See Nollkaemper 2011, 117 ff. For an overview of policy arguments pro and con direct application of treaties, see Jackson, 321.
359 Excluding for instance inter-state matters such as jurisdiction or immunity. Horizontal matters, where courts are requested to apply international law to private matters between individuals, are excluded from the notion of direct effect as discussed here. Even though a treaty is directly applicable in the domestic legal system, an important related issue is what Jackson labels as ‘invocability’, i.e. a determination may be needed to decide who is entitled to invoke or rely on the treaty norms; differentiation may for instance be necessary between vertical (e.g. between different units or levels of government) as opposed to horizontal disputes (between private citizens or enterprises). Jackson, 317.
360 See e.g. Bodenhausen, 13, on the rules of the Paris Convention for the Protection of Industrial Property (1883), as revised in Stockholm 1967.
361 von Bogdandy, 403 and Nollkaemper 2011, 121.
ment and its provisions, provided of course that the international provision is of such a character so as to permit direct applicability generally. It therefore seems that there exists a dual relationship between the character of the international agreement and the approach of the state in question. Both these factors must be fulfilled for the activation of the principle of direct effect, but it seems as if the weight given to one or the other could vary depending on several factors.

Although direct effect is mostly associated with (and possible) in states adhering to monism, there are cases that can be qualified as direct effect also in so-called dualist states. Case reports from the International Law in Domestic Courts database show that direct effect is found in cases around the world, but they are few and the results are inconsistent. Even though the US accounts for a majority of these decisions, more than 30 other states have employed rules of international law in domestic decisions. These findings concur with the view of pluralism with regard to states’ approaches to international law. The most prominent example of direct effect applied in a legal order is that of the EU, where the principle of direct effect of EU law coupled with the supremacy of EU law over the national law of Member States is of uttermost importance to preserve the autonomy of the Union in relation to national states.

Where an international treaty is directly applicable and invocable in domestic law, conflicts may arise where the treaty norm is inconsistent with other norms in the national legal system. Such norms may be constitutional, or simply legal statutes or other regulatory acts – prior or subsequent to the treaty in question. This situation requires a determination of hierarchy of norms which usually is done in accordance with domestic law. Constitutions, for instance, are often found to be superior to treaty obligations. In case of internal conflict, external responsibilities still remain. Even though domestic law may treat the provisions of an international agreement in a manner consistent with the internal legal system, such an act may still violate the treaty, and the acting nation may be liable as a matter of international law, to the Contracting parties of the treaty.

7.3.2.2 Consistent Interpretation

The principle of consistent interpretation is codified in Arts. 26–27 VCLT, and requires national law to be interpreted in accordance with international obligations, with a view to ensuring that the rules are given desired effect. This doc-

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365 See Jackson, 317.
366 Id., 318.
trine has been further elaborated on by national courts in the context of adherence of national law to international obligations. The difference between the principle of direct effect and the principle of consistent interpretation is that the latter uses an international rule to construe a rule of national law in the light of international law whereas the former uses that rule as an autonomous basis for a decision. The principle of consistent interpretation is therefore usually referred to as creating indirect effect of international law, that is, via a rule of national law.\footnote{See e.g. Betlem and Nollkaemper, 572.}

As with regard to the principle of direct effect, the position that the constitutional setting of the state applying the principle should be more relevant for its function than the character of the international provision subject to such interpretation has been put forward also with regard to consistent interpretation by e.g. the German Federal Constitutional Court in its Görgülü decision, however this particular decision is subject to severe criticism.\footnote{See e.g. Krisch, 109 and von Bogdandy, 403, with further references to BVerfGE 111, 307, 2 BvR 1481/01, 14 October 2004, Görgülü.} Giving effect to the principle of consistent interpretation entails a shift in power from politics to the judiciary. Obligations agreed upon in international treaties, but not incorporated or transformed into domestic law may thus not form part of the applicable law of a state (unless it is a true monist state). Through the application of the principle of consistent interpretation, however, domestic compliance with a treaty is ensured by the construction of national law in the light of international law, and this is performed by the courts, perhaps as compensation for the failure of the political branches to implement the agreed provisions.\footnote{See further Nollkaemper 2011, 143 ff.}

The function of the principle of consistent interpretation cannot be fulfilled in isolation from national principles of interpretation, but can definitely profit from such principles. An example of such mutual exchange is the application of the principles of reasonableness and legitimate expectation used in administrative review, which can be influenced by the principle of consistent interpretation so as to arrive at a result which is consistent with international law. Thus, the use of the principle may certainly strengthen the judicial independence in a state, but on the other hand, it is important that the use of the principle does not lead to a circumvention of the checks and balances provided by other branches of government.\footnote{Id., 158, 161.}
8.1 The Paris Convention and TRIPS Agreement

As patent law operates on different levels – international, regional and national – the question of the compliance to TRIPS norms on behalf of the EU (and the European Patent Organisation) needs to be investigated. Guidance is drawn from principles of international law as regards the relation of national (and regional) law to international treaties. More specifically, principles of incorporation, interpretation and the solution of norm conflicts assist in analysing the influence of the morality clause in TRIPS in relation to its counterparts in European law. The IP conventions of interest for the analysis of the patent morality clause are the Paris Convention and the TRIPS Agreement.

The demand for a modern IP protection emerged during the industrialization period in the 19th century and the creation of the Paris Convention in 1883 and the Berne Convention in 1886 came as a multilateral response to such need, and brought together a number of incoherent bilateral agreements. The decision to establish an international industrial property convention at this time rests on three important factors in addition to the industrial revolutions of Europe and North America. These factors were the expansion of international trade and investment, national trade and development policy and the economic recession of the late 19th century.

The national approaches to key areas of patent varied widely at this time, and the efficacy of patents was not universally accepted, even by industry. In addition, the opposition to patents in the European states was so strong during this time that a future patent system was in serious jeopardy. Even so, national patent systems were established to fulfil public policy objectives relating to economic and technological progress, but were bound to vary due to, for instance, different developmental opportunities and political situations in the states. This period was characterised not only by intense competition between states and enterprises but also by expansion of trade and investments. Whereas industry protectionism was favoured over open trade as the best strategy in states such as the US and Germany to deal with the British leading position, free trade movements against monopolies and privilege were nevertheless simultaneously growing strong. In this turbulent environment focus fell upon the relationship between patents, protectionism and free trade and economic de-

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373 Dutfield, 49-51. See also the references to Machlup and Penrose, 1950.
374 Id., 50.
velopment and as states’ responses to these issues varied. No real solution was presented and the topic remains as controversial today as it was during this period.\(^{375}\)

The ideological linking of patent protectionism with tariff protectionism and of patent monopoly with monopoly privileges in general had a tendency to favour the opponents of patent and in the same vein weaken its defenders. For instance, the elements of continental patent laws that mandated domestic manufacture under the possibility of revocation or compulsory licensing definitely blocked foreign competition and functioned as tariff-like instruments. It became strategically important to separate the idea of patent protection from the monopoly issue and the free trade issue.\(^{376}\) Although patents were associated with monopolies during this time it also became common to justify private property in terms of natural rights, which lead to some rather extreme positions of the proponents of the patent system, especially in the US.

The position of European governments during the 19th century gradually shifted from a notion of strict regulation of rights in the public interest to a more proprietary view. At the same time, the prevalent notion of protectionism favoured the elements of domestic manufacturing inherent in most continental patent laws, which not only ensured the survival of European patent laws but also made harmonising attempts possible in the form of the Paris Convention.\(^{377}\) The industrial and technological development and increasing international trade and intense competition, coupled with the possibilities to ensure some elements of protectionism still, favoured the creation of an international patent system where companies could secure protection in foreign markets. The Paris Convention established the Paris Union for the Protection of Industrial Property, which after mergers with the Berne Union in 1893 formed the Bureaux Internationaux Réunis de la Protection de la Propriété Intellectuelle (BIRPI), which in 1970 was transformed into WIPO.\(^{378}\) WIPO was, until the incorporation of IP in the WTO trade arena through TRIPS, the primary institutional policy actor.

The Berne and Paris Conventions are both based on the notion of principles and minimum standards accorded to the persons entitled to the benefit of the Conventions. The traditional perspective of the standard of the IP conventions is minimum protection, which leaves room for national states to choose to provide more extensive measures.\(^{379}\) The main aim of creating a harmonising convention was the agreement on a number of important principles for industrial property (especially patents and trademarks) in key areas of importance to

\(^{375}\) Dutfield, 52.
\(^{376}\) Id., 53, with further references to Machlup and Penrose.
\(^{377}\) Id., 53-54.
\(^{378}\) Id., 56.
\(^{379}\) Bodenhausen, 15-16 and Kur and Grosse Ruse-Khan, 361.
international commerce, notably the principle of national treatment, the right of priority and rules relating to local manufacture. The nature of the provisions varied in regard to the extent of the obligations and their treatment in national systems.\textsuperscript{380} The fundamental principle of national treatment, i.e. the right of foreign citizens to be treated as equal with nationals with respect to legal rights and remedies, is contained in Article 2 of the Paris Convention. On the other hand, the Convention is silent on three central issues of variation among national patent laws, thereby indicating a lack of consensus: (1) the issue of examination (or of patent offices acting merely as registrators), (2) the term of a patent, and (3) exceptions from patentability on the basis of industrial or technological fields, or of morality concerns.

The 1995 creation of the WTO and the entering into force of the TRIPS Agreement placed IP protection in the trade arena. The two main objectives of TRIPS are to reduce distortions and impediments to trade and to protect private property rights under a mandatory minimum standard. The basic structure of the international IP system in the 20th century is consequently based on two central pillars – the principle of national treatment and substantive minimum standards of IP protection. Despite raising the bar resulting in greater protection, the conceptual approach has persisted. Prior to the TRIPS Agreement, the substantive minimum protection was not very onerous and mostly reflected a level of a lowest common denominator – a consensus position. Many of the central concepts were left to national states to develop within their own national policies and values. Indeed, before the introduction of TRIPS and the WTO DSS, the lack of an enforcement structure reinforced these characteristics of the international IP system.\textsuperscript{381}

The TRIPS Agreement not only incorporated the Paris and Berne Conventions, but also regulated IP in the same vein as its predecessors, namely by extending the existing minimum standards of protection, but further than the Paris and Berne obligations.\textsuperscript{382} The global system before TRIPS offered national

\textsuperscript{380} The Convention contains four categories of provisions, which require different implementation methods with regard to national legislation. The first category contains provisions of international public law regulating rights and obligations of the Member states and establishing the organs of the Union created by the Convention, whilst the second category comprises rules that require or permit the States to legislate (e.g. details concerning the right to priority) within the field of industrial property. The third category encompasses substantive law regarding rights and obligations of private parties, but only to the extent of requiring the domestic law of the Member states to be applied to these parties (e.g. national treatment, or seizure of goods and other actions or remedies). Finally, the fourth category contains rules of substantive law regarding rights and obligations of private parties, rules which do not merely refer to the application of domestic laws, but the contents of which may directly govern the situation at issue (i.e. a body of common rules) that may be self-executing (e.g. the right to priority and the limitation of the possibilities of refusal and annulment of patents) The character of the provisions in the Paris Convention belonging to the third and fourth categories are of interest, since they are held to be directly applicable as such, subject to the constitutional position of the Member state in question. Bodenhausen, 13-13 and Dutfield, 57.

\textsuperscript{381} Dinwoodie, 996.

\textsuperscript{382} Kur and Grosse Ruse-Khan, 361.
states choices with regard to which treaties to adhere to, and also the possibility to make reservations in some cases. The impact of TRIPS contributed to a global reinforcement of IPR protection. Article 1 of TRIPS states that ‘Members shall give effect to the provisions of this Agreement.’ The means and level of effect required is subject to flexibility and left to the discretion of the Member. By considering national IPR systems as non-tariff trade barriers, the global political and economic context in which TRIPS operates has strongly influenced the tendency of international harmonisation and homogenisation of the regulatory framework.

The post-TRIPS WTO situation obliges all WTO Members to implement the minimum standards of every category of IP, and TRIPS puts major emphasis on the enforceability of the rights in national IP legislation. In addition, the linking of the rights (both earlier WIPO conventions and subsequent TRIPS provisions) to an international enforcement mechanism such as the WTO Dispute Settlement Understanding (DSU) makes the TRIPS system more effective and imperative in its functioning than its predecessors, which has also contributed to an increased polarisation between developed and developing countries.

Although the TRIPS text is based on norms of developed states, the driving force behind the establishment of strong IP regimes was to generate benefits for developing countries, such as the receiving of more trade by encouraging well-developed protection systems. The adjustment of internal legal regimes and systems of developing and least-developed countries would, however, require substantial efforts, which were handled by the introduction of so-called transition periods for Members for the bringing into conformity of TRIPS obligations.

Still, in relation to development-related impacts, TRIPS is controversial, and is the object of severe criticism. After the entering into force of TRIPS, the development of international IP law has however changed direction with the increased conclusion of post-TRIPS treaties on substantive IP law, so-called Free Trade Agreements (FTAs), of a bilateral, plurilateral or regional character. For these agreements, countries may enter into negotiations leading to trade-offs, often including obligations consisting of higher substantive protection (so-called TRIPS-plus standards). The present system is thus developing in parallel with the TRIPS Agreement.

383 Art 1(1), para 1 and 3 TRIPS.
384 Asheim, Valentin and Zeller, 52-53.
385 Deere, 11.
386 Levin 2011:2, 15.
387 Article 66 TRIPS, Roffe, 706.
388 Grosse Ruse-Khan 2011:2, 3.
389 See Grosse Ruse-Khan 2011:2 for an analysis of the international law relation between TRIPS and TRIPS-plus FTAs and their impact on TRIPS flexibilities.
The WTO Legal System

8.2.1 Norms and Functions

The legal system of WTO is, as mentioned, a so-called ‘sub-system’ of international law, and in a sense ‘self-containing’ at least with regard to state responsibility with its own rules, remedies and possibilities for (at least quasi-)judicial review. But at the same time it remains a specific branch within the larger system of international law, and party to its general legal sources as far as they are not replaced by lex specialis of WTO law. In particular the law of treaties is held to apply to the WTO legal system.

The sources of WTO law as created within and specific to the WTO context consists mainly of the WTO treaty, the multilateral trade agreements but also of acts of the WTO as an international organisation. Even though a specific WTO/GATT custom is not present within the system, the norms developed as a result of the operation of the organisation are referred to under a system of ‘subsequent practice’ in concordance with Article 31(3)(b) VCLT, denoting a discernible pattern of a sequence of acts implying a specific interpretation of an agreement. Such subsequent practice is not, however, applicable to the judicial decisions of the panels and Appellate Body which are exclusively binding on the parties and not legally binding outside that particular relation. But in practice they nevertheless constitute precedents. Although the clarification of existing provisions of the WTO Agreement outside the context of resolving a particular dispute has been formally rejected by the Appellate Body, adopted panel reports are nevertheless an important part of the GATT/WTO acquis and should be considered and taken into account, where relevant, by subsequent panels.

WTO rules are definitely binding rules on Members that form part of international law. Whether they are effectively enforced and complied with as national law, or in relation to other rules of international law, is another issue. The question of whether the WTO legal system is a ‘self-contained regime’, from the point of view of state responsibility, points to different answers. WTO rules are understood as either regulating completely the consequences flowing from the system (through e.g. the DSS) or that general international law remedies are still relevant also in the DSS. In addition, the nature of WTO obligations is mainly of a bilateral/reciprocal nature, i.e. not having an erga omnes char-

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390 Pauwelyn, 40.
391 See Pauwelyn 40, with further reference to Kuijper.
393 See US – Wool Shirts and Blouses, para VI, 19 and Japan – Alcoholic Beverages II, para E, 14.
394 Pauwelyn, 27.
395 Id., 39.
acter since a breach of a WTO obligation does not necessarily affect the rights of all other WTO Members.\(^{396}\) This distinction is important for the characterisation of WTO obligations as not only affecting states but also individual economic operators, naturally depending on the character of the national legal system in question.

8.2.2 The WTO DSS

The creation of the WTO DSS during the Uruguay Round negotiations resulted in Annex 2 of the WTO Agreement regarding the DSU, building on the already existing system under the old GATT but with a more elaborately structured process. Article 64.1 TRIPS specifically refers to the provisions of Articles XXII and XXIII of GATT 1994, providing an application of the DSU in disputes related to alleged violations of TRIPS obligations by Members.

The main aim of the DSS is to settle disputes and proceedings and is always preceded by a consultation phase in which settlement is sought. During the entire process mediation and consultation is possible. Even though the DSS does not pass judgment per se, the system has nevertheless a judicial character.

At the core of the system are the ad hoc panels, which issue panel reports.\(^{397}\) Panels consist of three panellists, unless the parties agree to a five person panel.\(^{398}\) A permanent Appellate Body, consisting of seven members sitting on four year terms, is set up to receive appeals with regard to the legal interpretation of the panel decisions, making the DSS a complete two instance procedure. The Dispute Settlement Body (DSB) is responsible for appointing the Appellate Body members as well as the panels (on request of the parties).\(^{399}\) The DSB is actually the General Council of the WTO, but acting under a separate chair with its own rules of procedure.\(^{400}\)

An important factor of the system is the responsibility of the DSB to adopt the panel and Appellate Body reports. This is done according to a quasi-automatic procedure under the so-called ‘reverse consensus’ rule where reports are always adopted unless there is a consensus not to adopt the report by the DSB.\(^{401}\) The possibility of such consensus is naturally restricted and reports are practically always adopted.\(^{402}\) After adoption, the report must be implemented

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\(^{396}\) Pauwelyn, 52 ff.
\(^{397}\) See Article 6 ff. DSU.
\(^{398}\) Article 8.5 DSU.
\(^{399}\) The establishment of a panel may only be prevented by an unanimous decision of the DSB. Article 6.1 DSU.
\(^{400}\) Article IV WTO Agreement.
\(^{401}\) Article 16(4) and 17(14) DSU. See Bakardjieva Engelbrekt 2011, 112.
\(^{402}\) Under the GATT 1947, panel reports could only be adopted if all Contracting Parties, including the losing one, agreed to do so. The blocking of the adoption of reports was consequently much easier, requiring only a simple vote against the adoption. Today, a Member would have to convince every other Member (including the complainant) to vote against the adoption. Roffe, 658.
by the Member concerned. The compliance of a Member with the conclusions of the report in the form of e.g. recommendations is subject to monitoring by the DSB in accordance with Article 21 DSU. If a Member fails to implement an adopted report, the parties to the dispute shall enter into negotiations with a view to develop mutually acceptable compensation.403 In case of failed negotiations, any party having invoked the dispute settlement procedures may request authorization from the DSB to suspend the application on the Member concerned of concessions or other obligations under the covered agreements.404

The status and role of international dispute settlement was profoundly changed by the introduction of the TRIPS agreement and its detailed common substantive standards, the effects of which resulted in questions of interpretation and compliance requiring guidance from the system closer to that of a classic tribunal.405 The TRIPS Agreement has so far been the object of 34 requests for consultations, of which at least ten have resulted in reports.406

Although the possibilities for judicial review and conflict resolution in international IP law were enhanced through the DSS, the inherent inequalities of the international system are reinforced by its function. For instance, the dispute settlement bodies do not have a say in the types of disputes brought to them (just as any national court), and the possibility to bring a dispute is open only to states. The states with economic means to enforce disputes and sanctions are the ones actively using the possibilities, while weaker states are rather negatively affected by the effects of higher standards and trade sanctions. The interests of economically and industrially advanced states and powerful creative industries are actually nurtured by the TRIPS agreement as such and consequently, the disputes mirror the aspirations of industries to even higher levels of protection, resulting in a structural bias both horizontally (between industries and users) and vertically (between developed versus developing and least developed states).407

403 Article 22(2) DSU.
404 Article 22(2) DSU. Suspension of concessions or other obligations should take place within the same sector or under the same agreement as that in which a violation has been found, but under certain conditions so-called cross-retaliation is possible (i.e. suspension of concessions or other obligations under another agreement or in another sector). See Article 22(3) DSU and Roffe, 655.
405 Bakardjieva Engelbrekt 2011, 123.
9.1 General Remarks

The EU is a separate legal order and a supranational system, where the Member States have transferred their sovereignty in specific fields and where there is an independent structure for decision-making, in order for it to create unification in specific areas. The EU legal system consists of a functional separation of powers between the institutions, where the CJEU demonstrates a responsibility to uphold a system of ‘checks and balances’ between the legislative, executive and judicial functions of the EU organs. This division of powers and limitations of the Union’s legislative powers is also upheld in the relationship with its Member States.

EU law does not only take precedence over national law, but Member States have a duty to set aside national provisions which are incompatible with EU law and national law has to be interpreted, as far as possible, as to avoid conflicts with EU law. The legislative powers of the EU are governed either by Article 114 TFEU (ex Article 95 TEC) or Article 352 TFEU (ex Article 308 TEC). The initiative lies with the European Commission, which develops policies and acts as a processor of integration in the EU. The Council of Ministers and European Parliament exercises combined legislative powers. The legal basis for the creation of legislation is important since it governs the legislative process in terms of voting rules and the role of the European Parliament as co-legislator (Article 114 TFEU) or consultative organ (Article 352 TFEU). Article 294 TFEU (ex Article 251 TEC) governs the legislative procedure.

There is an important difference between harmonisation of national laws as a means of promoting the internal market, which requires the procedures of Article 114 TFEU, and creating new Community (IP) rights under Article 352 TFEU. Until the coming into force of the unitary patent system, EU influence on patent law is restricted to the specific provisions of the EU patent legal acts (i.e. first and foremost the Biotech Directive), where the CJEU had jurisdiction only in matters where a national court is obliged to request a preliminary reference in accordance with Article 267 TFEU (ex Article 234 of the TEC). Due to

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408 See Wrange, 351 ff., discussing the concept of sovereignty in the context of European integration.
410 See Aerts, 173-174 and Bakardjieva Engelbrekt 2009, 234.
412 Treaty on the Functioning of the European Union.
413 Treaty Establishing the European Community.
the supremacy of EU law over national law, the national courts of Member States are consequently bound by the interpretations of the CJEU.414

In the EU, direct effect of EU law on the national law of the Member States is a fundamental building block of the legal order and subject to an extensive framework of case law regarding its application. Following Van Gend and Loos415, the principle of direct effect was disconnected from national law and became a matter for EU law. The decision in Costa v. Enel416 further established the supremacy of the Union’s law over national law. The acceptance of the Member States that future rules of unknown content and scope were no longer under their domestic control, but determined by the EU, created a practice unrivalled elsewhere in the world and a new legal order.417 The principle of direct effect in the unitary political setting of the EU has evolved in a completely distinct legal environment and serves as an exception to confirm the rule that the domestic legal order decides on the position and the effect of an international norm within its territory.418 In the EU legal order, such effect is a matter of EU law, not national law (at least with regard to the influence international law may exert on EU norms).

9.2 Norm Hierarchy in the EU Legal System

The EU legal order is held to exist on two different levels – a single EU level and the operation of the law in the national legal systems of its Member States. The characterisation of the EU as a new legal order of international law by the CJEU in van Gend en Loos419 is decisive for the understanding of the legal method of EU law. In fact, no uniform EU legal method exists, but a number of legal methods could be applied to the interpretation and application of EU legal sources. The unique characteristics of the EU legal system could rather be expressed as a method for handling the sources of law within the EU, because they are subject to an internal hierarchy within the specific EU legal order, which influences their use in legal science.420

The interaction of and relation between national legal sources and EU law has led to an Europeisation of the hierarchy of norms also in the Member States. The position of the CJEU as the foremost interpreter of EU legal acts

414 Case 26/62 NV Algemene Transport- en Expeditie Onderneming van Gend & Loos v Netherlands Inland Revenue Administration, [1963] ECR 1
417 Nollkaemper 2014, 106.
418 von Bogdandy, 403.
419 Case 26/62 NV Algemene Transport- en Expeditie Onderneming van Gend & Loos v Netherlands Inland Revenue Administration, [1963] ECR 1
420 Reichel, 109 ff.
and the centre of the development of EU law is a unique feature of the EU system. If the EU legal acts are generally considered to be of a legal-technical character, the interpretative role of the CJEU represents a freer stance in relation to the law than the role of courts traditionally in civil law jurisdictions. The development of EU law through general principles of law, protection of human rights and interpretation of the legal acts are the main features of the Court.

Primary EU law consists of the Treaties (TEU, TFEU, Charter of Fundamental Rights and protocols) and General principles of EU law. International law as negotiated and decided under the procedure of Article 218 TFEU occupies an intermediate position between primary and secondary EU law. The latter consists of legislative acts (Article 289 TFEU), delegated acts (Article 290 TFEU) and implementing acts (Article 291 TFEU).

The creative development of EU law on behalf of the CJEU is sometimes labelled ‘judicial activism’. But the capacity for development of EU law today also includes ‘administrative activism’, where administrative authorities within the Union and the Member States contribute to legal development, not least through the production of a vast bulk of soft law. 421 Soft law is usually characterised as non-binding norms and in this context consists of non-binding documents of various origins and with the overarching purpose of securing an effective and uniform application of EU law, for instance, guidelines and handbooks issued by EU organs, often in cooperation with national authorities. Since soft law cannot be subject to Court review and is essentially non-binding, such material still has a normative effect, not least for the purposes of gap-filling to achieve the intention of EU legislation. Preparatory works, such as green and white books, Commission proposals and Parliament Reports have traditionally had a weak position as legal norms within the Union, but the CJEU has on occasion referred to such material. 422

9.3 Division of Competences

The effect of EU legislation on national law is governed by the principles of supremacy, direct applicability and direct effect. The choice of legislative act (regulation or directive), the level of harmonisation and the choice of legal concepts further contributes to the balance between upholding uniform EU law and respecting differences between Member States. 423 The bulk of EU legislation, with the basis in the EU treaties, and as interpreted by the CJEU, forms

421 Reichel, 121, 127 ff.
423 Bakardjieva Engelbrekt 2009, 235 f.
not only the foundation but also the limits of the competence of the Union vis-à-vis its Member States.⁴²⁴

An important feature of the system is the procedure of reference for a preliminary ruling, in which national courts question the CJEU on the interpretation or validity of EU law. Article 267 TFEU specifies the circumstances under which a reference must be made; in cases of doubt regarding a European provision a national court must always refer the matter to the CJEU.⁴²⁵ The national court, however, remains competent as regards the original case. It falls on the national court to formulate the question(s) to be submitted, which should preferably be an abstract inquiry concerning the interpretation of EU law, and not a direct question related to the dispute in the case before the national court. The CJEU has quite a large room for manoeuvre to reformulate the questions asked, despite the task formally put on the national court. Questions are seldom dismissed by the Court, and reformulation is a means of treating the issue referred but at the same time respecting the allocation of jurisdiction between the CJEU and the national court. The reformulation need not always be a sign of failure to make a proper reference on the part of the national court. As the Court has shown this implied power to reformulate is sometimes used to refrain from deciding on controversial or dubious points of law.⁴²⁶

9.4 Biotech Patent Law Harmonisation

The influence of EU law within the patent law domain is, so far, mainly restricted to the harmonised area under the Biotech Directive. By the delegation of the sovereign powers of the EU Member States, normative development of the CJEU and the creation of EU-autonomous concepts is a logical conclusion. Still, outstanding questions remain as to the effects of the rules of the Directive in relation to national law.

Fundamental rights as laid down in (in particular) the European Convention on Human Rights (ECHR) have been dealt with by the CJEU as forming part of the legal system of the EU, and fundamental rights are included in the EU

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⁴²⁵ 'The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning:
(a) the interpretation of the Treaties; (b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union; Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon. Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court. If such a question is raised in a case pending before a court or tribunal of a Member State with regard to a person in custody, the Court of Justice of the European Union shall act with the minimum of delay.'

⁴²⁶ Broberg and Fenger, 214 ff.
legal order. Such inclusion in the biotechnology patent field is also apparent from Recital 43 of the Biotech Directive:

Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law[…]

The concepts of morality and ordre public (in a non-patent setting) have been interpreted in a number of decisions by the CJEU in the context of free movement of goods and services as well as in relation to secondary EU law.

In relation to the interpretation of the Biotech Directive’s articles, the legal status of recitals of directives in EU law has been debated. A tentative conclusion regarding their effect is that they fulfil the purpose of stating the reasons for enacting relevant acts of legislation (regulations, directives, decisions, etc.). Recitals are always subordinate to the operative provisions which they relate to. They have no operative effect on their own but a clear recital can limit the nature or the scope of an ambiguous operative provision. The preamble to a Community act has therefore no binding legal force and ‘cannot be relied on either as a ground for derogating from the actual provisions of the act in question or for interpreting those provisions in a manner clearly contrary to their wording’.

The European Commission uses a large number of consultative entities in the performance of its duties. The preparation of legislative proposals and policy initiatives, the preparation of delegated acts and the implementation of EU legislation, programmes and policies, including coordination and cooperation with Member States and stakeholders are all conducted with the aid of various expert groups. Such groups could be formal or informal, permanent or temporary and are subject to strict regulation as to their mandates, role and selection of members. The expert groups acts mainly as a forum for discussions and provide expertise from a wide range of sources and stakeholders. The input of the groups in the form of recommendations, opinions and reports is not binding on the Commission and its departments, which remain fully independent regarding the way they take into account the expertise and views gathered. Fur-

427 Charter of the Fundamental Rights of the European Union (2010/C 83/02).
thermore, the groups are not the sole source of expertise used by the Commission, as studies, European agencies, green papers, hearings etc. are complementary sources of information.\footnote{Register of Commission Expert Groups and Other Similar Entities, ec.europa.eu/transparency/regexpert/index.cfm?do=faq.faq&aide=2 (28 January 2015).}

In the biotech patent context, the operation of a specific expert group is of interest. According to Article 7 of the Biotech Directive ‘[t]he Commission’s European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology’. Recital 44 further states that:

Whereas the Commission’s European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law;

The European Group on Ethics in Science and New Technologies (EGE) is an advisory group on European ethics operating under the President of the European Commission.\footnote{See Articles 1-3 of the Mandate of the European Group on Ethics in Science and New Technologies 2011-2016, established by the Decision on the renewal of the mandate of the European Group on Ethics in Science and New Technologies (2010/1/EU) of 23 December 2009 (EGE Mandate). The mandate is found at cc.europa.eu/bepa/european-group-ethics/welcome/mandate-2011-2016/index_en.htm (3 July 2014).} Its mission is to:

[a]dvise the Commission on ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative. The Parliament and the Council may draw the Commission’s attention to questions which they consider to be of major ethical importance. The Commission shall, when seeking the opinion of the EGE, set a time limit within which such an opinion shall be given.\footnote{See Article 2 of the EGE Mandate.}

Despite the role given to the EGE in terms of the Directive and despite the fact that the EGE has issued Opinions on e.g. stem cell patenting, the opinions of the EGE have not been directly visible in the CJEU’s decisions with regard to the Biotech Directive.\footnote{Case C-377/98 Netherlands v Parliament and Council [2001] ECR I-07079, Case C-456/03 Commission of the European Communities v Italian Republic [2005] ECR I-5335, Case C-428/08 Monsanto Technology LLC v Cefetra BV and Others [2010] ECR I-6765, Case C-34/10 Oliver Brüstle v Greenpeace eV [2011] ECR I-9821 and Case C-364/13, International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, Judgment of the Court (Grand Chamber) of 18 December 2014.} Criticism has been voiced over the institutional design, role and limitations of the Group.\footnote{See Plomer 2008, 839-859 and Beyleveld, Brownsword and Llewelyn, 169. Cf. Hermerén, 34 ff.} Additional criticism was also delivered by the EPO Opposition Division with regard to the advice of the EGE in relation to patenting (in general) and stem cell patenting (specifically) expressed
in its Opinion 16. The Opposition Division totally disregarded the use of the Opinion in a patent law context. After considering the Opinion, the Opposition Division concluded that the Opinion (for several reasons) could not be taken into consideration, but should be disregarded in toto, due to ‘its many inconsistencies, logical flaws, and incompatibility with existing patent law and the EU Directive’. 435

9.5 International Agreements and the EU Legal Order

Even though the direct effect of EU law in national law is not disputed, the question of effect of international agreements within the EU legal order is of acute relevance, both with regard to the agreements concluded on behalf of the Union but also with regard to agreements concluded by its Member States. There are also situations which display a mixed competence, where the Member States and EU are both parties to the same agreement, which is the situation in the case of the WTO membership, and the related Agreements, such as TRIPS.

The question of influence of external treaties and agreements on the interpretation of EU legislation is complicated. From the point of view of European patent law, the question is the extent to which compliance with TRIPS is of relevance for the EU vis-à-vis its Member States. An analysis of the compliance of Union law to its international obligations therefore requires an investigation into the legal situation with regard to the relationship of EU law, international law and domestic law respectively from the point of view of the effect within the EU legal order of international agreements to which the EU is a part. To give a satisfactory answer, a number of issues need to be identified and described: the position of international law within the EU legal order (especially with regard to international treaties concluded by the EU and treaties concluded by its Member States both), the division of competence between the Union and its Member States in relation to treaties to which they are both parties, possibilities for judicial review of the EU legislation in case of norm conflicts, and the effects of non-compliance by the EU in relation to TRIPS obligations.

9.5.1 Status of International Law

Article 216(2) of the TFEU states that ‘[a]greements concluded by the Union are binding upon the institutions of the Union and on its Member States’, and forms the basis for the principle that binding international norms are part of the EU legal order, a principle likewise recognised by the CJEU. 436 The rule in

435 See Opposition Division decision of 21.07.2003 (Edinburgh), para 2.5.4.
Article 216(2) does not, however, solve the problem of conflict with other, equally binding norms. Validity in this sense does not equal the primacy of norms of international agreements over community norms. A related issue is whether the international norms may have direct effect in the EU (and perhaps also in the national) legal order(s) in the sense that individuals may challenge existing law based on obligations in an international agreement. The fact that a norm is valid does not automatically equal a possibility to apply them in case of a conflict.437

The position of international law and obligations within the EU legal system has traditionally been handled by the CJEU from an approach which preserves the autonomy of the EU, i.e. one of constitutional detachment from the dependence on Member States.438 The autonomy is necessary for the establishment of the principles of direct effect439 and supremacy – the ultimate elements of the construction of the EU legal order – and thereby to achieve uniformity in the application of Community law, and to prevent an indirect influence of international law into the EU legal order stemming from the Member States.

In a situation where the EU Member States have agreed to international obligations the solution of the EU (with regard to e.g. norm conflicts) between national law (incorporating international obligations) and EU law has been that of constitutional detachment on the part of the Union, usually by the application of the principle of supremacy.440 This choice of constitutional application is perhaps not surprising, as the autonomy and uniformity of EU law could otherwise be jeopardized by international obligations entering into the EU system via the route of national law. To award international obligations concluded by the EU Member States the same status in the internal EU legal order as agreements concluded by the Union is therefore not appropriate from the point of view of EU autonomy.

The result is that the EU Member States are forced to accept EU law at the expense of their own international obligations, which in unfortunate circumstances may lead to liability issues for the national states with regard to third parties in terms of international law. Therefore, the CJEU has opened up for the possibility to integrate rules of international agreements, to which all Member States are parties, into the EU legal order, by means of different types of 

437 See Wessel, 13 ff.
438 Including the use of the concepts of autonomy and reception. See discussions regarding the EU legal order as monistic or other in van Rossem, 59, Eeckhout, 326 and Wessel, 11 with further references in fn. 15 to Pescatore and Schermers.
439 The concept of direct effect of international law gives rise to a number of questions regarding its content and definitions. For a survey of the case law of the CJEU on direct effect, see Eeckhout, 331. For a comprehensive overview of literature on this topic, see Bonafé, 229 fn. 1-2.
440 van Rossem, 76.
solutions. The incorporated international law is placed on a rank below EU primary law in the internal hierarchy, as the former is characterized as the ‘ultimate frame of reference’.

9.5.2 Mixed Agreements

The EU is recognised as a highly relevant actor, sometimes alongside its Member States, in a number of international institutions. The EU Treaties establishes competence for the EU institutions to conclude agreements or undertake other obligations in various domains of policy-making, often very broadly defined. But the delimitations of competence of the Union vis-à-vis its Member States is not always clear cut, and sometimes gives rise to so-called mixed external action or the conclusion of mixed agreements. In such situations, the EU and its individual Member States are both parties to the same agreement. The TRIPS Agreement is such a mixed agreement.

When discussing the principles of mixed agreements it is important not to confuse the issue of external questions (responsibility towards third parties) with internal questions (enforceability and possibility for legislative review within the EU legal order). The competence of the EU to enter into international agreements on behalf of its Member States is restricted to the areas in which its Member States have transferred part of their sovereignty. The affiliation of the EU to the WTO Agreement and its Annexes (including TRIPS) was the object of a lengthy process. Several aspects of the affiliation and implementation related to fundamental legal problems: the division of powers between the EU and its Member States, the relation between treaty law and international law and the position of the EU vis-à-vis its Member States in the WTO. The problems were addressed by the CJEU in an Opinion, where the Court stated that the conclusion of TRIPS was made under joint competence and the WTO charter was signed as a mixed agreement by the EU and the Member States individually in relation to their specific capacities.

Following the statements of the Opinion, the division of competence of the EU and its Member States becomes an issue of whether the Union has retained

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441 The conditions for such transfer are first, that the EU has received full powers to act in a domain, and second, that the EU is capable to act at the relevant international level. See Joined cases 21 to 24/72 International Fruit NV v. Produktschap voor Groenten en Fruit [1972] ECR 1219.
442 van Rossem, 68.
443 For an analysis of the recognition of EU as a relevant actor in international institutions, see generally Gehring, Obertür and Mühleck.
444 Eeckhout, 212.
445 Id., 213.
446 Case 6/64, Costa v. ENEL [1964] ECR 585. See also Wrange, 351 ff.

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competence in the specific field (within the scope of the international treaty) by legislation and harmonisation efforts. Two situations may arise. The first is when the obligations of the international treaty are a matter for EU law, and the Member States incorporate the obligations or rights of the international treaty in terms of Union law. The second situation is where the EU has not retained competence, and the Member States must then handle the obligations and rights stemming from the international treaty in terms of their national law. In Parfums Christian Dior the CJEU held:

In a field to which TRIPs applies and in respect of which the Community has already legislated, [...] it follows from the judgment in Hermès, in particular paragraph 28 thereof, that the judicial authorities of the Member States are required by virtue of Community law, when called upon to apply national rules with a view to ordering provisional measures for the protection of rights falling within such a field, to do so as far as possible in the light of the wording and purpose of [...] TRIPs.

On the other hand, in a field in respect of which the Community has not yet legislated and which consequently falls within the competence of the Member States, the protection of intellectual property rights, and measures adopted for that purpose by the judicial authorities, do not fall within the scope of Community law. Accordingly, Community law neither requires nor forbids that the legal order of a Member State should accord to individuals the right to rely directly on the rule laid down by [...] TRIPs or that it should oblige the courts to apply that rule of their own motion.449

The CJEU confirmed its reasoning in the subsequent Merck450 decision, in which the question of direct application of Article 33 of the TRIPS Agreement by national courts was answered in the affirmative. The absence of Community legislation in the relevant field (patent law) made the Member States principally competent as regards the specific issue of direct effect, and they may therefore choose whether or not to grant direct effect to the rule in question (subject to the provisions of national law).451

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451 Case C-431/05, especially paras 31-36 and 46-48.
The EU has not harmonised patent legislation, only in the specific field of biotechnological inventions, although the patent with unitary effect will complement the EPC system and move the EU system closer to a full harmonisation. But the competence that EU exercises in relation to TRIPS is found in Article 207 (ex. Article 133) TFEU, which expanded the scope of the Common commercial policy according to the following: ‘[t]he common commercial policy shall be based on uniform principles, particularly with regard to […] the commercial aspects of intellectual property rights.’ It is suggested that with regard to IP rights, and the question of competence of the EU Member States in relation to the EU with regard to TRIPS, the position taken by Article 207 TFEU and the authority displayed by the EU renders any remaining national competence rather meaningless.452

Thus, the establishment of full competence of the EU with regard to ‘the commercial aspects of intellectual property’ by virtue of Article 207(1) TFEU may have the effect of rendering the question of division of competences irrelevant, as the whole of TRIPS is now placed within the scope of EU law.453 Eeckhout views the jurisdiction of the CJEU as now being complete (as already held by the CJEU in Merck454) and that it is only as regards questions of international responsibility, i.e. external issues, where the principles of competence with regard to mixed agreements are still relevant. The possibility for national law in Member States to determine e.g. questions of direct effect of international treaties in terms of national law is from such a point of view consequently removed.455

9.5.3 Legislative Review in Cases of Conflict of Norms

International agreements in fields in which the EU has asserted competence vis-à-vis Member states become part of the EU internal legal system and are handled by the EU legal order.456 The question of direct effect of the agreement within the EU legal order is evidently dependent of the nature of the agreement in question, the obligations adhered to and the nature of the rights created by the treaty. The issue of jurisdiction to interpret the rules of TRIPS is, however, a different matter as opposed to the question of direct effect of the rules in EU or national law. From the point of view of TRIPS compliance, the possibility

452 See Kuijper, 224 and Subramanian, 1014.
453 See Case C-414/11 Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v DEMO Anonimos Vionikhaniki kai Emporiki Etaireia Farmakon, Judgment of 18 July 2013, especially paras 57-60.
455 Eeckhout, 285-286.
456 van Rossem, 72.
for legislative review is important, and direct effect of the rules has a bearing on this particular question.

The CJEU retains full competence of interpretation of TRIPS, as evidenced in *Merck* by the reference to the conclusion of the Agreement 'by the Community and its Member States by virtue of joint competence.' Such joint competence does not only give the CJEU jurisdiction to define the obligations arising from the Agreement, but also to interpret the provisions. When the competence of the EU becomes a criterion for jurisdiction, problems arise as the former may be very complex and particularly difficult to ascertain.

The obligations falling on Member States according to TRIPS cannot be subject to conflicting regulation from the EU. If internal acts of the EU institutions (i.e. secondary EU law) are in conflict with the provisions of an international agreement binding upon the EU, the possibility to challenge the legality of such acts on the basis of a violation of the latter is an important issue. Since the EU has retained full competence with regard to the scope of TRIPS, Member states could find themselves in a situation of conflict between their international obligations and obligations stemming from EU law. The possibility of legislative review by the CJEU of such conflicts of norms is important as otherwise the Member State will face a situation of breach of obligations, either in relation to EU law or in terms of the international agreement. In addition, where the EU is a part of an international agreement, such as TRIPS, non-compliance of EU law in relation to its international engagement could, especially considering the binding force of the TRIPS obligations, risk the initiation of DSS proceedings for failure to comply with the rules. The same is true for a Member State, which in a situation of conflict of norms will not only risk being subject to DSS proceedings for failure to comply with TRIPS obligations, but also be in risk of breach of EU law entailing consequences within the EU legal system.

The CJEU has stated that lawfulness of an EU instrument, such as e.g. the Biotech Directive, cannot be assessed in the light of instruments of international law which 'are not in principle, having regard to their nature and structure, among the rules in the light of which the Court is to review the lawfulness of measures adopted by Community institutions.' On the other hand, measures taken by the EU need to be TRIPS-compliant, something that is further ensured by Article 1(2) of the Biotech Directive.

When determining the possibility of legislative review the first issue is whether the EU is bound by the international obligation, and in the case of

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458 Id.
TRIPS this is evident. The second issue is whether compliance with the international obligation can be secured within the EU legal system. Usually this issue is treated according to whether the international obligations have direct effect within the Union, in the sense of creating rights which individuals (or Members) could rely on directly before the courts. As mentioned in Section 7.3.2.1, the question of direct effect is partly related to the character of the international treaty (in the sense that it contains norms which can create such rights) and partly related to the legal tradition of the EU system.

The Court has generally tied the question of direct effect of an international obligation to the presence of dispute settlement mechanisms for the enforcement of an international agreement. The WTO DSS does not from this perspective fulfil the principle of creating enforceable decisions, as it is regarded by the CJEU as founded instead on principles of negotiations and reciprocity. In the case of a breach of WTO obligations the outcome is not a matter of strict compliance with the primary obligations but rather a matter of allowing parties ‘to negotiate a mutually satisfactory solution of the dispute’. Although it is possible to find cases where the negotiation alternative is exhausted within the DSS procedure and thereby requiring implementation of the outcome of the DSS decision, indicating a situation where full compliance is the only remaining option, the CJEU has not recognised arguments based on such a scenario. In general, the lack of the pure enforcement character of the WTO DSS makes EU secondary legislation immune from judicial review in relation to WTO law, even though such legislation may be inconsistent with TRIPS obligations.

As mentioned, the CJEU has denied direct effect to WTO law in general, including the TRIPS provisions, in the sense that it lacks capacity to serve as a basis for a legality review of EU acts. If attributed with direct effect, WTO law would have a constitutional function for the EU legislator. The CJEU only

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462 Cf. Miller, 597 ff.
464 Tancredi, 254 ff.
465 The absence of ability for legality review was criticised by Advocate General Jacobs in the Opinion in Case C-377/98, stating that ‘[i]t might be thought that it is in any event desirable as a matter of policy for the Court to be able to review the legality of Community legislation in the light of treaties binding the Community. There is no other court which is in a position to review Community legislation; thus if this Court is denied competence, Member States may be subject to conflicting obligations with no means of resolving them.’ Opinion of Advocate General Jacobs, delivered on 14 June 2001, Case C-377/98, Netherlands v Parliament and Council, para 147.
denies direct effect to WTO law when it comes to forcing the legislative institutions of the EU to comply with the WTO – but this does not preclude the presence of any effect at all.467

The perspective applied by the CJEU towards the nature of WTO obliga-
tions has rather been of a dualistic character in terms of the effects these norms have been given within the EU legal system. On the other hand, the Court has displayed a willingness to recognize the direct effect of a number of other international treaties, a practice that fits with the notion of the EU as an alleged monist legal order.468 Also, the conclusion of the CJEU that direct effect is required if legality review of EU acts in the light of an international agreement should take place is interestingly enough not without exception, as indicated by the Court in the Netherlands case469 (of annulment of the Biotech Directive). Despite the seemingly clear position of the CJEU on the matter of direct effect, some interesting statements are found in that decision.

One of the claims for annulment was based on the opinion that the Biotech Directive violated not only TRIPS but also the Agreement on Technical Barri-
ers to Trade (TBT, another WTO agreement), the EPC as well as the Convention on Biological Diversity (CBD). Initially the CJEU declined legality review of the Biotech Directive on the basis of established principles in relation to treaties to which the Community was not a part (EPC) as well as treaties to which the Community is a part, but with reference to the lack of direct effect (WTO law in general; here TRIPS, TBT).471 But with regard to the CBD the Court stated that the exclusion from review applied to the WTO law but did not apply to the CBD, ‘which, unlike the WTO agreement, is not strictly based on reciprocal and mutually advantageous arrangements’.472 Despite the fact that the CBD did not contain provisions of direct effect (as held by e.g. the Council), the CJEU did not preclude review of compliance with the international obligations falling on the EU as a party to that specific agreement, despite the

467 von Bogdandy, 404.
470 Convention on Biological Diversity (concluded in Rio de Janeiro on 5 June 1992)
471 The Court held that ‘[i]t is common ground that, as a rule, the lawfulness of a Community instrument does not depend on its conformity with an international agreement to which the Community is not a party, such as the EPC. Nor can its lawfulness be assessed in the light of instruments of international law which, like the WTO agreement and the TRIPS and TBT agreements which are part of it, are not in principle, having regard to their nature and structure, among the rules in the light of which the Court is to review the lawfulness of measures adopted by the Community institutions’. Case C-377/98 Netherlands v Parliament and Council [2001] ECR I-07079, para 52 with reference to Case C-149/96 Portugal v Council [1999] ECR I-8395, para 47. The foundational cases of International Fruit (Joined Cases 21 to 24/72 International Fruit Company NV v. Produktie voor Groenten en Fruit [1972] ECR 1219 are the legal precedent, also confirmed by Case C-377/02 NV Firma Léon Van Parys v. Belgisch Interventie- en Restitutiebureau [2005] ECR I-1463.
nature of the obligations. The CJEU rather focused on the nature of the strict obligations contained in the CBD.

Such a statement must be read in the light of established case law which, at least with regard to GATT and WTO, uses the issue of direct effect (the creation of rights) as a prerequisite for the review of legality. The recognition of CBD, with its incapacity to create rights, as an instrument to be used in a legality review, is therefore surprising. The Court unfortunately refrained from elaborating on that particular statement, and held instead that the plea of the claimant should ‘be understood as being directed, not so much at a direct breach by the Community of its international obligations, as at an obligation imposed on the Member States by the Directive to breach their own obligations under international law, while the Directive itself claims not to affect those obligations’. From this point of view of argument, the Court proceeded to examine the allegations and found no violation of the agreements on behalf of the Directive. The legality of the Biotech Directive in relation to TRIPS was in this respect not treated as a substantive issue by the Court, but rather from the point of view of the obligations imposed on the Member States by the Directive.

The impossibility of direct judicial review of the legality of EU acts in relation to TRIPS in particular and WTO law in general leaves little room for manoeuvre. Should the prospect of legality review then be treated as totally impossible? Perhaps not, if recourse is made to application of the principle of ‘consistent interpretation’ which may serve as an indirect possibility to review EU secondary legislation in the light of its international obligations. The CJEU has recognised the principle of consistent interpretation with regard to secondary Community legislation in its relation to the EU Treaties as well as the international agreements concluded by the Union. The result of the Court’s interpretation in conformity with the principle is that international provisions lacking direct effect are given a kind of indirect effect within the EU legal order. In the case of WTO, not only TRIPS provisions but also adopted Appellate Body or panel decisions form the bulk of law according to which EU law needs to be interpreted in a consistent manner.

Still, despite the recognition of the principle of consistent interpretation in the Court’s case law there are remaining difficulties and inconsistencies. The CJEU seems, for instance, reluctant to solve clashes between international and EU law, a stance which has been criticised as leading to legal uncertainty where

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473 See Eeckhout, 297.
476 Gattinara, 284, with further reference to Eeckhout (fn. 75).
international law content is interpreted with the primary aim of reducing such inconsistencies.\textsuperscript{477} It has been argued that by failing to (correctly) apply the rule of consistent interpretation, the Court thereby placed international agreements (in this case, TRIPS), in an intermediate position between primary and secondary EU law.\textsuperscript{478} In the context of TRIPS, conformity with the principle requires national or EU rules to be consistent with the fundamental principles of the Agreement, as expressed particularly in Article 8 TRIPS. Such a requirement will have the effect that measures adopted by TRIPS Members need to be necessary to meet the objectives of TRIPS, otherwise the consistency principle may not be fulfilled.\textsuperscript{479}

9.6 EU Law Under Pressure?

International law is often described as being founded in domestic law, and the international legal order depends on its enforceability within the domestic legal systems.\textsuperscript{480} The inclusion of international obligations and their internal effect on national law is often subject to the constitutional principles of monism or dualism, although a strict division between the two systems is difficult to uphold. The EU legal order forms a specific case between the spheres of international and domestic systems, and it is not evident how the EU should be treated as an actor on the international legal stage. The concepts of dualism and monism are not suitable to describe the influence of international obligations within the EU legal system, because of its foundations being based on the transfer of competences from its Member States and where the principles of autonomy and uniformity have created a legal order with its own unique legal principles and rules for inclusion of external acts and the division of competences between the Union and its Member States. From the perspective of international law, the reasons for preserving the EU legal order which affects the international obligations of the Union and its Member States both may not always be valid.\textsuperscript{481}

In the case of TRIPS compliance, the EU retains full competence both as regards the question of direct effect, but more importantly also to decide on conflict of norms between EU legislation and TRIPS obligations. The possibilities for legislative review of EU legislation in the light of its TRIPS obligations is, however, limited under the general EU principles applied by the CJEU. The principle of consistent interpretation may lead to indirect compliance of EU

\textsuperscript{479} See Subramanian, 1009, especially fn. 82.
\textsuperscript{480} van Rossem, 88.
\textsuperscript{481} Id., 89.
law, but the possibilities are limited. In sum, the EU seems reluctant to solve norm conflicts between EU legislation and international law, as evidenced in relation to the Biotech Directive.
10 The European Patent Organisation

10.1 General Description

The European Patent Organisation\textsuperscript{482} was established on 7 October 1973 on the basis of the EPC, signed in Munich in 1973 and entered into force in 1978. The Organisation has the nature of a classical intergovernmental organization based on an international treaty, the EPC, and an executive body in the form of EPO in Munich.\textsuperscript{483}

In contrast to the EU, the Organisation only has powers in a specific and well-defined field of activity. The validity of national laws is restricted to the territory of each state and the basic principle is that patent protection is to be taken out on a territorial basis, i.e. a patent must be sought in each state where protection is desired. The EPC system is an exception to this rule, where one application to the EPO\textsuperscript{484} entails a common procedure for examination and grant, and where the resulting European patent may be confined to as many of the Contracting States as the applicant designates in the application.\textsuperscript{485} The EPC thus establishes a uniform granting procedure for patent applications for the Contracting States of the Convention.

\textsuperscript{482} Whereas the Organisation is independent from the EU, all 27 EU Member States plus 11 more states are members of the European Patent Organisation. The EPC area forms the largest single patent region in the world – a single grant procedure which can lead to patent protection in a potential market of more than 500 million people, considerably larger than that of the USA and Japan together. www.epo.org/about-us/organisation/member-states. (2 May 2015).

\textsuperscript{483} Paterson, 24. On supranational elements in the structure of the Organisation and its financial autonomy see van Empel, 27.

\textsuperscript{484} The procedure in the EPO consists generally of the following steps: The Receiving Section is responsible for the examination on filing and the examination as to formal requirements of each European patent application. It is also responsible for the publication of the European patent application and of the European search report. An Examining Division examines each European patent application from the time when the Receiving Section ceases to be responsible. An Examining Division consists of three technical examiners. Oral proceedings are held before the Examining Division itself. If the Examining Division considers that the nature of the decision so requires, it shall be enlarged by the addition of a legally qualified examiner. An Opposition Division is responsible for the examination of oppositions against any European patent. An Opposition Division consists of three technical examiners, at least two of whom shall not have taken part in the proceedings for grant of the patent to which the opposition relates. Oral proceedings may be held. If the Opposition Division considers that the nature of the decision so requires, it shall be enlarged by the addition of a legally qualified examiner who shall not have taken part in the proceedings for grant of the patent. The Boards of Appeal are responsible for the examination of appeals from the decisions of the Receiving Section, Examining Divisions, and of the Opposition Divisions. The Boards of Appeal consist of combinations of technically and legally qualified members, depending on the nature of the appeal in question. Decisions of a Board of Appeal may be applied to the Enlarged Board of Appeal. However, the Enlarged Board of Appeal rules only on points of law, referred to it by Boards of Appeal, or gives opinions on points of law referred to it by the President of the European Patent Office.

\textsuperscript{485} See also for example the procedures established by the African Regional Industrial Property Organization, ARIPO, www.aripo.org/ (9 April 2015), as well as the simplified application procedure established by the PCT.
Ratification of the EPC does not formally imply a harmonisation of national laws, but the majority of the Contracting States have voluntarily amended their laws to achieve conformity.\textsuperscript{486} Membership in the European Patent Organisation requires acceptance of the decisions by the EPO to grant or refuse a patent application.\textsuperscript{487} From this point of view it is important to emphasize that the EPC only regulates the pre-grant and granting phase but not the post-grant effects of a patent.\textsuperscript{488} The post-grant proceedings for EPC-patents are handled by the UPC once the Agreement regarding the Court enters into force.\textsuperscript{489} Until such time as the UPC starts to function, infringement and validity proceedings will still be a matter for each national jurisdiction, and will also exist as a parallel option under certain circumstances in the future.\textsuperscript{490} Under the system with national jurisdictions, a harmonizing factor is Article 138 EPC, which limits the grounds for invalidation of European patents, but the joint grounds do not remedy the differences in interpretation, which still exist between the courts and administrative authorities of the EPC Contracting States. The same European patent may be found valid in some states but revoked in others. Issues of scope of protection and validity considerations lead to legal uncertainty. The introduction of the European patent with unitary effect and the UPC will be a means to remedy this situation.\textsuperscript{491}

10.2 The Organisation\textsuperscript{492}

The aim of this section is to briefly point out some specific features of the present system of the structure, powers and decision-making in the European Patent Organisation. By its institutional role as creator, interpreter and executor of the EPC, the Organisation sets the current patent philosophy and economic policy in the European context, with a direct influence on its Contracting states. Even though there is room for reciprocal action between the Organisation and the states, such action usually consists of the adoption of EPO-created standards and principles.

The main organs of the Organisation are the EPO and the Administrative Council.\textsuperscript{493} While the EPO exercises executive functions the Administrative

\textsuperscript{486} Bakardjieva Engelbrekt 2009, 249.
\textsuperscript{487} Article 2 EPC.
\textsuperscript{488} Cf. Article 105b EPC:
\textsuperscript{489} See the Agreement on a Unified Patent Court, Council of the European Union, Brussels, January 11, 2013, especially Articles 1-3. The future European patent system is described in Chapter 11.
\textsuperscript{490} Cf. Article 69 EPC and its connecting Protocol. See the function of the future patent system in Chapter 11.
\textsuperscript{491} See Chapter 11.
\textsuperscript{492} On the issue of legitimacy see e.g. Bakardjieva Engelbrekt 2009, 247-269, Borrás, 594-610 and Schneider, 619-628.
\textsuperscript{493} Article 4 EPC.
Council acts as the EPO’s ‘supervisory body’, and thereby ‘exercises legislative powers on behalf of the Organisation, is responsible for policy issues relating to the Organisation and supervises the Office’s activities.’ The representation by the Contracting states in the Administrative Council consists almost entirely of specialized persons such as e.g. high-ranking national patent officials. As mentioned, amendments to the EPC require unanimity among the Contracting states, a difficult and time-consuming process. The Implementing Regulations can, on the other hand, be amended by the Administrative Council, to which concentration of additional powers was further achieved through the 2000 EPC revision.

The patenting procedure is by nature an administrative procedure, but the possibilities for appeal to the Boards of Appeal has resulted in the procedure being held not to be of the strictly administrative domain.

The decisions of the Boards of Appeal are an important source of interpretation of the EPC. Although the EPC provisions (not least the procedural ones) aim at securing their independence, the lack of effective measures to guarantee such independence from a practical point of view, especially with regard to the role of the President of the EPO, could be questioned. The President is not only responsible for the management of the Boards but has also the right to nominate its members and has a right to comment on questions of general interest which arise before the EBA. In addition, there is poor transparency in the distribution plans for assigning cases to the Boards. The fact that there is a practice of appointing the Vice President of the EPO as a Chairman of the EBA further contributes to arrangements which ‘undermine confidence in the fairness of the system.’ Aerts concludes that:

Patent law-making under the EPC system appears to be a predominantly intergovernmental process, wherein the European Patent Organisation and particularly the Administrative Council play – next to their executive roles – a legislative role, and the Conference of the Contracting States possesses the most significant law-making power. Amendments are designed and adopted within the system; there is no active participation of a democratically elected body, and there is no judicial review of adopted legislation.

Thus, the institutional structure of the European Patent Organisation is not only questionable from a legitimacy point of view, but furthermore the rules do

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495 Bakardjieva Engelbrekt 2009, 249.
496 Achieved by the transfer of provisions from the EPC to the Implementing Regulations and the competence to amend certain parts of the text of the Convention. See Bakardjieva Engelbrekt 2009, 250.
497 Holtz, 64.
498 Bakardjieva Engelbrekt 2009, 251.
499 Id.
500 Aerts, 169.
not ensure an independent setting for the Boards of Appeal. In addition, access for various political groups, NGO’s and individuals to the patent granting procedure is given through the possibility for third parties to give notice of opposition to a granted patent as well as the possibility to submit third-party observations and request oral proceedings. Although the aim of such participation and access is clearly to ensure active engagement on the part of the public and raise public awareness, the drawback is that in such a quasi-judicial setting as that which the EPO operates in, isolation from public pressure cannot be guaranteed.

The EPO, its President and the Administrative Council ‘exercises the combined powers of initiative of law-making, law-making itself and execution of the law.’ The lack of legitimacy in various aspects of the institutional setting of the European Patent Organisation and the failure to ensure independence for the Boards of Appeal from internal as well as external considerations is important when considering the role of the EPO as the foremost interpreter of European patent law, not least when entering such a problematic field of patent law as biotech invention and related moral issues. With this background it is interesting to proceed to the issue of the inclusion of the Biotech Directive as a supplementary means of interpretation of the EPC, and the consequences of opening up the (already troubled) EPC system to the additional influence of EU law and principles.

10.3 Principles of Interpretation

10.3.1 Internal Principles

According to Article 164 EPC, the Implementing Regulations and Protocols of the EPC are an integrated part of the Convention. In cases of conflict the Articles of the Convention have precedence. The amendment of the Implementing Regulations only requires a majority vote and the decision by the Administrative Council, whereas amendments to the Convention require unanimity of the Contracting States.

An additional source of interpretation of the EPC is the Guidelines for examination in the European Patent Office, which give instructions on the practice and procedure to be followed in the various aspects of the examination of European applications and patents and have the character of administrative

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501 See Articles 99, 115, 116 and 128 EPC respectively.
503 Aerts, 173.
504 Article 35 EPC.
regulations adopted by the President of the EPO. The importance of the Guidelines as an interpretative source decreases the higher in the appeal hierarchy a decision climbs, and the Boards of Appeal are not bound by any instructions, only the provisions of the EPC.

The Divisions and Boards of the EPO are according to Article 114 EPC generally subject to an *ex officio* principle: ‘In proceedings before it, the European Patent Office shall examine the facts of its own motion; it shall not be restricted in this examination to the facts, evidence and arguments provided by the parties and the relief sought.’ The first-stage examination is naturally conducted on the basis of the patent application, while the appeal review process may widen the scope of relevant issues. The civil nature of the EPO *inter partes* proceedings puts the responsibility on the initiating party for the presentation of legal facts in order to fulfil the relevant prerequisite. In the matter of morality and *ordre public* this means that the party must invoke the relevant norm corresponding to the legal prerequisite and the issue relative to a breach of that norm. This must be substantiated by the facts relevant to the issue and it is ultimately the authority or the court that decides on the norm in question. And even if the *ex officio* principle in Article 114 EPC applies to all stages of the procedure, it is usually on appeal that the relevant facts, evidence and arguments take form. The EPO appeals procedure is also sufficiently broad to provide the Boards of Appeal with full powers according to ‘the language of the law’ to decide on whether a patent shall be awarded or not, even where the scope of the issues goes beyond the requests and facts presented by the parties.

The Boards of Appeal acknowledge the principle of free evaluation of evidence. This means that anyone (including the employees of parties) except the parties themselves may be heard as witnesses. The Boards can also decide whether or not the presented evidence is of any use or not. Irrelevant evidence, in addition to matters which cannot be considered as evidence, may be rejected as inadmissible.

In terms of legal precedent, Article 112(3) EPC states that a decision by the EBA only binds a referring Board of Appeal. See also Guidelines for Examination in the European Patent Office (November 2014), General Part, 1, 3. See also Article 10(2) EPC. See Article 23(3) EPC. Article 114(1) EPC. See e.g. G 10/93 (Ex parte examination) and Holtz, 74. See Holtz, 81-82. Wennersten, 48. See also Article 117 EPC on evidence. Holtz, 272-273. See also Article 117 EPC on evidence. Holtz, 448. Id. See also Guidelines for Examination in the European Patent Office (November 2014), Part E-IX, 7.
The decision of the Enlarged Board of Appeal referred to in paragraph 1(a) shall be binding on the Board of Appeal in respect of the appeal in question.

But according to Article 21 of the Rules of Procedure of the Boards of Appeal, deviation from principles of an EBA decision is only possible if necessary, and then only by referral to the EBA:

Should a Board consider it necessary to deviate from an interpretation or explanation of the Convention contained in an earlier opinion or decision of the Enlarged Board of Appeal, the question shall be referred to the Enlarged Board of Appeal.

Divergence is thus not possible for a Board of Appeal without further reference to the EBA. Furthermore, there is a presumption of precedent between Boards of Appeal decisions as well, since Article 20 of the Rules of Procedure states that the grounds for deviation from an earlier decision must be given, and that the President of the EPO should be informed of the Board’s decision. This applies also to deviation from the Guidelines.

Furthermore, the decisions of the EPO Boards of Appeal are an important source of law regarding the interpretation of the EPC, and consequently, the interpretation of European patent law. National patent practices and law regarding the pre-grant process is nearly unanimously harmonized and adapted to the EPC and follow the principles and decisions of the case law of the Boards of Appeal with great attention. Conversely, the EBA has held that the creation of a harmonized patent system necessitates that the EPO, especially the Boards of Appeal, ‘take into consideration the decisions and expressions of opinion of courts and industrial property offices in the Contracting States. The system, thus, rests upon principles of reciprocal action between the EPO and national courts and other authorities. However, the question of whether the Boards should take national legislation into account when interpreting the EPC is contentious and that specific principle has been refuted by the Boards of Appeal in later decisions.

515 The EPO carries out searches and substantive examinations on a steadily rising number of European patent applications and international applications filed under the PCT route. The Technical Boards of Appeal and the Legal Board examine appeals from the decisions of the receiving, examining, legal and opposition divisions of the Office. To ensure uniform application of the law, or if an important point of law arises, a question can be referred to the Enlarged Board of Appeal, either by a Board of Appeal or by the President of the Office.

516 See e.g., the Swedish decisions of RÅ 1990 ref. 84 (Talsignal), RÅ 1998 ref. 55 I (Jordbruksvält) and RÅ 1998 ref. 4 (Problemuppfinning). See Levin, 2011:1, 232 ff. and Wennersten, 366 f.


518 See e.g. T 1213/05, Reasons for the Decision, para 55 (national legislation) and T 452/91, Reasons for the Decision, para 5.4.1 (national court decisions).
10.3.2 External Norms

The EPC contains principles for the interpretation of the Convention, the Implementing Regulations and the Protocols, as well as rules of interpretation in the relation to PCT and the Paris Convention. There are no written rules or principles in relation to the inclusion of external treaties or texts as additional sources of interpretation. As a general rule of international law, states can only be bound by the document they have ratified. Further international agreements and treaties between the same parties can certainly be used as a source of interpretation of an earlier treaty. It that vein, it has been established that the EPC, as an international treaty has to be interpreted in compliance with the VCLT, a fact which is confirmed by the EBA as well as the Boards of Appeal.

In relation to the TRIPS Agreement the Board of Appeal found that although it may not be applied directly to the EPC, since TRIPS is binding only on its Member States, it is still appropriate to take it into consideration, ‘since it is aimed at setting common standards and principles concerning the availability, scope and use of trade-related intellectual property rights, and therefore of patent rights. Thus TRIPS gives a clear indication of current trends.’ From this statement it seems as if the TBA was more concerned with ensuring the establishment of common standards than with disregarding the application of an international treaty on formal grounds.

Nevertheless, the relation between TRIPS and the EPC is important for the Contracting states of the European Patent Organisation. Would a conflict of norms occur between TRIPS and the EPC, for instance in relation to the scope and application of the morality clause, the individual Contracting state may find itself in a situation where the interpretation of the EPC with a precedential value (i.e. by the EBA), if followed in national law, may lead to a conflict with its TRIPS obligations.

In addition, the Disciplinary Board of Appeal has stated that those provisions in the European Convention for the Protection of Human Rights which express general principles of law common to the Member States of the European Patent Organisation form part of the legal system of the EPO and should be observed by all its departments. It is of interest to note that the Opposition Division drew on principles regarding approval for informed consent from

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519 Wennersten, 367.
520 Bakardjieva Engelbrekt 2009, 256.
521 Id., with further reference to Straus: ‘This should, however, reasonably require a participation of all Contracting States to the original agreement in the subsequent agreements’.
522 Formally the VCLT is not applicable to the EPC since the former had not yet entered into force when the EPC was created. See Wennersten, 368. For the use of the VCLT see G 2/06, Reasons for the Decision, para 16 (with further references) and Singer and Stauder, 10. See also Porter 2009:2, 352 f.
523 T 1173/97 (Computer program product/IBM), Reasons for the Decision, para 2.
Article 13 of the (then) draft Bioethics Convention in its reasoning to allow a patent for the human substance Relaxin.\textsuperscript{525}

The principle that parties to an international agreement can use other, later common agreements for the interpretation of the earlier ones seems to have taken root in the practice of the EPO Boards. Although the decisions to use such instruments as a source of interpretation of the EPC have not been subject to either lengthy or deeply analytical considerations, they are notwithstanding an indication of a desire to align the EPC with common international standards and principles agreed upon between the Contracting States. This desire can certainly be applauded from the point of view of securing the reliance upon internationally agreed principles. But the lack of basic principles for inclusion of international agreements results in a flawed decision-making process. This is especially so when considering the use of an instrument such as the Biomedicine Convention\textsuperscript{526}, to which not all EPC Contracting States adhere to.

The inclusion of the Biotech Directive as a ‘supplementary means of interpretation’ of the Rules of the EPC and the Implementing Regulations opened up for the use of EU legal principles in relation to the handling of applications for biotech inventions in the EPO. Such inclusion has led to a number of questions regarding the legitimacy of and principles for the use of EU law in the EPO institutional setting. Despite the perceived difficulties, EU law in the form of the Biotech Directive now forms part of the EPC legal order through decisions of the EBA confirmed by the TBA:s.

10.3.3 The EPC and the Biotech Directive

10.3.3.1 Supplementary Means of Interpretation

In principle, biotechnological inventions are patentable under the EPC.\textsuperscript{527} To ensure a coherent European approach to the patenting of biotechnological inventions, the Directive’s articles were inserted into the Implementing Regulations of the EPC as part of the new EPC 2000, thus making them an integral part of the Convention.\textsuperscript{528} For European patent applications and patents con-
cerning biotechnological inventions, the relevant provisions of the EPC are to be applied and interpreted in accordance with the provisions of Rules 26-34 of the Implementing Regulations. It is furthermore stated in Rule 26(1) of the Implementing Regulations that the Biotech Directive is to be used as a supplementary means of interpretation. According to the Guidelines it is in particular the recitals to the Directive that are also to be taken into account.529

Even if all the EU Member States are also parties to the EPC, the European Patent Organisation and the EU are two separate institutional and judicial bodies governed under separate systems and rules. Both of these systems have their own structures for handling the influence of and relation to other international agreements. The Biotech Directive and its inclusion into the EPC Implementing Regulations opened up for a correspondence in legal rules, but without a corresponding and overarching system for its interpretation. The Boards of Appeal of the EPO have on several occasions had the opportunity to decide on matters related to the Directive, but there is no institutional solution to the division of competences and the risk of the EPO and CJEU arriving at different conclusions in decisions regarding the same legal matter.530

The risk of divergent interpretations of the corresponding rules, more specifically the morality exclusion, was raised in the Netherlands case on the basis of the (then) slightly different wording between Article 6(1) of the Directive and Article 53(a) EPC.531 At that time, Article 53(a) EPC used the terms ‘publication of exploitation’ whereas Article 6(1) of the Directive used ‘commercial exploitation’.532 The CJEU seemed to imply that despite the perceived differences the interpretation would be common to the different institutions; EPO, CJEU and national authorities and courts respectively, by stating that ‘[i]n the absence of specific examples to the contrary, it seems reasonable to suppose that a breach of ordre public and morality as regards a specific invention could be equally well established by reference to its publication, exploitation or commercial exploitation.’533 This statement would prove to be rather optimistic in light of later developments.

10.3.3.2 The Question of CJEU Referral

By the overlapping of relevant Articles of the Biotech Directive and the EPC, the EBA had to assess the question of referral for a preliminary ruling to the CJEU in the WARF decision.534 The appellant was seeking referral of questions to the CJEU on the argument that since Rule 28(c) EPC repeats

530 See e.g. G 2/06, Reasons for the Decision, paras 1-11.
532 The wording of Article 53(a) EPC was amended to ‘commercial exploitation’ in the 2000 EPC revision.
534 G 2/06 (Use of embryos/WARF).
the wording of Article 6(2)(c) of the Directive, the EBA is interpreting European Union law and should refer the question of interpretation to the CJEU.\textsuperscript{535} The EBA declined the argumentation by a thorough interpretation of the legal acts establishing the respective organisations – the EPC and the Treaty respectively.\textsuperscript{536}

\textsuperscript{535} G 2/06, Reasons for the Decision, para 2.
\textsuperscript{536} Id., paras 1-9.
Future Perspectives

The European patent law landscape is complex. Rules exist on different levels and in different institutional settings. Presently, there is a division of competences as well as corresponding rules in the different legal systems. TRIPS sets the international framework for patent legislation. But the national rules are to a large extent dependent on the EU and the European Patent Organisation. The EU Member States must adhere to the harmonisation under the Biotech Directive and follow the CJEU’s interpretation. This stems from the delegation of their sovereign powers to the EU, in order for the EU to create harmonisation in specific areas. At the same time, the European Patent Organisation and the EPC has to a large extent contributed to a harmonisation of the substantive patent law of its contracting states, but such efforts are largely the result of a voluntary adaptation. From such a perspective, the EU law takes precedence over the EPC, at least from the point of view of legal foundation of the rules in the national systems.

Generally, in terms of the EPC, European patents shall have the same effects and are subject to the same conditions as national patents. A European patent confers on its proprietor the same national rights as would be conferred by a national patent granted in that state; also, European patents are given the same or more protection upon publication of the application as that of a published national application. Furthermore, European patents may only be revoked on the grounds specified in the EPC. Finally, European patents must have the same prior right effects as a national patent application and a national patent.

In 2012 the majority of the EU Member States and the European Parliament agreed on the so-called ‘patent package’, a legislative initiative which consists of two regulations (unitary patent protection and translation arrangements) and an international agreement (Unified Patent Court) and established a unitary patent protection and a unified patent court in the EU. The regulations entered into force on 20 January 2013 but will apply only from the date of entry into force of the Agreement on a Unified Patent Court.

The Agreement on a Unified Patent Court creates a specialised patent court (UPC) with exclusive jurisdiction for litigation relating to European patents and

537 Article 2, EPC.
538 Articles 64 and 67, EPC.
539 Article 138 EPC, which also contains the grounds for revocation.
540 Article 138, EPC.
unitary patents. The Court is thus created in terms of an international agreement and not in terms of an EU legal act. The establishment of a supranational organ with competence to interpret European patent law with effect for the majority of the EPC and EU Member states is seen as an important measure, which solves the problem of post-grant divergence handling of European patents. The UPC ‘will not be ready before the end of 2015’. 543

The Unitary Patent route (a European patent with unitary effect within the EU) will be an additional option to European patents within the EPC-system and national patents. Through the (patent) regulation and UPC Agreement, the EPC is effectively made to be substantive law. After the EPO decision of grant, at the patentee’s request, a unitary effect for the territory of the participating states will be given. 544 The system presumes no changes to substantive law, but only in procedural and administrative aspects. Such statement may, however, prove optimistic, since a number of outstanding issues remain, in addition to established national variations. The obstacles have to be solved within the new system which promises an interesting future for developments within European patent law. 545 And it remains to be seen how well the system will adjust and meet the substantive and procedural challenges posed by the European patent law system.

544 See Articles 2-4 of Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection
545 See Kaisi, 170-180 and Romandini and Klicznik, 524-540.
IV

PATENT LAW MORALITY EXCLUSIONS

As evident from the functioning of the European patent legal system, patent morality clauses are found within various legal acts, in various institutional and judicial settings and on different levels: the EPC, the Biotech Directive and national law, respectively. National states, as well as the EU, are also formally bound by its international obligations through agreements, most notably the TRIPS Agreement (and the Paris Convention). In order to properly treat the functions of the morality exclusions the specific provisions within each system have to be investigated separately. The systematisation must start in the international framework, and Chapter 12 therefore deals with the morality clause in Article 27.2 of the TRIPS Agreement. The integration of the Biotech Directive’s provisions into the EPC Implementing Regulations has, as mentioned, created a connection between the European Patent Organisation and EU legal systems, which blurs the borders of each system’s applicability. The chapters on the European morality clause will start with Article 53(a) EPC and examine the case law from the EPO, including also the provisions imposed by the Directive in Rule 28 EPC, in Chapter 13. The investigation then proceeds in Chapter 14 to a description of the case law of free movement in relation to the concepts of morality and ordre public. Chapter 14 also treats the process of enactment of the morality clause in the Biotech Directive as a background to the analysis of Article 6.1 and 6.2 of the Biotech Directive in the EU setting in Chapter 15.

546 As mentioned, morality exclusions exist not only in patent law, but through the whole range of IPR. For instance, Article 6quinquies of the Paris Convention contains the traditional trade mark exclusion. See e.g. Wennersten, 243 ff. See also Articles 13 and 14 of the WIPO Draft Substantive Patent Law Treaty, SCP/10/2, 30 September 2003.
12.1 Structure

As an international IP convention, TRIPS builds on and incorporates the Paris and Berne Conventions. It is thus natural to trace the origins of Article 27.2 TRIPS back to Article 4quater of the Paris Convention. This is addressed in Section 12.2. Section 12.3 contains an overview of the requirements of Article 27.2 TRIPS. As the case law under Article 27.2 TRIPS in the WTO setting is scarce, or rather non-existent, the possibilities of drawing guidance from corresponding principles in the GATT and GATS context is explored in Section 12.4. Section 12.5 treats the notions of morality and *ordre public*, principally from GATT and GATS, and in Section 12.6 the content of the expression ‘necessity of preventing the commercial exploitation of the invention for the protection of *ordre public* or morality’ is scrutinized, including the various interpretations with regard to the necessity tests and the qualification with regard to national prohibitions in the last sentence of Article 27.2 TRIPS. The findings are analysed in Section 12.7 and conclusions are drawn in Section 12.8.

12.2 Article 4quater of the Paris Convention

Of specific interest in the context of European morality exclusions is Article 4quater of the Paris Convention, entitled ‘Patentability in Case of Restrictions of Sale by Law’ which has the following content:

The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law.

The provision was inserted into the Convention at the Revision Conference of Lisbon in 1958, suggested by *inter alia* the Nordic countries.\(^{547}\) The main aim of the stipulation is to state that for the grant of a patent right it is irrelevant whether a practical possibility to work the patent is present. The sale could, for instance, be regulated for reasons of safety or quality. Another situation could be that the state has granted a monopoly or exclusive concession for sale of the invention in question to a private or public entity. The reason for a provision such as Article 4quater is that it was regarded as unjust to prevent a patent grant under such circumstances, since the law or contractual situation could be modi-

\(^{547}\) Godenhielm 1966, 298.
fied or repealed, and the application of the invention would consequently be allowed. Such restrictions were not regarded as justification for invalidation or refusal of patent grant.548

12.3 The Legal Requirements of Article 27.2

Article 27.1 TRIPS establishes the general principle of eligibility to be patented, provided that the necessary criteria are met. Based on a long established tradition in patent law (particularly in the European context), TRIPS allows (but does not mandate) exceptions to patentability based on ordre public and morality in its Article 27.2, which is an exception from the general principle of patent eligibility in Article 27.1.

Article 27.2 TRIPS reads as follows:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

The implementation of the exception, which needs to be provided for under national law in order to be effective, means that a WTO Member may, in certain cases, refuse to grant a patent where it deems it necessary to protect higher public interests.549 During the TRIPS’ negotiations the formulation of Article 27.2 went through extensive rewordings, and the final text is rather close to that of Article 53(a) EPC. The question whether of guidance can be drawn from the EPO case law in the interpretation of Article 27.2 (or vice versa) is complicated. First and foremost, the TRIPS text is not identical to Article 53(a) EPC but contains an important qualification in the assessment of ‘necessary prevention’ of commercial exploitation; a concept which Article 53(a) EPC lacks. The foundation for the exclusion in Article 53(a) EPC is instead the evaluation of those inventions whose commercial exploitation is contrary to ordre public or morality. Despite the textual differences many commentators draw support for the interpretation of Article 27.2 from the findings in EPO case law, at least with regard to what constitutes the concepts of ordre public and morality.

A provision allowing a general exclusion based on ordre public or morality concerns leaves a gap which is open to interpretation, and Article 27.2 is not an

548 Bodenhausen, 65-66.
549 See Roffe, 376.
exception. On the contrary, the provision contains a number of criteria for a state to fulfil to be able to exclude an invention from patentability in compliance with TRIPS. But the precise conditions under which a WTO Member may rely on Article 27.2 to justify denial of patentability are lacking in clarity and thereby leave a rather large policy scope for Member states’ national implementation. In essence, the contents of Article 27.2 may be divided into at least three (or four, depending on school of interpretation) individual elements which interact in the application of the exclusion.

First, the prevention of an invention’s commercial exploitation should be ‘necessary to protect ordre public or morality’. The first criterion in Article 27.2 TRIPS thus includes the determination of the contents of the concepts ordre public and morality – the standards towards which the necessity of preventing the commercial exploitation is assessed.

Second, the provision incorporates a so-called necessity-test: ‘the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality’ (emphasis added). The most probable term to be the object for a necessity test is the prevention of the commercial exploitation of the invention, which is assessed in relation to the protection of ordre public or morality in a particular Member state. This necessity-test is introduced to assess whether protection of an overriding social interest is justified. However, the necessity test has been held to be binary, including assessment of both the necessity of prevention of the commercial exploitation and the necessity of excluding the invention from patentability.

It is common knowledge that a patent does not entail rights or powers to prevent the commercial exploitation of an invention. Still, the operation of the provision requires considerations regarding the necessity to prevent the invention’s commercial exploitation. This has led to a discussion regarding the link between the decision of patentability of an invention and regulation of its commercial exploitation. Patent offices do not have the authority or even possibility to prevent the commercial exploitation of an invention. Their only authority includes the decision of whether or not a patent right should be granted. The meaning of the term prevention is therefore crucial for the functioning of the Article, and differing interpretations of the term will lead to different results. The uncertainty regarding how the terms of the Article should be interpreted, not only on their own but also in relation to each other, is visible already at this stage.

Third, ‘the exclusion from patentability should not be made merely because the exploitation is prohibited by a Member state’s national law’. This qualification is formulated in the negative and its contents are tied to the second and third criteria. The presence of a national legal prohibition on an invention’s commercial exploitation influences the determination of the necessity of preventing the commercial exploitation, and thereby the application of the exclu-
sion from patentability. Exactly how this influence is achieved is subject to differing interpretations.

A WTO panel or the Appellate Body have not been called upon to solve any disputes arising under Article 27.2 TRIPS, and case law regarding the interpretation of Article 27.2 TRIPS is therefore lacking. TRIPS constitutes the **lex specialis** for the handling of patent issues within the WTO framework, but it is nevertheless likely that in the absence of TRIPS-specific decisions, the existing bulk of GATT/WTO jurisprudence will play a role in the interpretation of Article 27.2 TRIPS in a DSS proceeding. GATT and GATS both contain general exceptions from the free trade principles for the protection of higher social interests, e.g. public morals and public order. Many claim that it is highly likely that the meaning ascribed to the terms public morals and public order as interpreted by the Panels, as well as the conditions for the application of the clauses, would be of relevance for an Article 27.2 TRIPS interpretation.550

12.4 The Influence of GATT and GATS Concepts

Article XX GATT and Article XIV GATS contain ‘General Exceptions’ and serve as justification for national laws and measures which are otherwise inconsistent with obligations deriving from any other provision in the treaties.551 Despite the goal of trade liberalisation, the exceptions clauses in GATT and GATS set out to reconcile such liberalisation with other societal values and interests.552 The exceptions clauses in GATT, GATS and TRIPS have the same goal – to allow deviations from the core agreement if specific circumstances are fulfilled. There is no system of formal **stare decisis** in the WTO dispute settlement process, but the Appellate Body has stated that previous decisions ‘create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute.’553

Article XX GATT contains two parts; a general part and a list of measures:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between

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551 GATT and GATS are WTO multilateral agreements that contain basic rules for international trade in goods (GATT) and services (GATS). Originally, GATT rules primarily covered duties on industrial goods and other traditional trade barriers, while the current WTO agreements also cover other trade barriers. The main agreements consist of the General Agreement on Tariffs and Trade (formerly GATT), the General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The WTO also has special rules on settling trade disputes. It is understood that the general observations on Article XIV GATS are derived from and are equally applicable to Article XX GATT. See e.g. Grosse Ruse-Khan, 2011:1, 186.
552 Van den Bossche, 615.
553 Japan – Alcoholic Beverages II, para E, 14. See also Japan – Alcoholic Beverages II (Panel Report), paras 6.7-6.13.
countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(a) necessary to protect public morals;
(b) necessary to protect human, animal or plant life or health; [...] 

Article XX is drafted as a defense and will be invoked by a Member state only when a measure of that member has been found to be inconsistent with another GATT provision, and is used to justify that particular measure. The list of exceptions is exhaustive and the measures are justified only to the extent that the particular conditions in Article XX are fulfilled. Despite its character as a list of exceptions, the WTO Appellate Body has rejected a construction of narrow interpretation and recognised the importance of domestic public policies pursued via measures recognised under Article XX GATT. The resulting interpretation of exceptions in Article XX GATT must take into account the interests embodied in the clause and must aim at an ‘overall balance between trade liberalisation and other societal values’.

The reasoning regarding the nature, function and structure of Article XX GATT applies equally to the ‘General Exception’ clause contained in Article XIV GATS with a very similar content, applicable to obligations on trade in services under the General Agreement (GATS):

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures:

(a) necessary to protect public morals or to maintain public order;
(b) necessary to protect human, animal, plant life or health; [...] 

554 ‘(c) relating to the importations or exportations of gold or silver; (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices; (e) relating to the products of prison labour; (f) imposed for the protection of national treasures of artistic, historic or archaeological value; (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption[...]' Sections (h), (i) and (j) relate to obligations under international commodities agreements; efforts to ensure essential quantities of materials to a domestic processing industry; and products in general or local short supply.

555 The test is a two-tier, including meeting the requirements of one of the listed exceptions and the requirements of the chapeau. Van den Bossche, 617.


557 The original footnote to the GATS Agreement Article XIV(a) read: 'The public order exception may be invoked only where a genuine and sufficiently serious threat is posed to one of the fundamental interests of society'.
When using the approach of the general exceptions of Article XX GATT and Article XIV GATS in the context of Article 27.2 TRIPS, some important aspects need be considered. The Panel and Appellate Body decisions with regard to the former could probably serve the purpose of contributing to the understanding of some aspects of Article 27.2 TRIPS. For instance, the decisions on the GATT and GATS terms of public morals and public order could assist in determining the contents of the terms ordre public and morality in Article 27.2 TRIPS, since the interpretation is made within the WTO framework.

Other aspects are not equally easily transferred between the three WTO Agreements. A fundamental difference between the exclusion in Article 27.2 TRIPS and Article XX GATT and XIV GATS is that the Articles relate to their respective documents differently. Harper, for instance, with regard to the relation between Article XX GATT and Article 27.2 TRIPS, states that:

Article XX removes the obligation for general compliance with the fundamental policies of GATT when a state seeks affirmative conduct matching the exceptions. Article 27.2 removes the obligation of a sovereign to respond to a request for an affirmative grant. A dispute under Article 27.2 is more likely to constitute gap-filling than interpretation, as have many of the Article XX cases. [...] It is the exception, which frames the grant of patentable subject matter, that allows member nations to exclude from national treatment certain categories of inventions. In contrast, Article XX is a separate article that presents a general exception to all the obligations of the General Agreement. Further, it is conceivable that TRIPS Article 27.2 could be read to conflict with GATT Article XX in both terms of obligation and wording. In that case, Article 27.2 would govern.559

From Harper’s point of view, a number of differences with regard to the basic functions of these Articles as such (which also includes Article XIV GATS) would make a comparison inappropriate, at least from the point of view of the necessity tests. The reason is that the necessity required for fulfilling the exceptions based on public morals and public order in GATT and GATS has been developed within a system based on meeting criteria for removing a general obligation for a state.560 The application of Article 27.2 TRIPS, on the other hand, is based on the situation where a state wishes to refrain from meeting a request for patent grant, and not on the introduction of a measure that needs to be assessed in relation to the necessity of such measure, which would constitute

\footnote{558 ‘(c) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement including those relating to: (i) the prevention of deceptive and fraudulent practices or to deal with the effects of a default on services contracts; (ii) the protection of the privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individual records and accounts; (iii) safety; […]’. Sections (d) and (e) relate to inconsistencies with specific GATS obligations due to the collection of direct taxes.}

\footnote{559 Harper, 400.}

\footnote{560 Harper is supported by Gervais, 341.}
a trade disturbance or discrimination. On the other hand, Article 27.2 TRIPS does contain a relationship between the removal of grant, i.e. denial of patentability, and the corresponding commercial exploitation of the invention, including the necessity to prevent such exploitation. In relation to the necessity to prevent commercial exploitation, the measures present in a Member state can perhaps influence the decision on denial of patentability. The influence of such measures depends on what type of approach is taken towards the interpretation of the concept of ‘necessary’ in Article 27.2 TRIPS.\textsuperscript{561}

On the basis of the considerations accounted for with regard to the guidance drawn from GATT and GATS to TRIPS, the following Sections will treat the notions of \textit{ordre public} and morality (Section 12.5) as well as the concept of ‘necessary’ in connection with the concept of commercial exploitation in Art. 27.2 TRIPS (Section 12.6).

\section*{12.5 The Notions of Morality and Ordre Public}

The concepts of morality and \textit{ordre public} are not defined in TRIPS, nor in any other international or regional legal instrument. Morality and \textit{ordre public} are not possible to define in a conclusive manner, because they are dependent upon and adapt to specific eras, societies and cultures. The task of the legislation and judiciary is rather to define their framework of application and a general method for establishing their content on a case-by-case basis.

Since no Panel or Appellate Body decisions are rendered in relation to Article 27.2 TRIPS, an extended platform for guidance is suggested. The term public order was used during the GATT negotiations, and was originally used in the Chairman’s text (GATT 1990). The term is primarily recognized from general clauses in domestic law.\textsuperscript{562} During the TRIPS negotiations, however, the initial term ‘public order or morality’ in Article 27.2 was replaced with the terms ‘\textit{ordre public} or morality’. The French concept of \textit{ordre public} was held to be closer to the concept of public policy than to public order, and was found to have a more precise and narrower meaning, especially in international private law.\textsuperscript{563} The qualification under Article 27.2 TRIPS that exclusions must not be made merely because the exploitation is prohibited by a Member’s national law underlines the fact that the laws of a Member do not necessarily form part of \textit{ordre public}.\textsuperscript{564} The enumeration in the second part of the provision indicates that at least the protection of life and health of humans, animals and plants as well as

\textsuperscript{561} The concept of ‘necessity’ is treated in Sections 12.6.2-12.6.3.
\textsuperscript{562} Leskien and Flitner, 16.
\textsuperscript{563} Correa 2007, 287 and Leskien and Flitner, 16.
\textsuperscript{564} Leskien and Flitner, 16.
the protection of the environment may be regarded as essential elements of *ordre public*.

12.5.1 *Ordre public*

There are two views of the *ordre public* concept. A broader definition implies the equation of *ordre public* to ‘public order’ or ‘public policy’, concepts which by their flowing nature embrace a range of considerations. A narrower definition of *ordre public* is supported by e.g. Gervais, Roffe and Straus. Gervais asserts that *ordre public* is an evolutionary concept ‘that concerns the fundaments from which one cannot derogate without endangering the institutions of a given society.’ According to Roffe, *ordre public* ‘expresses concerns about matters threatening the social structures which tie a society together, i.e., matters that threaten the structure of civil society as such.’ Straus holds that the notion of *ordre public* ‘comprises only the ‘major principles of the legal order’, such as the inviolability of human dignity and the right to life, physical integrity, and personal freedom, as for instance laid down in Article 2 (2) of the Basic Law (Constitution) of the Federal Republic of Germany’. These interpretations are similar to that of the EPO Boards of Appeal, at least in terms of the concept consistency, and denote a narrower concept than that of ‘public order’.

From EPO decisions it has been deduced that *ordre public* is linked to a notion of security. In this respect, it covers the protection of public security and the physical integrity of individuals as part of society – both individual and collective security. Whilst a similar notion of physical security is contained elsewhere in TRIPS, it is argued that the Article 27.2 concept of *ordre public* only contains a notion of protection against physical damage, and not a general and abstract idea of collective interest. Such a view does not harmonise with the understanding of *ordre public* as concerning the fundamental structures of a given society as asserted by Gervais, Roffe and Straus. Therefore, among commentators, there is no generally accepted notion of *ordre public* in the WTO, and the flexibility that Members may use in defining the term is often emphasised.

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565 Leskien and Flitner, 16.
566 Gervais, 343.
567 Roffe, 375.
568 Straus 2013, 22, with numerous references in fn. 13.
569 This view is also supported by Correa, who endorses guidance from EPO. Correa 2007, 289 ff.
570 See e.g. Article 73 TRIPS.
12.5.2 Conservation Objectives

Article 27.2 TRIPS clarifies, unlike equivalent precedents in national laws, that protection of *ordre public* or morality includes the protection of ‘human, animal or plant life or health or to avoid serious prejudice to the environment’, thereby explicitly allowing for exceptions to patentability when any of these interests may be negatively affected by patent grants. The protection of these interests, especially so as to avoid serious prejudice to the environment, is considered to be generally included under the *ordre public* concept, although the wording of Article 27.2 TRIPS does not unambiguously associate them with that specific term.\(^{573}\)

A similar provision is contained in Article XX(b) GATT and Article XIV(b) GATS, where national measures ‘necessary to protect human, animal or plant life or health’ may form the basis for exceptions from the GATT and GATS obligations. The provision lacks the phrase of ‘to avoid serious prejudice to the environment’, but is otherwise consistent with the Article 27.2 TRIPS obligation.\(^{574}\)

The concept of ‘health’ may be deemed to encompass not only medical care, but also the satisfaction of basic requirements such as adequate food, safe water, shelter, clothing, warmth and safety.\(^{575}\) A health crisis could for instance be a matter of *ordre public*. In the GATT context, a WTO Panel has interpreted the ‘environment’ as referring to the ‘surrounding objects, region, or conditions, especially circumstances of life of person or society’.\(^{576}\) The term ‘serious’ is an imprecise standard, and Member states may employ different levels of environmental protection – what appears serious to one state may be tolerable for others. It is entirely up to the Member states to decide when a prejudice is serious or not.\(^{577}\)

12.5.3 Morality

The nature of the morality concept is broad and elusive. It is a vaguer concept than *ordre public*, usually held to depend upon the collective beliefs of a society. The TRIPS notion of morality seems to correspond with the European view, in as much as that the concept is naturally varied and thus difficult to define its contents on a more general level. Such an approach is natural from the perspec-

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\(^{573}\) Stoll, Busche and Arend, 491, Leskien and Flitner, 16 and Correa 2007, 290. See the analysis of the scope of Article 27.2 TRIPS with regard to terminology and environmental concerns Haugen, 348 ff.

\(^{574}\) The EPO Boards of Appeal has explicitly recognised that *ordre public* encompasses protection of the environment. T 356/93, Reasons for the Decision, para 5.

\(^{575}\) Roffe, 376, with further reference to Beaglehole and Bonita and Mustard.

\(^{576}\) Id., with further reference to The Concise Oxford Dictionary.

\(^{577}\) Correa 2007, 290.
tive of TRIPS’ function in this particular domain, namely adaptation into national law. In short, morality is ‘the degree of conformity to moral principles (especially good)’. It corresponds to the French concept of *bonnes moeurs*. The term public morals was interpreted in *US – Gambling* to denote ‘standards of right and wrong conduct maintained by or on behalf of a community or nation.’ In the same vein, morality in terms of the EPO is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong. This belief is founded on the totality of the accepted norms rooted in a particular culture. For the purposes of EPC, this culture is the culture inherent in European society and civilization. From the guiding principles found both in the WTO and EPO context, the common denominator is that the concept of morality is relative to the values prevailing in a society. For the purposes of TRIPS, morality depends exclusively on collective beliefs that naturally vary between societies; depending more on cultural beliefs, religious values and historical perceptions than geographical borders.

12.5.4 Guidance by GATS

The concepts of public order and public morals are both present in Article XIV(a) GATS but only public morals is listed in the exceptions clause in Article XX(a) GATT. The only case law that exists regarding these concepts in a GATT context to date concerns Article XIV(a) GATS. In the Panel and Appellate Body decisions in *US – Gambling*, a number of US federal and state laws, including the Wire Act, the Travel Act and the Illegal Gambling Business Act, prohibiting the remote supply of gambling and betting services (including Internet gambling), were assessed for GATS-consistency. The question was whether such measures could be justified under Article XIV(a) GATS, as being necessary to protect public morals and maintain public order. The two-tier test in Article XIV(a) necessitated the Panel to determine as a first step whether these laws were designed to protect public morals and maintain public order. As a second step, the Panel had to determine whether these measures were necessary to protect public morals or maintain public order. With regard to the first element of the test, namely the protection of public morals and maintenance of public order, the Panel held that:

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578 Roffe, 375, with further reference to The Concise Oxford Dictionary.
579 Gervais, 345 and Straus 2013, 26 f.
582 See e.g. Pires de Carvalho, 298 and Roffe, 375, with further reference to Bercovitz.
The content of these concepts for Members can vary in time and space, depending upon a range of factors, including prevailing social, cultural, ethical and religious values. Further, the Appellate Body has stated on several occasions that Members, in applying similar societal concepts, have the right to determine the level of protection that they consider appropriate. […] Although these Appellate Body statements were made in the context of Article XX of the GATT 1994, it is our view that such statements are also valid with respect to the protection of public morals and public order under Article XVI of the GATS. More particularly, Members should be given some scope to define and apply for themselves the concepts of "public morals" and "public order" in their respective territories, according to their own systems and scales of values.\footnote{US – Gambling (Panel Report), para 6.461.}

A difference between the GATT general exceptions and the patent specific exceptions in Article 27.2 TRIPS and Article 53(a) EPC is the use of the term ‘public’. Whereas the GATT concepts of public order and public morals both contain the notion ‘public’, the corresponding terms in TRIPS (and the EPC and the Biotech Directive) is morality and ordre public. The Panel in \textit{US – Gambling} turned to the \textit{Shorter Oxford English Dictionary} for the interpretation of the term, and found the following definition: ‘Of or pertaining to the people as a whole; belonging to, affecting, or concerning the community of nation’. The Panel consequently found that ‘a measure that is sought to be justified under Article XIV(a) must be aimed at protecting the interests of the people within a community or a nation as a whole.’\footnote{Id., para 6.463.} The Panel considered the term ‘public morals’ to denote ‘standards of right and wrong conduct maintained by or on behalf of a community or nation’.

The Panel in \textit{US – Gambling} defined in the dictionary as ‘a condition in which the laws regulating the public conduct of members of a community are maintained and observed; the Rule of law or constituted authority; absence of violence or violent crimes’. In addition, the clarifying footnote 5 to Article XIV(a) GATS states that ‘The public order exception may be invoked only where a genuine and sufficiently serious threat is posed to one of the fundamental interests of society’. The Panel found that the dictionary definition of the word ‘order’, read together with footnote 5, suggested that ‘public order’ refers to the preservation of the fundamental interests of a society, as reflected in public policy and law. These fundamental interests can relate, inter alia, to standards of law, security and morality.\footnote{Id., para 6.465.}

The definitions of public order and public morals in \textit{US - Gambling} shows an overlap between the concepts, in that the fundamental interests that public order is set to preserve may include e.g. morality. Public order therefore seems
to cover a larger field of application, which to some extent includes morality. The difference between morality and public morals was not discussed in US – Gambling, but the notion of public implies that the concept of public morals is, as defined by the panel, morality in a community or national context. Perhaps morality may be found in a more narrow sense within a nation or even a community, whereas the concept of public order must always be applied on a community level at least.

12.5.5 Guidance by EPO Case Law

Since it has been asserted that the text of Article 53(a) EPC laid the foundation for the terms ordre public and morality in the TRIPS Agreement, it has been proposed that the EPO Boards of Appeals’ understanding of the concepts would therefore serve as a guiding principle for the interpretation of their TRIPS counterparts. This presumption is perhaps problematic, as questions remain as to whether the European interpretation of the concepts would fit automatically into a WTO context. Correa asserts for instance that ’there is no reason to apply an interpretation of the concept[s] which has not been internationally accepted’. This statement can be interpreted to mean that the EPO points of view must be confirmed by the proper WTO authority in order to gain status as legal content in the WTO context.

On the other hand, the interpretation of ordre public and morality within in the GATS framework are quite similar to their European counterparts, including the EU framework. A majority of the commentators also draw guidance from the EPO case law when asserting the general contents of Article 27.2 TRIPS, even though the exact content of the terms morality and ordre public may differ in some aspects.

It is of course necessary for the European legislation to be TRIPS compatible. However, the European standards are interesting due to the perceived influence of Article 53(a) EPC on the drafting of Article 27.2 TRIPS. This influence may be partly attributed to the notion of the convergence of international law with regional or national law. The influence is especially transparent in the choice of the term ordre public instead of ‘public order’. The similarities are present not only in the interpretation of the content of the concepts, but also in the fundamental principle to leave a large margin of appreciation for each member state to determine the exact contents of morality and ordre public in

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588 Pires de Carvalho, 297.
592 See Section 7.3.1.
accordance with its own values and perceptions of each of these terms. Furthermore, each individual case should be decided on its own merits, in its own context, as no generally applicable rule exists even on a national level. The aim of Article 27.2 TRIPS and Article 53(a) EPC do not differ on this point. This is reinforced by the text of Article 27.2 TRIPS, which refers to the prevention of inventions within the territory of a member state, thereby not aiming at a uniform and universally substantive definition of ordre public and morality. This also allows the member states a considerable flexibility to define the interests covered by ordre public or morality.

12.6 Necessity of Preventing the Commercial Exploitation

12.6.1 Commercial Exploitation

The provision in Article 27.2 TRIPS necessitates that the prevention of the commercial exploitation of the invention must be necessary to protect ordre public or morality. The term ‘commercial exploitation’ is crucial to the interpretation of this particular part of the provision. From the drafting history of Article 27.2 TRIPS follows that the common intention of the parties was to establish a central role for the prevention of the commercial exploitation of the invention in order to justify exclusions from patentability. The early Anell Draft read as follows:

1.4 The following [shall] [may] be excluded from patentability:
1.4.1 Inventions, [the publication or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [public health,] [or the basic principle of human dignity] [or human values]. […]

In the later Brussels Draft, the scope of the provision was narrowed down:

2. PARTIES may exclude from patentability inventions, the prevention within their territory of the publication or any exploitation of which is necessary; to protect public morality or order, including to secure compliance with laws or regula-

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594 See Sections 13.5, 14.2 and 15.4.1. See also Bakardjieva Engelbrekt 2009, 238.
595 Correa 2007, 288 ff.
596 See Porter 2009:2, 355 ff., 359. The drafts preceding the final formulation of the provision in Article 27.2 referred to a broader standard, namely ‘any exploitation or publication’.
tions which are not inconsistent with the provisions of this Agreement; or to protect human, animal or plant life or health.\footnote{Multilateral Trade Negotiations, the Uruguay Round, Trade Negotiations Committee, MTN.TNC/W \hspace{1pt} 35/Rev. 1, 3 Dec. 1990 (The Brussels Draft).}

The final version saw the deletion of the reference to ‘publication’, which demonstrates the intention of the parties to focus entirely on the prevention of commercial exploitation of the invention as a criterion for the application of the clause.\footnote{Article 53(a) EPC 1973 entitled EPO Contracting states to refuse patent protection on the grounds of prohibitions on publication, and at the time was considered contrary to Article 27.2 TRIPS. See c.g. Straus 1998, 181. The reference to publication in Article 53(a) EPC was removed in EPC 2000, thus rendering the Article TRIPS-compatible at least in terms of concepts.} It is evidence of general agreement to the fact that Article 27.2 TRIPS applies to all modalities of exploitation listed in Article 28 TRIPS such as the making (manufacturing), using, offering for sale, selling or import a product or a product directly obtained from a patented process. The application is limited to a commercial, or market-based approach.\footnote{Canada – Pharmaceutical Patents, paras 7.54-7.55. See also Porter 2009:2, 355 and Pires de Carvalho, 304. Cf. Henckels, 14 and Kur, 228 f.} The conditions in Article 27.2 TRIPS cannot be met if there is a need to prevent non-commercial uses of the invention, e.g. scientific research.\footnote{Roffe, 378.} This notion is derived from an analogy to the expression ‘normal exploitation’ in Article 30 TRIPS, and is supported by the findings in the Panel Report Canada – Pharmaceutical Patents, where the Panel held that ‘exploitation’ refers to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent, thereby excluding non-commercial exploitation.\footnote{Canada – Pharmaceutical Patents, para 7.54.} The parties’ interpretation of the concept of exploitation, seemingly accepted by the Panel, was the ‘working’ of the patent by the modalities of (1) selling the product in a market from which competitors are excluded, or by (2) licensing others to do so, or by (3) selling the patent rights outright.\footnote{Id., para 7.51.} The central point of focus, on which the parties disagreed, was the concept of ‘normal exploitation’, which the Panel defined as:

The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws. Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws can-
From the reasoning of the Panel the concept of normal exploitation is related to the competition met in a typical market. The term can therefore vary and be adapted to different kinds of situations and markets. The core content of the term is however the modalities of exploitation listed in Article 28 (making, using, offering for sale, selling, or importing), based on the normality concept as outlined by the WTO Panel in *Canada – Pharmaceutical Patents*. The concept thus includes a broad range of activities, being intrinsically tied to the exercise of the exclusive right in a market setting.

The term ‘exploitation’ in the last part of Article 27.2, on the other hand, is held to be broader, and there is general agreement that this concept covers any type of exploitation, including non-commercial exploitation, since it lacks the qualifying prefix of ‘commercial’. Such exploitation would therefore cover not only market-based exploitation but also other types of exploitation that do not fall within the narrower field of having a commercial intent or effect. The delimitation between the two concepts by the term commercial does not seem to have a profound practical effect.

The character of the chosen terminology of Article 27.2 is of interest for patent law terminology in general. Torremans argues, for instance, that the distinction between grant and exploitation is well established in patent law, and that Article 27 specifically reflects this by the choice of terminology. Commercial exploitation therefore needs to be distinguished from the grant of the patent or the manufacture of the patented product. To view commercial exploitation as a concept that encompasses all these phenomena would be contrary to well established traditions in patent law.

### 12.6.2 Necessity Tests

Article 27.2 TRIPS provides that ‘Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality’. The application of the provision requires an assessment of the necessity of the prevention of the commercial exploitation of the invention for the protection of *ordre public* or morality. The term necessary exists in seven Articles in the TRIPS Agreement. From the employment of these terms, it is possible to deduce that the

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604 *Canada – Pharmaceutical Patents*, para 7.55.
605 See e.g. Pires de Carvalho, 304.
606 Torremans 2009:1, 168.
607 Articles 3.2 (exceptions to the national treatment principle), 8.1 (measures necessary to protect public health and nutrition and to ensure the implementation of public policies), 27.2 (exceptions to patentability for
term necessary implies two notions – the purpose of the measure and the level of necessity.\textsuperscript{608} The purpose of Article 27.2 TRIPS is identified in the Article itself as: the protection of \textit{ordre public} or morality. The level of necessity, on the other hand, is more difficult to establish. The reason for this is that it is not exactly clear from Article 27.2 TRIPS as to what the term ‘necessary’ relates to.

The required necessity has been held to mean that a causal connection must exist between the measure taken, i.e. prevention from commercial exploitation, and the effect sought, i.e. protection of \textit{ordre public} or morality.\textsuperscript{609} But the formulation of the provision is not entirely clear. Is it the exclusion from patentability that must be regarded as a necessary measure if the commercial exploitation of the invention in a Member threatens the interests contained in the \textit{ordre public} and morality criteria? Or is the purported necessity only to be applied in connection to the criterion of prevention from commercial exploitation? Or should the necessity be assessed in relation to the protection of \textit{ordre public} or morality? Is it actually so that what needs to be assessed is if it is necessary to prevent the commercial exploitation of the invention to protect the values of \textit{ordre public} or morality? Or should the test relate to whether or not it is necessary to protect \textit{ordre public} or morality and thereby prevent the commercial exploitation of the invention, implying that the exclusion from grant equals the prevention of commercial exploitation? Is there an actual difference between the formulations? Or is it, as advocated by Straus, an explicit requirement that (1) the commercial exploitation is not permitted in a state (i.e. prevented) and (2) that such prevention is necessary in order to protect the interests of \textit{ordre public} or morality?

It seems as if both the \textit{prevention of commercial exploitation} and the \textit{exclusion from patentability} in the text of Article 27.2 TRIPS could be interpreted as being subject to the assessment of the necessity of the measure for protection of \textit{ordre public} or morality. This point of departure has been developed by Pires de Carvalho. He suggests that the formulation of Article 27.2 TRIPS contains a two-step test, including:

\begin{itemize}
\item the protection of \textit{ordre public} or morality, 39.2 (disclosure of test data and other data for the protection of the public), 43.2 (information necessary for a judicial authority to make a decision), 50.5 (information necessary for identifying infringing goods), and 73(b) (measures necessary for the protection of national security interests).
\item According to Pires de Carvalho, in the legal system of the WTO, when a Member assesses the necessity of excluding an invention from commercial exploitation, the provisions of Article 2.2 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) must be taken into account, which provides that such measures must be based on scientific principles and not maintained without sufficient evidence. If such evidence is found and corroborated, the necessity of exclusion must be assessed in relation to the provisions of Article 2 of the WTO TBT Agreement, where less trade-restrictive measures than exclusion should be chosen, if appropriate for the fulfilment of the goal of protecting \textit{ordre public} or/and morality. Pires de Carvalho, 299.
\end{itemize}
(1) the necessity of preventing an invention from commercial exploitation to protect *ordre public* or morality; and
(2) the necessity of excluding an invention from patentability to prevent its commercial exploitation.\(^{610}\)

In order to endorse Pires de Carvalho’s two-step test, it is indispensable to support the point of view that prevention of commercial exploitation should precede the decision of denial of patentability. This is due to the fact that the first step requires implementation of restrictions outside the scope and application of the TRIPS Agreement. The first step of the test is consequently not patent-related. The second part of the test is purely patent-related, and consists of an assessment of the necessity of excluding the patentability of an invention as a necessary condition for the implementation of the restrictions.

The impact that can be invoked is only within the territory of the country concerned. Members may not take restrictive measures to address morality or *ordre public* concerns of other Members.\(^ {611}\) If, on the other hand, the term necessary in Article 27.2 is interpreted as referring only to the necessity of preventing the commercial exploitation of the invention, then the test would only consist of the first step of the test suggested by Pires de Carvalho; the necessity of preventing an invention from commercial exploitation to protect *ordre public* or morality.\(^ {612}\)

The majority of the commentators argue that in relation to the assessment of the necessity, relevant provisions of other WTO Agreements should be used.\(^ {613}\) So-called necessity tests are for instance used to scrutinize measures adopted under the exceptions clauses for domestic policy reasons, and have been the subject of several GATT panel decisions.\(^ {614}\) The provisions that include necessity tests relevant for *ordre public* and morality concerns include GATT Article XX(a) (protection of public morals) and (b) (protection of human, animal or plant life or health) and GATS Article XIV(a) (protection of public morals and maintenance of public order) and (b) (protection of human, animal or plant life or health).\(^ {615}\) The existing bulk of decisions could lend support to the interpreta-

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\(^{610}\) The test is advanced by Pires de Carvalho, 298 f. See also Porter 2009:2, 363, who on the other hand views the test as a one-step assessment, focused on the necessity of preventing the commercial exploitation of the invention, with support of the established WTO jurisprudence on the general exception clauses in Article XX GATT and Article XIV GATS.

\(^{611}\) This is evident from the text of Article 27.2 TRIPS: ‘Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality […].’ See also Pires de Carvalho, 300.

\(^{612}\) See Porter 2009:2, 362.


\(^{614}\) See Leskien and Flitner, 15.

\(^{615}\) The paragraphs of Article XX GATT and Article XIV GATS contain enumerations of various categories of measures which WTO Members may carry out in pursuit of different legitimate state policies or interests. Different terms are used in respect of different categories: ‘necessary’ (e.g. protection of public morals), ‘essential’, ‘relating to’, ‘for the protection of’ etc.
tion of the necessity test in Article 27.2 TRIPS. In general, the necessity part of the tests have proven more problematic to establish than judging whether a measure is designed to protect the policy goals of public morals, public order or life or health.616

In Thailand – Cigarettes, the GATT Panel interpreted the term ‘necessary’ under Article XX(b) GATT617 in relation to measures employed by Thailand to prohibit the import of cigarettes. The Panel held that the meaning of the term was the same as under the other paragraphs of Article XX, i.e. Article XX(d), since the both paragraphs share the same term and objective – ‘to allow contracting parties to impose trade restrictive measures inconsistent with the General Agreement to pursue overriding public policy goals to the extent that such inconsistencies were unavoidable’.618 The fact that the paragraphs related to inconsistencies with different causes did not justify different interpretations of the term ‘necessary’.619 The Panel held that a national measure could be considered to be ‘necessary’ in terms of Article XX(b) ‘only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives.’620 The findings of the Panel in Thailand – Cigarettes with regard to the necessity test in Article XX(b) GATT are still valid and form the basis of

616 Van den Bossche, 623.
617 Article XX(b): ‘Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures […] necessary to protect human, animal or plant life or health’.
618 Thailand – Cigarettes, para 74.
619 Id., para 74.
620 Id., para 75. The principal health objectives put forward by Thailand to justify the import restrictions on cigarettes were twofold: to ensure the quality of cigarettes so as to protect the public from harmful ingredients in imported cigarettes, and to reduce the overall consumption of cigarettes in Thailand. By the application of the necessity test, the Panel first examined ‘whether the measures aimed at ensuring the quality of cigarettes consumed in Thailand could be met with measures consistent, or less inconsistent’, with GATT. The conclusion was that measures already introduced in other countries such as strict, non-discriminatory labelling and ingredient disclosure regulations etc., which, implemented on a national treatment basis, would be an alternative consistent with GATT. It could reasonably be expected by Thailand to take such measures to address the quality-related policy objectives, instead of pursue them through an import ban on all cigarettes whatever their ingredients. With regard to the second issue, the overall consumption, the Panel examined how Thailand might reduce the demand for as well as the supply of cigarettes. Thailand had argued that competition between imported and domestic cigarettes would necessarily lead to an increase in the total sales of cigarettes, and that Thailand therefore had no option but to prohibit cigarette imports (while permitting the sale of domestic cigarettes). The Panel found, in contrast, that there were measures consistent with GATT that were reasonable for Thailand to control the quality and quantity of cigarettes smoked (such as e.g. bans on advertising and regulation by governmental monopolies), which could achieve the health policy goals pursued by the Thai government without restricting the importation of cigarettes. The Panel found therefore that Thailand’s practice of permitting the sale of domestic cigarettes while not permitting the importation of foreign cigarettes was an inconsistency with the General Agreement not ‘necessary’ within the meaning of Article XX(b) GATT. Conclusively, a measure is necessary within the meaning of Article XX(b) GATT only when no alternative measure exists, that is GATT-consistent (or less inconsistent), and that a Member could reasonably be expected to employ to achieve the public health objective pursued. (Thailand – Cigarettes, paras 75-81).
The test, along with additional considerations which may vary over time and decisions.

The case law on the necessity requirement in Article XX(d) GATT is likewise relevant for the interpretation and application of the necessity requirement in Article XIV(a) GATS. In US – Gambling the Panel and Appellate Body built on the factors of the test already developed in the GATT context when explicitly stating the factors relevant for the necessity test:

(a) the importance of interests or values that the challenged measure is intended to protect. (With respect to this requirement, the Appellate Body has suggested that, if the value or interest pursued is considered important, it is more likely that the measure is ‘necessary’.)
(b) the extent to which the challenged measure contributes to the realization of the end pursued by that measure. (In relation to this requirement, the Appellate Body has suggested that the greater the extent to which the measure contributes to the end pursued, the more likely that the measure is ‘necessary’.)
(c) the trade impact of the challenged measure. (With regard to this requirement, the Appellate Body has stated that, if the measure has a relatively slight trade impact, the more likely that the measure is ‘necessary’. The Appellate Body has also indicated that whether a reasonably available WTO-consistent alternative measure exists must be taken into consideration in applying this requirement.)

The inherent contents of the test are thus subject to slightly various interpretations, which also shows that the Panel and Appellate Body have fine-tuned the test as well as taking different approaches to it in their decisions, with regard to not only the facts of each case but also with regard to the nature of the provision at issue. In addition to the findings outlined above, it is also exclusively

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621 Article XIV(a) GATS: ‘Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures […] necessary to protect public morals or to maintain public order’.

622 The decision concerned a complaint brought by Antigua, which asserted that a number of US federal and state laws which prohibit the remote supply of gambling and betting services, including Internet gambling, was GATS-inconsistent since they constituted a ban on the cross-border provision of Internet gambling services. The US had argued that the measures at issue could be justified under Article XIV(a) GATS, as necessary to protect public morals and to maintain public order. From the US point of view, Internet gambling posed threats in relation to organized crime, money laundering, and fraud, risks to children and risks to health due to addiction to anonymous, 24-hour online gambling. The Panel held that the US measures failed the necessity-test; whereas the Appellate Body reversed the Panel’s analysis on this particular matter, finding that no reasonably available alternative measure was present. US – Gambling, para 325. See also US – Gambling (Panel Report), para 6.535.

623 The conclusions built also on the Appellate Body’s guiding principles in Korea – Various Measures on Beef, paras 159-178 and EC – Asbestos, paras 170-175.


625 According to the analysis of Grosse Ruse-Khan, a measure is only necessary when it consists of three elements: the least trade restrictive measure; which is reasonably available to the Member State; and is equally effective in achieving the desired policy objective. Grosse Rhuse-Khan, 2011:1, 190. Van den Bossche argues
up to the Member at issue to determine the level of protection they consider appropriate for health or the environment (or any other protected interest). The level of protection chosen by one Member cannot be challenged by another Member. Only the necessity of the measure at issue to achieve that level of protection is open to argumentation, but it is not a necessity of the policy objective as such but a necessity of the disputed measure to achieve that objective which is at issue. In sum, the necessity tests in relevant exclusions in GATT and GATS share some core elements, but the application of the tests constitute an overall balancing act in which the weight given to individual elements may vary from case to case.

The inclusion of general exceptions clauses in these WTO instruments provides a degree of scope for a Member wishing to justify exclusions of certain products or services. If WTO case law on GATT and GATS general exceptions is taken into account for the application of the concept of ‘necessary’ in Article 27.2 TRIPS, necessity should be measured in relation to the exclusion from patentability. The resulting main balancing act would be focused upon the assessment of whether the objective of preventing the commercial exploitation of the invention to protect ordre public or morality can be achieved in a manner that does not require excluding inventions from patentability; if so, then that way is the preferable one. According to such an interpretation, it is thus the exclusion from patentability that is the measure that should be necessary in a WTO context. Exclusion from patentability must therefore be necessary for the protection of ordre public or morality, and the prevention of commercial exploitation of the invention is thus achieved by excluding the invention from patentability. The interpretation consequently differs from the two-step test as endorsed by Pires de Carvalho.

This reasoning is unfortunately subject to a major flaw. The exclusion from patentability is not relevant for the actual possibilities of commercial exploitation of an invention. The denial of patentability may of course have negative economic effects for the individual inventor or company, but it will not automatically prevent the commercial exploitation of the invention. In some cases, denial of patent grant may even facilitate dissemination of the invention or

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626 EC – Asbestos, para 168.
technology in question, since the invention is not subject to exclusive rights and may be exploited by an infinite number of competitors on the market. It is therefore advocated, as proposed by several commentators, that the necessity should perhaps be judged instead in relation to the prevention of commercial exploitation, closer to a two-step test.

12.6.3 Necessary to Prevent

The guidance from GATT and GATS panel decisions points to an interpretation of the necessity in relation to the exclusion from patentability. However, following a literal interpretation of the text in Article 27.2 TRIPS, an equally legally correct interpretation (at least in the absence of guidance by a panel decision) puts the necessity in relation to the prevention from commercial exploitation of an invention. By the formulation that inventions may be excluded from patentability only if the prevention of their commercial exploitation is necessary, the scope of application is accordingly limited to the situations where the prevention of the commercial exploitation is deemed necessary for the protection of ordre public or morality. Article 27.2 TRIPS is thereby dependent on a link between the prevention of commercial exploitation and the denying of patentability of the same invention. The prevention should, in addition, be deemed necessary.

The question whether non-patentability only can be established if the commercial exploitation of the invention that is deemed non-patentable is prevented in the territory of the respective WTO Member is subject to extensive debate. The nature and effect of the link is, however, not apparent. The lack of guidance from case law regarding Article 27.2 TRIPS makes the analysis of case law of neighbouring fields, such as the general exceptions in GATT and GATS as well as doctrinal opinions necessary.

An interpretation of the provision requiring a link between the prevention of commercial exploitation and the exclusion from patentability rests upon the presumption that the patentability of an ethically challenging invention is dependent upon the prevention of the commercial exploitation of that same invention. In the Oxford English Dictionary, the meaning of ‘prevention’ is explained as ‘the action of keeping from happening or making impossible an anticipated event or intended act’, i.e. a defensive act. Prevention could, however, be interpreted as either prohibition or regulation. Also, the prevention could be subject to actual authority decisions in order to be performed, especially in situations of regulation by legislation. An example is the pre-market control of

pharmaceuticals and agrochemicals. Such products are subject to extensive marketing permit application procedures before the product can be commercially exploited. The outcome of such procedures is subject to authority examination and grant. Although the commercial exploitation of these products are subject to regulation through legislation, the actual result of such legislation (prohibition or permission to commercially exploit) is a matter for the competent authority to decide, based on the provision of proof by the applicant that the product in question is e.g. safe and effective, or whatever conditions apply in a particular situation.

But the question remains as to what kind of act(s) the term ‘prevention’ covers. Is the purpose of this condition to prevent a situation where an invention would be excluded from patentability on the grounds of morality or *ordre public*, while the invention itself is in fact exploited commercially in a state, as advocated by e.g. Straus and Van den Bossche? Or can the situation occur where an invention is excluded from patentability because the criterion of ‘necessary to prevent the commercial exploitation of the invention to protect *ordre public* or morality’ is considered fulfilled, even though the commercial exploitation of the invention is not in fact prevented, prohibited or banned in a Member?

The formulation in Article 27.2 TRIPS rests on the basis of the necessity of preventing such commercial exploitation. It may be argued that the application of the Article is not based on a criterion of actual prevention, only the necessity of such. The main question thus evolves around the contents of the concept of ‘necessary to prevent’, and more specifically exactly what is meant by prevention. Does the term imply a legal ban, an authoritative decision or simply an assessment of the necessity of such a ban?

The understanding of the exact definition of the terms in Article 27.2 TRIPS has caused disagreement amongst commentators. The authors seem to support two different alternative approaches to the interpretation of ‘necessary to prevent’, and in this study they are labelled as ‘the prohibition approach’ and ‘the necessity approach’ respectively. According to the *prohibition approach*, the concept of ‘prevention’ requires an actual prohibition of the commercial exploitation of an invention as a presumption for the exclusion from patentability on the grounds of *ordre public* or morality. The *necessity approach*, on the other hand, does not require an actual ban of the commercial exploitation of an invention as a condition for exclusion from patentability, only an assessment of the necessity of prevention of commercial exploitation of the invention suffices for the application of Article 27.2 TRIPS. The approaches, *prohibition* and *necessity*, are treated in the following Sections 12.6.3.1 and 12.6.3.2 respectively.

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12.6.3.1 The Prohibition Approach

The main argument offered by the prohibition approach is that by including the concept of prevention, Article 27.2 TRIPS requires an actual prohibition of the commercial exploitation of an invention in question as a presumption for the exclusion of the same invention from patentability. Without such prohibition or decision on prohibition, denial of patentability would be impossible under Article 27.2 TRIPS. According to Straus, Article 27.2 TRIPS establishes that regulations that are necessary to protect the life or health of humans, animals or plants or to avoid serious damage to the environment constitute *ordre public*. Following the formulation of the provision, the patenting of the invention is necessarily tied to the prohibition on exploitation of the same invention:

[P]atenting of such inventions can only be precluded if the relevant country refrains from exploitation of such inventions. The reason is that the exclusion from patentability pursuant to Article 27(2), TRIPs Agreement, requires explicitly that the commercial exploitation of the invention concerned is not permitted in the relevant Member country, and secondly, that such prohibition is necessary in order to protect the interests described in detail in Article 27(2).

Straus states that the provision seems to imply two tests. First, the commercial exploitation of the invention should not be permitted, i.e. be prohibited. Second, such prohibition should be necessary for the protection of *ordre public* or morality. Straus is of the opinion that pursuant to Article 27.2 TRIPS, it is not possible to declare certain subject matter patentable, while at the same time permit exploitation; e.g. marketing, distribution and sale thereof. It will thus amount to a breach of Article 27.2 TRIPS if a patent authority or any other relevant judicial body denies an invention patent protection on the basis of *ordre public* or morality concerns, e.g. where the commercial exploitation of the invention would damage the environment, and at the same time the marketing of that invention is permitted in the country in question.

Furthermore, proponents of the prohibition approach are of the opinion that a simple prohibition on exploitation, i.e. a national legal prohibition or marketing regulation, is not sufficient to render such invention ineligible from patentability. The existence of such legal or marketing prohibition cannot guarantee the actual prohibition of a particular invention, since there are often decisions to be made by competent authorities after patent grant but before

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634 Id. Straus’ interpretation is supported by Correa in Correa 1994, 328, but later he seems to have changed his opinion. Cf. Correa 2008, 231.
635 Straus 1996, 183, with further reference to Bernhardt and Krassner.
marketing and sale. One example is the pre-marketing controls exercised for pharmaceuticals and agrochemicals, where such subject matter is generally prohibited to market unless expressly permitted by the competent authority.

This point of view also finds support in the text of Article 27.2 TRIPS itself. Article 27.2 TRIPS does not require that for its application the laws or regulations of a Member prohibits the invention. On the contrary; the fact that a national law prohibits the exploitation of the invention is not sufficient to render such invention ineligible for patent protection. The qualification in the final half-sentence of Article 27.2 TRIPS ‘makes clear that other, simple prohibitions of exploitation will not suffice as the basis for the exclusion from patentability of certain inventions’, and is thus interpreted as such in support of the view that Article 27.2 requires more than the existence of a legislative provision for its application.\textsuperscript{637} From the point of view of the prohibition approach, it is necessary for the application of Article 27.2 TRIPS that the commercial exploitation of the invention is actually prevented.

Proponents of the prohibition approach find support in the argument that without the necessary link between actual regulation and prohibition of commercial exploitation the patent exclusion would certainly lack practical effect. Such reasoning entails the effect that the exclusion from patentability must therefore be preceded by a real exclusion from commercial exploitation, when exclusion from commercial exploitation is necessary to protect \textit{ordre public} and morality.\textsuperscript{638} This approach coheres with a key principle in the whole WTO setting, namely that deviations from WTO obligations should not be made lightly.\textsuperscript{639} Accordingly, if a Member was allowed to exclude an invention from patentability on the grounds of a mere regulation (or simply an assessment by the patent authority), without actually banning the product, this would create a possibility to bypass Article 27.2 TRIPS.\textsuperscript{640} On the other hand, the practical effects of this interpretation seem to necessitate that the decision on prohibition is already made when the patentability is assessed, something which could certainly be problematic in practice, due to two circumstances.

\textit{First}, the act of filing a patent application always precedes the act of commercial exploitation, because of the novelty criterion. This is especially true regarding inventions that through legislation are subject to necessary pre-market controls, such as pharmaceuticals and agrochemicals. Although there are, however, compelling arguments for the coordination between patent grants and commercial regulation, this is not possible to achieve in practice. Even though the examination procedure at the patent authority may take time, the necessary applications and other requirements are always made after the filing

\textsuperscript{637} Straus 1996, 181.
\textsuperscript{638} Pires de Carvalho, 298.
\textsuperscript{639} Porter 2009:2, 347.
\textsuperscript{640} See e.g. Cheney, 533.
of the patent application (and perhaps also the patentability decision). The patent authorities cannot be required to await the decision from the regulatory authority. But the isolation of the control decision from the reward decision invites competition between the policies, which weakens both. For instance, an invention may possess both negative and positive effects and they are inseparable from each other. A product may offer a great social benefit along with an intense hazard. The risk associated with a hazardous product bears a social cost, and this means that there is a less compelling argument for society to encourage economic exploitation – and a lesser interest in rewarding the inventor. But the reverse is also true. This is therefore an argument for the view that prohibition or authority decision on the commercial exploitation should exist before the decision on patentability. But in practice this is not possible to coordinate within the present system.

Second, the concept of commercial exploitation may also not cover premarket controls. There must be a difference between e.g. pre-market R&D and commercial exploitation. This is apparent not least from the formulation of Article 27.2 TRIPS as such. In the first part of the provision, the term ‘commercial exploitation’ is used. In the second part, where the effect of a national legal prohibition is set out, the term used is ‘exploitation’. The two concepts are not equal, and it is generally held that the term exploitation covers a broader field of application, including non-commercial exploitation. The effect of using different terms is thus that a national legal prohibition against any exploitation, including non-commercial exploitation, is not enough to render the Article applicable. However, the prevention prescribed by the first part of the Article is directed towards the commercial exploitation, thereby implying that the criteria of Article 27.2 TRIPS are not fulfilled if e.g. only the necessity of preventing (non-commercial) exploitation is apparent. It must be necessary to prevent the commercial exploitation, and the scope of application of the Article is thereby limited to the prevention of such acts that are covered by the term ‘commercial exploitation’, i.e. any use of the invention in a commercial setting, including the making (manufacturing), using, offering for sale, selling or import of a product or a product directly obtained from a patented process. It is uncertain whether the concept of ‘commercial exploitation’ would also cover R&D connected to the invention, including applying for a marketing permit for the invention. On the other hand, such a procedure would probably be included in the concept of marketing, since it is a pre-stage condition. The concept of ‘publication’ is already separated from the exploitation, and the removal of publication from Article 27.2 TRIPS shows an intention to exclude such acts from the area of application of the provision.

641 Harper, 389.
642 See Section 12.6.1.
According to the prohibition approach, the necessity test is applied after establishing that the commercial exploitation is prohibited in the Member in question. The assessment is focused on the necessity of preventing the commercial exploitation for the protection of *ordre public* or morality. This reasoning implies that existing prohibitions based on other concerns than the protection of *ordre public* or morality would not fulfil the criteria established by Article 27.2 TRIPS, which would be non-applicable in such situation. Thus, the point of view of the prohibition approach necessitates that the prohibition of the commercial exploitation should be based on *ordre public* or morality concerns, or at least that the patent authority could find such foundations even though they are not specifically expressed in relation to the existing prohibition. There would be a correspondence between the protection of *ordre public* and morality within a state’s regulation of commercial exploitation of products and services and the protection of *ordre public* or morality within the patent system as a basis for excluding inventions. The effect of such interpretation is that a Member may, by the application of patent law, influence certain technological development or the exploitation of their results, by requiring the prohibition of exploitation.643

The prohibition approach is definitely appealing from a practical perspective. It implies a correspondence between the *ordre public* or morality expressed within a state’s laws and the concepts of *ordre public* and morality within the patent system. If the argumentation is reversed, it would entail the effect that the laws of a Member would not give effect to the principles of *ordre public* and morality, a fact which actually corresponds to the legal situation with regard to Article 53(a) EPC.

12.6.3.2 The Necessity Approach

Proponents of the necessity approach argue that the text of the Agreement does not support the interpretation proposed by the prohibition approach, because according to the necessity approach the application of Article 27.2 TRIPS does not require an actual ban of the commercial exploitation as a condition for exclusion from patentability.644 The requirements set out in Article 27.2 TRIPS are instead directed towards an assessment of the necessity of prevention of commercial exploitation of the invention, which is not necessarily embodied in the presence of an actual prohibition as such. The result of such an interpretation is that the application of Article 27.2 TRIPS only requires an assessment (by the competent authority), preferably expressed in a formal decision, about the need to prevent the commercialization of the invention, not an actual prohibition.645 The competent authority in this respect could (and should)

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645 Id.
be the patent authority. This approach finds its strongest arguments in the text of the Agreement, as argued by Leskien and Flitner:

[...] Art. 27(2) TRIPS does not require an actual ban of the commercialization as a condition for exclusions; only the necessity of such a ban is required. In order to justify the exclusion under Art. 27(2) TRIPS, a member state would therefore have to demonstrate that it is necessary to prevent – by whatever means – the commercial exploitation of the invention. Yet, the member state would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited.646

The necessity approach interprets the qualification in the last half-sentence of Article 27.2 TRIPS by separating the assessment of the ‘necessity to prevent’ from the state of the national legislation in relation to the invention. The reasoning behind such stance is that if the drafters had intended to exclude only those inventions from patentability whose commercial exploitation already was prohibited, different language could have been used. For now, the formulation ‘the prevention [...] of the commercial exploitation of which is necessary [...]’ strictly construed does not, from the point of view of the proponents of the necessity approach, require an actual prohibition, only an assessment of the necessity of preventing the commercial exploitation of the invention. This argumentation entails the consequence that conversely, a particular invention could be excluded from patentability although its commercial exploitation is permitted under a Member’s national laws.

The usual time delay between the technological development and the legal regulation of its results seems to lend support to the necessity approach. It requires that a state should be free to consider the prevention of the commercial exploitation of an invention as being necessary to protect ordre public or morality. Such a situation could occur where the prohibition of the commercial exploitation of an invention has not yet been established by law or decision, perhaps due to the introduction of a new technology which has, at the time of patent examination, not yet been subject to applications for marketing permission or permission for field trials. In the rare situation that an immoral invention of a new technology reaches the patent office before entering into the regulatory system, absence of a decision or legal provision prohibiting the commercial exploitation should not prevent the denial (or grant) of patentability of an invention.647 Needless to say, a ban or legal prohibition could of course be merely one way in which such necessity can be demonstrated, but it is not a requirement, at least not from a textual point of view.648 It is instead the assess-

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646 Leskien and Flitner, 15.
647 Id., note 5.
648 This view is endorsed by Porter 2009:2, 348.
ment of the necessity of such a ban, an assessment that can be made at any point in time and which does not require a corresponding actual prohibition (as required by the prohibition approach).

The necessity approach is more compatible with a literal reading of the provision than the prohibition approach. The practical results of the necessity approach are, however, less consistent with the aims of the rule. Such interpretation would require the patent authorities to make an assessment of the necessity to prevent the commercial exploitation of the invention, but the means at their disposal of actually achieving such prevention is only the denial of patent protection. The effects of removing the economic incentives for pursuing certain research or developing applications for the market will of course have a bearing in a long term perspective, but the actual commercial exploitation of an invention will not be prevented by denying the inventor an exclusive right. On the contrary – the removal of a monopoly position for a single actor will benefit competitors and at least in a short term perspective more players will have the opportunity to enter the market with the invention.

12.6.4 The Qualification

The exclusion in Article 27.2 TRIPS is subject to a qualification in its last sentence: ‘provided that such exclusion is not made merely because the exploitation is prohibited by their law’. Depending on the point of view of the different approaches – prohibition or necessity – the qualification in will entail different effects. On the one hand, Article 27.2 TRIPS as interpreted by the prohibition approach requires something extra for its application besides a simple legislative prohibition: a factual prohibition, paired with an assessment of the necessity of such a prohibition in order to deny patentability. On the other hand, according to the necessity approach the existence of national legislation on the prohibition of commercial exploitation is not an actual criterion for the application of Article 27.2 TRIPS because what is actually required is an assessment of the necessity of preventing the commercial exploitation for the protection of ordre public or morality.

Thus, the discussions on the effects of national legislative prohibitions will centre around the fact that the existence of such a prohibition is not enough for the application of Article 27.2 TRIPS. It is either because it does not equal a factual prohibition, which has to be established (prohibition approach), or the decision on the necessity to prevent the commercial exploitation of the invention does not require a national legislative prohibition but instead an assessment of the necessity to prevent the commercial exploitation without requiring a specific situation in terms of a practical prohibition or actual legislation (necessity approach).
It is asserted that according to the final phrase of Article 27.2, the existence of a national exclusion of the exploitation of the invention may not be a sufficient condition for patentability. However, it can still be a necessary condition. The reason for this is the suggestion that the concepts of illegality and immorality need to be separated and distinct within TRIPS, as held by Porter:

The sale and distribution of certain inventions might be prohibited by laws or regulations that reflect concerns of a more technical, as opposed to moral, nature. The final phrase of Art. 27(2) simply reflects the idea that patentability should not be denied for this narrow category of inventions.

This means that the final phrase of Article 27.2 TRIPS would reflect the notion that laws or regulations that are founded on technical (or non-moral, including non-ordre public) concerns should not hinder the patentability of inventions that are nevertheless legally prohibited, if no morality or ordre public concerns are applicable to the inventions in question. If such morality or ordre public concerns exist in relation to the invention, the existence of a legal prohibition would fulfill the prevention criterion in Article 27.2 TRIPS and would therefore act as a sufficient criterion for denial of patentability of the invention. Such an interpretation supports the notion of the need for a broader analysis with regard to Article 27.2 TRIPS in line with the necessity approach. Consequently, a Member cannot exclude an invention from patentability based on a restriction on its commercialization, but an invention can be excluded from patentability where the exclusion is necessary to enforce a restriction on its commercialization. In this respect, Article 27.2 TRIPS reinforces the intent of Article 4quater of the Paris Convention.

It is also apparent that the contents of the terms morality and ordre public in an Article 27.2 TRIPS-setting does not necessitate that the inherent normative values or social interests in these concepts are expressed in national laws. The interests or values that these concepts represents and that Article 27.2 TRIPS is set to protect may be found elsewhere, or at least the fact that they are contained in a national law does not suffice to render them status as ordre public (or morality). Exclusions that are not actually based on the specific grounds set forth in Article 27.2 TRIPS are thus outlawed, even if prescribed by national law. This is supported by the text of Article 27.2 TRIPS, if by the terms ‘the necessity of preventing the commercial exploitation’ is considered to indicate to

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650 Porter 2009:2, 361.
651 Article 4quater of the Paris Convention reads as follows: ‘The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions resulting from domestic law.’
652 Correa 1994, 328.
a broader context in which the prevention must take place, than resort to the existence of a legal prohibition only.

It is often stated that Article 27.2 TRIPS takes into account Article 4$^{\text{quarter}}$ of the Paris Convention. This is true to the extent that the gist of Article 4$^{\text{quarter}}$ is certainly present in Article 27.2 TRIPS. However, there is a major difference between the formulation of these two Articles. Article 4$^{\text{quarter}}$ states that the fact that the sale of an invention is subject to restrictions resulting from domestic law is not an adequate ground for refusal of grant or invalidation of a patent right. In Article 27.2 the corresponding term is ‘exploitation is prohibited by […] law’. The concept may include a total prohibition of exploitation, which is broader than its counterpart in Article 4$^{\text{quarter}}$ of the Paris Convention. The restrictions and limitations mentioned in Article 4$^{\text{quarter}}$ only relate to the sale of an invention, and are not applicable to the manufacture of an invention.$^{653}$

Depending on the point of view of interpretation, Article 27.2 TRIPS, on the other hand, may require a total prohibition of exploitation for an invention to be denied patent eligibility, and simple restrictions or limitations by law are not enough, because they cannot as such guarantee total prohibition. Such legal restrictions or limitations are nevertheless covered under the application of Article 27.2. However, the requirement of a necessary prevention, coupled with the qualification in the last sentence, seems to require that the threat to morality or ordre public needs to be substantiated not only by law or authority regulation, but by a deeper analysis of what constitutes ordre public or morality in a Member, and if it is necessary to prevent the commercial exploitation of the invention to protect these values. There has to be a specific link between the commercial exploitation of the invention and the threats posed to ordre public or morality in a particular state. This threat needs to be substantiated by the prohibition – by any means – of the exploitation of the invention in order for the patent office to be able to deny patentability for the same invention. The patent examiners must therefore perform an analysis to determine the norms of ordre public and morality, and whether the exclusion from patentability is necessary to prevent the commercial exploitation of the invention.

The view that a corresponding prohibition on commercial exploitation is necessary for denial of patentability is appealing due to its inherent logic, since it requires a reasonable degree of consistency between a state’s ordre public or morality standards expressed within the domestic regulation governing the sale and distribution of products (inventions) and those expressed within a state’s patent legislation. If Article 27.2 TRIPS does not necessitate a corresponding prohibition on commercial exploitation, the situation could arise where an invention is denied patent protection for protection of (social or ethical) interests

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$^{653}$ Bodenhausen, 65.
expressed in the patent law framework, while at the same time those interests are not mirrored in the handling of the invention’s commercial exploitation.\textsuperscript{654}

Following the formulation of Article 27.2 TRIPS as such, there are compelling arguments for the view that a particular invention may be excluded from patentability although its commercialization is (still) permitted under a Member’s national laws.\textsuperscript{655} The main support for the view that the prohibition of commercial exploitation is not necessary for a denial of patentability could be found in the inclusion of the final phrase in Article 27.2 TRIPS.\textsuperscript{656} The wording of the paragraph includes the condition that the exception is limited by forbidding exclusion ‘merely because the exploitation is prohibited by their law.’ A Member should be able to give a non-protectionist justification for national exclusions.\textsuperscript{657} This diminishes the importance of the clause, since a legal prohibition on exploitation on its own will not be sufficient to stop the invention from being patented.\textsuperscript{658} In the context of the aforementioned discussion of the impact of approval or disapproval of the commercial exploitation by national laws, regulations or authority decisions, a legal prohibition is, thus, not a condition for the application of the exclusion. Neither is it a sufficient criterion for justifying a national exclusion of patentability without a complementary analysis from this perspective.

12.7 A Functional Framework

The application of Article 27.2 necessitates an underlying assessment of the morality or \textit{ordre public} raised by the invention in question. If such concerns exist, the fundamental point is whether it is necessary to prevent the commercial exploitation of the invention to protect the interests of \textit{ordre public} and morality? This necessity to prevent may be interpreted to have different implications depending of interpretative approach.

The prohibition approach represents the view that by necessity of prevention means a total prohibition of the commercial exploitation of the invention in question. The necessity approach takes the view that it is only the necessity

\textsuperscript{654} This situation is supported by some of the opinions expressed in EPO case law, i.e. that Article 53(a) EPC may exclude an invention from patentability even though the exploitation of that same invention is permitted in some of the Contracting states. It would seem as if the prohibition interpretation is followed, TRIPS prevents such a situation. EPC would in such situation be non-compliant with the Agreement. See Chapter 18.

\textsuperscript{655} Leskien and Flitner, 16. See also Recital 14 of the Biotech Directive: ‘[s]ubstantive patent law cannot serve to replace or render superfluous national European or international law which may impose restrictions or prohibitions which concerns the monitoring of research and of the use or commercialisation of its results […]’.

\textsuperscript{656} Leskien and Flitner, 15.

\textsuperscript{657} Harper, 416.

\textsuperscript{658} Torremans 2009:2, 289.
of the ban that should be taken into account, not the presence (or lack thereof) of an actual prohibition.

In this regard, the effect of the qualification in the last half-sentence of Article 27.2 TRIPS must be taken into account. The impact of this qualification on the different approaches towards the interpretation of ‘necessity to prevent’ should be assessed. If it is found to be necessary to prevent the commercial exploitation of the invention to protect ordre public or morality, then the exclusion from patentability for the invention in question is allowed under Article 27.2 TRIPS.

By tying the invention’s patentability to the regulation of its commercial exploitation under Article 27.2 TRIPS the task of the patent examiners is also greatly simplified, at least in situations where the law does not prohibit the commercial exploitation of the invention. Pires de Carvalho suggests that in such cases, the invention must not be denied a patent:

In the presence of an invention that [the patent examiner] thinks offends public ethical values, an examiner must, first, check where the law excludes such an invention from commercial exploitation. If the law does not prohibit the commercialization of the claimed invention, the examiner must examine it and, if it fulfils the patentability requirements, accept the application.659

The task becomes more difficult in the presence of a legal prohibition, since according to the two-step test, which is also in line with the prohibition approach, the patent examiner’s decision requires an assessment of the necessity of excluding an invention from patentability to prevent its commercial exploitation:660

However, if the law does prohibit its commercialization, the patent examiner must assess whether rejecting the application is necessary to prevent the invention’s commercialization. This is indeed a difficult analysis, and the patent examiner probably will not be in control of all the elements to perform such an analysis, which is mostly of a commercial nature. Moreover, it is not by accepting an application that the invention automatically obtains marketing approval. The relation of cause and effect, therefore, between rejecting a patent application and preventing the commercial exploitation of the claimed invention is not evident. However, even if the examiner is able to conclude that the application must indeed be rejected so as to prevent it from being commercialized (its commercialization being prohibited by law), he or she must then proceed to check whether there are other measures available that would be less restrictive, and this second

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659 Pires de Carvalho, 300 f.
660 The task of the patent examiner is presented in accordance with the two-step necessity test, see Sections 12.6.2 and 12.6.3.
check is clearly beyond the scope of examiners’ activities as well as of their technical capacities.661

The last test is in line with the general presumption that deviations from the Agreement should not be made lightly.

In this context the role which patents play in the promotion of new technologies is of interest. If the role of patents is merely to contribute to the promotion of technology, then the denial of patentability will be subordinate to the denial of commercial exploitation in the task of discouraging technological development. From a practical viewpoint the refusal of patent protection has no effect upon the later commercialization of the invention and such a refusal may therefore seem to be redundant in relation to the broader aim of preventing commercialisation of the invention. The tie between the promotion of technology and the denying of patent protection is, from this point of view, not automatic.662

The exclusion applies to certain inventions, not categories of inventions. However, the handling of inventions under Article 27.2 TRIPS may indeed depend upon which category the invention belongs to. Differences in approach between Members may give rise to disputes under Article 27.2 TRIPS. For example, in environmental law, the aim is to reduce or control risk through a variety of legal mechanisms.663 Prior to use of a chemical, it is often required to show that safety requirements have been followed regardless of country of origin. If a country bans a chemical found to be dangerous, the process may reduce the risk to society at the cost of proving its safety. But what happens under TRIPS if a chemical patentee from a state that grants patents without regard to the environmental impact seeks a patent from a second state that requires a showing of environmental safety? According to Harper, the second state appears to have the authority to reject a risky patent on the grounds of a precautionary domestic law.664 The rejection could apply to a whole class of chemicals, believed to pose an unacceptable risk to the state’s citizens. Another more considered approach includes the evaluation of the safety of individual chemicals. The inventor would in such a case be required to satisfy a preliminary showing of safety, which gives the nation an opportunity for pre-grant control, prior to the ‘making, using, offering for sale, selling or importing’ of the invention.

Thus, such a reasoning requires that patent offices accept prior controls by the relevant authority as proof of compliance with Article 27.2 TRIPS, under the national equivalent rules. The question in this regard is whether such pre-

661 Pires de Carvalho, 300 f.
662 See e.g. Pires de Carvalho, 294.
663 Harper, 385.
664 Id., 386.
market controls are contained in the concept of commercial exploitation of the invention. What is actually necessary is an assessment of the necessity of the prevention of the commercial exploitation of the invention in a Member. The existence of a legal prohibition will not be sufficient, neither in terms of the prohibition approach nor by the necessity approach. It is the significance of the prevention that will be decisive for the application of Article 27.2 TRIPS, not the mere existence of a legal rule. The prevention may thus vary, depending on its nature. Pre-market controls would perhaps suffice since they are an actual criterion for the invention’s commercial exploitation. But on the other hand, the existence of a legal rule may simplify the task of the patent examiners. By tying the application of the morality clause to the existence of a legal or authority prohibition (or permission), patent offices can simply just follow that particular framework.

12.8 Conclusions

The nature of Article 27.2 TRIPS allows, but does not mandates, exclusions from patentability based on \textit{ordre public} or morality grounds. If a Member employs a morality clause within its national patent law and in the patent grant procedure, the requirements of Article 27.2 needs to be fulfilled. The terms of the Article enable, in particular, two different interpretations.

According to the prohibition approach, Article 27.2 requires that it is necessary to prevent the commercial exploitation of the invention to protect \textit{ordre public} or morality as a presumption for the exclusion from patentability. The necessity to prevent the commercial exploitation must be expressed in an actual prohibition of the commercial exploitation of the invention in question. The proviso in the last part of Article 27.2 TRIPS, namely that ‘such exclusion is not made merely because the exploitation is prohibited by their law’ is interpreted as indicating that apart from the actual prohibition, a second assessment regarding the necessity to exclude the invention from patentability for the protection of \textit{ordre public} or morality is required. An invention should never be denied patentability in the absence of an actual prohibition of its commercial exploitation.

The necessity approach does not require an actual prohibition of the commercial exploitation of the invention for the application of Article 27.2 TRIPS. The assessment is instead directed towards the need to prevent the commercial exploitation of the invention for the protection of \textit{ordre public} or morality. The application of Article 27.2 is, thus, detached from the (legal) position of the invention within the regulatory system. The qualification in the last part of Article 27.2 is interpreted as supporting such a disconnection, and the result is a separation of the patent law morality and \textit{ordre public} assessment from the state of the national regulatory legislation with regard to the invention in question.
13 The Morality Exclusion in the EPC

13.1 Structure

In comparison to the WTO and the EU legal system, the creation of norms with regard to the interpretation of the morality clause is most prominent in the EPO setting. This is due to its function as a patent examination and granting authority for the European states. The availability and existence of legal sources enables a theorisation of the operation of the morality clause. In order to properly examine the full extent of the functioning of Article 53(a) EPC, a number of aspects need to be considered. This Chapter starts with a historical background in Section 13.2, general observations in Section 13.3 and the principle of narrow construction in Section 13.4, including the quantitative nature of the morality clause and the principles related to offensive versus non-offensive uses of an invention. Section 13.5 treats the concepts of morality and ordre public, the attempts to define them as well as their interrelation. Section 13.6 concentrates on the methodology that the EPO has constructed with regard to the operation of Article 53(a) EPC, namely the standards and tests that have evolved in the application of the provision. In addition to the concepts of morality and ordre public, the study necessitates an analysis of the requirements of ‘invention’ and ‘commercial exploitation’. Section 13.7 deals with the notion of invention. Thereafter, Section 13.8 is devoted to the fundamental requirement of commercial exploitation, including a categorization of moral objections and a discussion of their applicability. Section 13.9 examines the impact of the so-called proviso in the last sentence of Article 53(a) EPC, and Section 13.10 contains a discussion on evidence. Section 13.11 includes a discussion on the interface between patent and regulatory systems, including a discussion of EPO’s role and competence of examiners in ethical matters. Section 13.12 is devoted to Rule 28(c) EPC, and the outcome of the Boards’ interpretation in relation to the requirements of Article 53(a) EPC. The Chapter ends with a concluding analysis in Section 13.13.

13.2 Article 53(a) EPC

The morality exclusion in the EPC is found in Article 53(a) EPC which stipulates that:

European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.
The exception in Article 53(a) EPC rests on the foundations of Article 2(a) of the Strasbourg Convention which provides for an exclusion of inventions from patentability on the basis of ordre public or morality concerns. In fact, the Strasbourg Convention, focussing on the unification of European substantive patent law, was fully incorporated into the 1973 EPC as the Contracting states agreed that the former’s provisions should be drawn upon for the purposes of formulation of the EPC. Many of the patent law concepts were thus adopted from the Strasbourg Convention. The Strasbourg Convention was sketched on the basis of the preparatory works by the Scandinavian countries on a Nordic patent law and of the work by the six original members of the European Economic Community on a common European Patent Law. As the Strasbourg Convention rested heavily on the principle of unification, it has had a real influence on the legislative development of European patent law.

Considering the historical background of the morality provision as being one of the uniformly defined basic minimum requirements of the Strasbourg Convention it can be assumed that its purpose was to prevent the patentability of inventions that were based upon morality concerns common to all Contracting states. When the negotiations on the EPC started in 1961, the point of departure was that the concept of patentability in European patent law must be as wide as possible, and exceptions to patentability should consequently be narrowly construed. Early questions included the competence of single Contracting States and the EPO on the decision on inventions contrary to ordre public or morality. This concerned in particular whether grant of a European patent would be excluded if the use of an invention is found to be contrary to ordre public or morality in one state. The concept of exploitation was inserted at a later stage, since the early discussions were centred on the concept of ‘use’ of the invention. Also, it was discussed whether differences in national views on ordre public or morality could be solved by the possibility of withdrawal of protection by the Contracting State concerned.

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666 “The Contracting States shall not be bound to provide for the grant of patents in respect of: inventions the publication or exploitation of which would be contrary to ordre public or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation.”
667 Wadlow, 123 and Singer and Lunzer, 108.
668 Mills, 26.
669 Wadlow, 147-148.
670 See the description of the Reimer and De Haan proposals leading up to the Convention in Wadlow, 130 ff., 148.
patent law shows that the intent of the legislator was to establish morality and *ordre public* concerns on the basis of sources external to the patent system. 674

As with Article 27.2 of the TRIPS Agreement, Article 53(a) EPC likewise takes Article 4quarter of the Paris Convention 675 into account by indicating that the mere fact that something is prohibited by law or regulation in some, or even all, of the Contracting States, does not of itself preclude patentability. 676 This reasoning rests upon the notion of patents as negative rights, giving its holder the possibility to prevent third parties from exploiting the invention but not entailing any positive rights with regard to exploitation of the patent holder. A product could still be manufactured under a patent for export to states in which its exploitation is not prohibited. 677 Thus, marketing restrictions as such were not by themselves a sufficient criterion for justifications of exclusions from patentability by the time of drafting, at least.

In the EPC revision of 2000, the wording ‘publication or exploitation’ was replaced by ‘commercial exploitation’. The objective of this amendment was to bring Article 53(a) EPC into line with both Article 27.2 of the TRIPS Agreement and with Article 6.1 of the Biotech Directive. 678 Both TRIPS and the Biotech Directive exclude from patentability only those inventions that must be barred from ‘commercial exploitation’ to protect *ordre public* or morality. The word ‘publication’ used in the 1973 version of Article 53(a) EPC was consequently deleted. It is stated in the *travaux préparatoires* that the deletion entails no change to EPO practice. 679 The amendments made to the text of the Convention are more consistent with the practice of the EPO, where the application is checked by the Receiving Section before publication, and any subject matter contrary to *ordre public* or morality in the description or drawings is omitted. The substantive examination is performed by the Examining Division, usually after publication, where objections raised against the invention as such on grounds of *ordre public* or morality will be taken into account. 680

675 ‘The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions resulting from domestic law.’
676 Singer and Lunzer, 125. Cf. Article 27.2 of the TRIPS Agreement.
678 MR/2/00, Basic proposal for the revision of the European Patent Convention, EPO Administrative Council, Munich 13 October 2000, 45.
679 Id.
13.3 General Observations

Article 53(a) EPC states that ‘European patents shall not be granted in respect of […] inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States’. The provision rests of four fundamental concepts, namely:

- morality and ordre public
- inventions, and
- commercial exploitation, and
- the so-called proviso (in the last sentence).

In order to properly understand the functioning of the morality clause it is necessary to treat each of these categories. The manner in which the EPO Boards and Divisions as well as legal doctrine interpret the concepts, and consider their mutual relations, are decisive for the application of Article 53(a) and Rule 28 EPC. Unfortunately, there are differences in interpretation of the concepts.

The EPO has dealt with objections under Article 53(a) and Rule 28 EPC on a number of occasions. This analysis is built on the 14 published decisions from the EPO that relate in various extents to the interpretation of Article 53(a) EPC. Decisions relating to the exemplifying list in Rule 28 EPC treat issues exclusively with regard to Rule 28(c) and (d) EPC, and the analysis is therefore directed towards these two particular categories.

The decisions are mainly from the Boards of Appeal (9), but some decisions are from the Examining Division (1), Opposition Division (2) and the Enlarged Board of Appeal (2) respectively. All decisions concern biotechnological inventions, with one exception, namely, a traditional pharmaceutical decision (compositions of preparation of medicaments for use in lower mammals). Some of the patent applications under scrutiny concern human material (DNA sequences, proteins, cells, processes, etc.), and other decisions concern in particular hESCs. Others cover genetically modified plants and plant material (processes for production, plant cells, plants etc.), genetically modified animals (methods

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681 T 49/83 (Propagating material/CIBA-GEIGY) and T 320/87 (Hybrid plants/LUBRIZOL) related to Article 53(b) and have not been considered in relation to Article 53(a). To the extent that the interpretation of Article 53(b) is of relevance to Article 53(a), the two cases have been taken into account.

682 Rule 28 […] (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

683 T 866/01 (Euthanasia Compositions/MICHIGAN STATE UNIVERSITY) (Euthanasia compositions).

684 V 8/94 (Howard Florey/Relaxin) (Relaxin), T 272/95 (Relaxin/HOWARD FLOREY INSTITUTE), T 1213/05 (Breast and ovarian cancer/UNIVERSITY OF UTAH) (Breast and ovarian cancer).

685 Opposition Division decision of 21.07.2003 (Edinburgh), T 1374/04 (Stem cells/WARF), G 2/06 (Use of embryos/WARF) (WARF), T 522/04 (Stem cells/CALIFORNIA) (Stem cells).

686 T 356/93 (Plant cells/PLANT GENETIC SYSTEMS) (PGS), G 1/98 (Transgenic plant/NOVARTIS II).
of production, animals etc.), and xenotransplantation. The cases were decided between 1992 and 2009, and thus represent 17 years of development of case law in the EPO with regard to the morality clause in Article 53(a) EPC, as well as its exemplifying list in Rule 28 EPC.

13.4 The Principle of Narrow Construction

13.4.1 Article 53(a) EPC

Article 53 EPC excludes patent protection for three entirely different groups of inventions:

a) inventions the commercial exploitation of which would be contrary to ordre public or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; and

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

The exclusions in Article 53 EPC applies even if an invention otherwise meets all basic substantive requirements for a European patent laid down in Article 52(1) EPC. The underlying objective of the EPC is to establish a comprehensive patent protection between the Contracting States. As an exception to the general entitlement to patent in Article 52(1), it is often held that Article 53 should be construed narrowly, against the background of the underlying presumption that the concept of patentability should be as wide as possible.

687 V 6/92, T 19/90 (Onco-Mouse) (Oncomouse I), T 315/03 (Transgenic animals/HARVARD) (Oncomouse II).
688 Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal) (Leland Stanford, T 1262/04 (Non-invasive localization/LELAND STANFORD) (Non-invasive localization).
689 T 866/01, Reasons for the Decision, para 5.2.
690 See the preamble of EPC. See also e.g. Singer and Stauder, 85 and T 866/01, Reasons for the Decision, para 5.2.
691 Cf. G 1/98, Reasons for the Decision, paras 3.3.1, 3.3.3, 3.6-3.7 and G 2/07, Reasons for the Decision, paras 2.4-2.5, 4.8.1.
Interestingly enough the principle of narrow construction only applies (with restrictions) to Article 53(a) and (c) EPC.\textsuperscript{602} Article 53(b) EPC is, at least in respect of the prohibition on patenting plant varieties, directed towards assessing whether a claimed subject matter falls within the application of a particular definition since the purpose of the provision is to prevent double protection for plant subject matter by both patents and plant variety rights simultaneously.\textsuperscript{603} The application of Article 53(b) is thus necessarily dependent on an investigation of the claimed subject matter in relation to the definition of the concept of ‘plant variety’ in the UPOV Convention and the Regulation 2100/94 on Community plant variety rights.\textsuperscript{604}

The EPO Boards of Appeal have on several occasions stated that the exclusion in Article 53(a) should be narrowly construed,\textsuperscript{605} and this notion is generally also supported in doctrine.\textsuperscript{606} Such a narrow interpretation appears to be not only generally accepted but correct and justified against the background of first and foremost the general patent eligibility principle\textsuperscript{607}, although it has also been stated that regard must be given to the (individual) facts of each case.\textsuperscript{608}

Although a narrow construction thus seems firmly based not only in the case law of the EPO, but in legal doctrine as well, subsequent developments in the stem cell domain show that this may not always be the case. Against the background of the increasing number of decisions in which objections under Article 53(a) EPC has been raised, it is also evident that the EPO has gone from a generally narrow construction to favour a more case-by-case basis approach to the morality clause, thereby opening up for the possibility of a broader interpretation of the clause in individual decisions.\textsuperscript{609} The reason for this shift in legal practice is perhaps the influence on EPC by the Biotech Directive, in particular the interpretation of the exemplifying list in Rule 28 EPC that has had such a consequence. On the other hand, in the majority of decisions Article 53(a) EPC has been found not to apply, lending support to the conclusion that the provision is in fact interpreted narrowly.

\textsuperscript{602} See G 1/98, Reasons for the Decision, para 3.7 and Singer and Stauder, 85, 93 f.
\textsuperscript{603} G 1/98, Reasons for the Decision, paras 3.4-3.7.
\textsuperscript{604} Definition of ‘plant variety’ is found in Article 1(vi) of the 1991 UPOV Convention and Article 5.2 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.
\textsuperscript{605} T 356/93, Reasons for the Decision, para 8, V 8/94, Reasons for the Decision, para 6.2.2. (with reference to T 320/87 and T 19/90), V 6/92, Reasons for the Decision, para 3, T 315/03, Reasons for the Decision, para 7.4, and T 866/01, Reasons for the Decision, paras 5.3-5.4.
\textsuperscript{606} See Mouflang 1998, 70 (with further references to Benkard and Bruchhausen, Mouflang and Beier, Haertl and Schricker), 74, and 1994, 505, and Crespi, 163.
\textsuperscript{607} Article 52 EPC. Cf. Kur 213 ff.
\textsuperscript{608} T 356/93, Reasons for the Decision, para 13. See also T 866/01, Reasons for the Decision, paras 5.2-5.4. The Board of Appeal referred in particular to V 8/94 and doctrine.
\textsuperscript{609} See in this respect T 315/03, Reasons for the Decision, paras 6.1-6.3 and 10.5-10.8.
13.4.2 Rule 28 EPC

With the implementation of Rule 28 (ex Rule 23d) in the Implementing Regulations of EPC the question of status of these Regulations vis-à-vis the Articles, i.e. the relation between Rule 28 and Article 53(a), is also of interest. Rule 28 EPC reads as follows:

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The EPO Boards of Appeal confirmed in the Oncomouse II case that it follows already from the preamble and use of the words ‘in particular’ that the Rule is not intended to provide an exhaustive list of inventions excluded from patentability but that, on the contrary, it is limited to four categories, and that:

[i]ts effect is simply to ensure that inventions which fall within sub-paragraphs (a), (b), (c) or (d) of Rule 23d EPC [presently Rule 28] must not be granted patents under Article 53(a) EPC.701

The effect of the Rules is to ensure that any cases falling within the categories in the exemplifying list is denied patent protection. However, cases not falling within the limited exclusions of Rule 28 EPC can, and in some cases must, then be considered under Article 53(a) EPC.702 There are thus in effect two quite different Article 53(a) EPC objections - on the one hand, a Rule 28-type Article 53(a) objection which requires only that the invention is assessed as to whether or not it falls into one of the four limited categories set out in the Rule and, on the other hand, a proper Article 53(a) objection which requires an assessment as to whether or not commercial exploitation of the invention in question would be contrary to morality or ordre public. The first assessment requires an

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700 The Rules of the Implementing Regulations to the European Patent Convention are cited as numbered according to the amended Implementing Regulations to the European Patent Convention which entered into force on 13 December 2007, with the old numbering where appropriate given in brackets, except when quoting decisions, legislation, doctrine etc.
701 T 315/03, Reasons for the Decision, para 6.1.
702 Such situations may for instance occur regarding transgenic animal inventions, where there are two distinctive tests available: a Rule 28(d) test (established by legislation) and an Article 53(a) test (established by case law (T 19/90 test). See further this Section.
interpretation which is focused on the defined subject matter of the list, without any recourse to an ethical evaluation, as is required by the latter assessment. But it must be presumed that despite the absence of an Article 53(a) assessment with regard to Rule 28, such an evaluation must be presumed as underlying the specific examples of the list. They are, after all, implementations of the general principle.

It is not entirely clear whether the principle of narrow interpretation applies equally to Rule 28 EPC. When the list was introduced in the EPC Implementing Regulations on September 1, 1999, it created doubts as to whether the list was applicable to patent applications already pending before that date. The Boards of Appeal soon came to the conclusion, confirmed by the EBA, that the function of the list is to supply provisions for the application and interpretation of the pre-existing provisions of the EPC. It was held that the list only gives a more detailed interpretation of the meaning of Article 53(a) as intended from its inception, and the law was not changed by the terms in the list, only exemplified. As a rule, the exemplifying list is non-exhaustive and subject matter relating to the categories of (almost exclusively) biological material in Rule 28 EPC, belong equally to the category of inventions to be found not allowed under the main morality clause in Article 53(a).

A narrow construction is dependent upon the type of invention that is under assessment, and as mentioned, this principle of narrow construction could be abandoned on a case-by-case evaluation in which a broader interpretation is possible. In relation to Rule 28, such an evaluation is already established by the Boards of Appeal. In cases concerning the genetic modification of animals, a ‘two-stage’ balancing test is imposed in order to assess whether or not an invention is patentable. The first test is outlined by the legal provision in Rule 28(d) EPC (the Rule 28(d) test), which states that:

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: […] processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

In the Rule 28(d) test, the suffering of animals must be weighed against the medical benefit to man or animal. To the extent that an invention ‘passes’ the Rule 28(d) test, the invention proceeds to a further assessment under the general Article 53(a) EPC. The legal basis for this second test is the test outlined by the

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703 See e.g. G 2/06, Reasons for the Decision, paras 12-14 and T 315/03, Reasons for the Decision, para 7.7.
704 See e.g. T 272/95, Reasons for the Decision, para 4 ff.
705 EPC Implementing Regulations, Chapter V, Rule 26(1). See T 272/95, Reasons for the Decision, para 5, 7 and T 315/03, Reasons for the Decision, para 5.1.
Board of Appeal in *Oncomouse I* (the so-called *T 19/90 test*), where the suffering of animals and possible risks to the environment is weighed against the invention’s usefulness to mankind.\(^{706}\) The *T 19/90 test* is broader in nature and allows for a wider range of considerations to be taken into account, either by way of adapting the test or by way of considering other matters outside the framework of the test.\(^{707}\)

However, it is debatable whether the tests employed to these specific types of inventions (genetically modified animals) and their impact on the scope of the application of Rule 28(d) (narrow) and Article 53(a) EPC (broader) have had a general effect on the principle of narrow construction in relation to the general Article 53(a) EPC assessment with regard to other inventions. As outlined in e.g. *Oncomouse II*, many considerations could possibly fit into such an Article 53(a) assessment, which makes moral objections likely to appear whenever animal inventions are at issue.

The notion that the examples in Rule 28(a)-(d) EPC are excluded on the basis of the general morality clause in Article 53(a) EPC has gained support both in case law and doctrine.\(^{708}\) From this perspective Rule 28 EPC can be said to implement Article 53(a) EPC, and should consequently fit in under a generally narrow construction.\(^{709}\) Indeed, considering the origin of Rule 28 as founded in Article 6(2) of the Biotech Directive, it has been argued that the interpretation of the Rule must be definitional and directed towards the literal content of the provision.\(^{710}\)

Despite the different points of view of the subject matter covered by Rule 28 EPC, it is important to keep in mind that the Implementing Regulations by way of Article 164 EPC is an integral part of the Convention, but in cases of conflict the provisions of the Convention prevail.\(^{711}\) Article 53(a) EPC thus belongs to a higher norm category than Rule 28 EPC. It is therefore crucial that the already developed case law with regard to Article 53(a) EPC plays a role in the assessment of Rule 28 EPC, from the perspective of both content as well as context of its operation. Article 53(a) EPC is based on a higher norm than Rule 28 (Convention and Implementing Regulation, respectively). The relation between Rule 28 EPC and Article 53(a) EPC must therefore be assessed from the starting point that the conclusions reached in case law on Article 53(a) EPC needs to adhere to, or at least not be contradicted in the application of Rule 28

\(^{706}\) See *T 19/90* generally.

\(^{707}\) See in this respect *T 315/03*, paras 6.1-6.3, 10.5-10.8.

\(^{708}\) See e.g. *T 272/95*, Reasons for the Decision, para 4 ff. and Torremans 2009:1, 142.

\(^{709}\) Another point of view is represented by the notion that the exclusions are effectively not patentable subject matter, and Article 53(a) is then a general safeguard clause that exists even for those inventions that cover *inter alia* patentable subject matter with effects for *ordre public* or morality. If such is the case, then Rule 28 EPC does not implement Article 53(a) EPC. See Torremans 2009:1, 142.

\(^{710}\) Plomer 2009:1, 189 ff.

\(^{711}\) Article 164(2) EPC.
EPC. Such a conclusion also has the effect that the content of the Rule 28 EPC Rules should not be wider than an Article 53(a) EPC assessment, partly due to the relation between the Convention and its Implementing Regulations, and partly due to the principle of narrow construction, because of the nature of the relationship as expressed in the text of Rule 28 EPC.

13.4.3 The Quantitative Nature of Article 53(a) EPC

By its nature as an exception to the general principle of a broad area of patentability, Article 53(a) EPC is not expected to be frequently invoked, apart from in very exceptional circumstances. This approach is signalled by the Guidelines, which state that the rule is likely to be invoked only in rare and extreme cases, and that the general purpose of the rule is to "deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour." Often-cited examples of such inventions are anti-personnel mines and letter bombs. The main test for application of the morality exclusion proposed by the Guidelines is of a quantitative nature: to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.

The quantitative nature of its use does not equal the principle of narrow construction. While the former principle concerns the frequency with which Article 53(a) EPC should be put to use, the latter concerns the scope of application of the exclusion. A narrow construction of the provision has nothing to do with how frequently the provision is invoked in proceedings. However, these two principles are sometimes confused. A narrow construction of Article 53(a) EPC will have the effect that the exclusion will very seldom apply, notwithstanding how frequently the provision is invoked. But the principle that Article 53(a) should be invoked only in very rare and extreme cases is a signal to the examiners to be very cautious with its application. To the extent that the EPO can decide what types of provisions are invoked by a patent application, the use of Article 53(a) EPC may be controlled. But since any person is entitled to raise opposition proceedings against a granted patent at the EPO on the grounds of Article 53(a), the provision will be invoked in the majority of cases.

712 See in this regard e.g. Torremans 2009:1, 143.
713 The operation of Rule 28(c) EPC is treated in Section 13.12.
715 See e.g. EPO Staff Notice 8/98-IV.
716 The examiners usually have a list of criteria to follow when deciding whether to raise an objection under Article 53(a). Such criteria may include questions such as: Does the invention offend against human dignity? Solely aim at facilitating criminal acts? Violate international conventions? Involve badly controllable risks? Involve cruelty (to) animals? Lead to a genetic change of the human germ line? See e.g. EPO Staff Notice 6/92.
relating to publicly disputed patents on biotechnological inventions. The only subsequent control the EPO can thus sustain is the narrow construction of the provision in question, if such is preferred, or even correct.

13.4.4 Offensive and Non-offensive Uses

Nearly all inventions may have different purposes, and it is quite easy to find uses that would be contrary to ordre public or morality. However, Article 53(a) EPC only applies when the non-permissible use of the invention can be deduced from the very nature of the invention. There is unanimity in legal doctrine of the principle, that if the invention can be exploited in a way that does not infringe the concepts or ordre public or morality, a patent should be granted provided that the other patentability criteria are met. Such a proviso has been deemed necessary since most inventions can have a dual (or more) purpose of which only one purpose may be caught by the application of the morality clause; an interpretation which is in line with the criteria of a narrow approach.

The legality or illegality of the purpose itself can be defined in terms of the mental intent of the person carrying out the act. But the provision goes further than to relate to the illegality of an invention. It actually refers to the moral quality of the act. The unpatentability of an invention is not necessarily assessed in relation to the existing legislation in a state, which is in line with the proviso in Article 53(a) EPC. A similar principle likewise applies to the situation where the invention can have both moral and immoral uses – i.e. an invention is not deemed to be automatically in breach of Article 53(a) EPC just because it may be exploited in a way that contravenes morality or ordre public. The mere possibility of abuse of an invention is therefore not sufficient to deny patent protection pursuant to Article 53(a) EPC, if the invention can also be exploited in a way which does not and would not infringe ordre public or morality.

Thus, the denial of patent protection pursuant to Article 53(a) EPC should only take place if the intended commercial exploitation of the invention would infringe ordre public or morality. Schatz lends further support to this conclusion

717 Articles 99 and 100 EPC.
718 The matter of legitimate use has not been discussed extensively in the decisions, but the EPO divisions and Boards nevertheless seem to adopt such a stance. See e.g. T 866/01, Reasons for the Decision, para 9.6, with further references to Benkard and Mellulis, Singer, Stauder and Schatz and MGK and Mounaf, Guidelines for the Examination in the European Patent Office (November 2014), G-II, 4.1.2, and Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal) Reasons for the Decision, para 8(51).
719 See e.g. Mounaf 1998, 72, with further reference to Benkard and Brunkhausen, Cornish, Mounaf, Beier, Haertel and Schricker, Schatz, and Straus.
720 WIPO SCP/15/3, Experts’ Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights, Annex IV, 48.
721 Schatz, 160.
by stating that ‘Article 53(a) EPC can only apply when the non-permissible use of the invention can be deduced from the very nature of the invention’. \(^{723}\) It is not sufficient for the application of Article 53(a) that the invention has one use that would breach the principles of *ordre public* or morality. \(^{724}\) The use must be sufficiently clear from the nature of the invention as well as the intended commercial exploitation as reflected in the patent application.

The Opposition Division has stated on occasion that the practice of each individual embodiment of every invention is subject to approval by the appropriate regulatory bodies in the Contracting States. By reference to national regulatory legislation, the conclusion is that as long as the invention has one acceptable use then patenting should be possible. It is then a matter for the individual states to authorise only those embodiments deemed acceptable in that state. \(^{725}\)

13.5 Morality and Ordre Public

13.5.1 Introduction

Before entering into an analysis of the operation of Article 53(a) EPC as handled by the EPO Boards and Divisions, it is necessary to study the attempts to define the concepts of *ordre public* and morality and the interrelation of the respective concepts. This Section therefore studies the historical background of the concepts, followed by the definitions of *ordre public* and morality respectively. Finally, the question is raised as to whether the concepts are actually treated as two separate notions or if there is a tendency to treat them as representing one single standard.

The concepts of *ordre public* and morality are fundamental to the application of Article 53(a) EPC. At first glance, the concept of *ordre public* has been less difficult to scrutinize than morality, perhaps since the concept traditionally has a closer relation to (national) legislation. This is also apparent from the discussion in relation to the definition of the concept in the context of TRIPS. The influence of existing legislation on the concept of *ordre public* (and morality) displays an inherent conflict between traditional views on *ordre public* and the interpretations of the concept by the EPO Boards and Divisions. Such conflicting views are also found in doctrine. In this respect, the conflicting views do not only concern the definitions of the concepts, but also the question as to whether the concepts are synonymous in the sense of representing one single

\(^{723}\) Schatz, 161.

\(^{724}\) See e.g. T 866/01, Reasons for the Decision, para 6.4.

\(^{725}\) Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, para 8(50).
assessment, or if they indeed form two different sources for the application of Article 53(a) EPC. In this study the concepts are treated as two separate entities, but the arguments for treating them as one single assessment are nevertheless scrutinized in Section 13.5.4.

13.5.2 Historical Background

Already the Working Party of the EPC recognised that there was no European definition of morality. But the Party refrained from referring to national concepts in the text of Article 53(a), because it would have given too great a prominence to national concepts in the EPC. The existence of a European-wide concept of morality was thus anticipated already in the travaux préparatoires; a concept which should be a matter for the European institutions. The Chairman of the Working Party, on the other hand, foresaw problems with this approach. The EPO ‘was liable to interpret the concept of morality in a manner at variance with a national concept’, something that the States were particularly sensitive to. As regards ordre public, the Working Party investigated the existence of the concept in the national states and concluded that in the Netherlands, the concept existed and enabled the exclusion of an invention merely because it contravened a single law. In the rest of the states, apart from Germany, the ordre public requirement existed but had no practical importance. The Working party considered making no mentioning of the concept at all in EPC, but finally decided to mention ordre public with the qualification that the mere fact that an invention is contrary to a national law is not sufficient for ordre public to be invoked.

From this reasoning it can be deduced that the proviso originally served the purpose of qualifying the concept of ordre public by not equalling ordre public to a legislative provision as such (as in the Netherlands). An invention is not necessarily in breach of the principle of ordre public just because it is contrary to a national law. On the other hand, it was also pointed out that the Office should not be required to know in detail all the provisions of national laws’ ordre public. This reasoning points to an autonomy for the EPO to decide the contents of the ordre public principle, without being required to pay attention to national laws. The main aim of giving such autonomy to the EPO was to avoid situations where the Office had to determine national ordre public, since such powers

727 Id., 8.
728 Id.
729 Id.
might infringe principles of national law. In such situations the power vested in the EPO was restricted, as the aim was to refrain from giving definitions to such items that were left to national authorities to decide.

In the majority of the EPO decisions on Article 53(a) EPC, the Divisions and Appeal Boards have accordingly refrained from defining the concepts of *ordre public* and morality. The *PGS* decision contains the first and consequently the most cited definitions of *ordre public* and morality, repeated in the *Edinburgh* and *Oncomouse II* decisions (the former only in relation to the concept of morality), and referred to in *Euthanasia compositions*. By reference to the EPC *travaux préparatoires*, the Board of Appeal concluded that it was not possible to find a European definition of morality, and that the interpretation of this concept (as well as *ordre public*) should be a matter for European institutions, a statement completely in line with the reasoning in the *travaux préparatoires*. However, the question remains whether the effects of such reasoning fulfils the purpose of the preparatory works in the present legal situation in Europe.

13.5.3 Definitions

13.5.3.1 *Ordre public*

First, it must be mentioned that the *ordre public* concept is viewed differently in the context of national patent law on the one hand and European patent law on the other. In national law, the concept of *ordre public* usually means a body of positive law, albeit the status of such laws as a source for *ordre public* could be debated. In European patent law, the concept has taken on a different character. Before treating the EPO’s interpretation(s) of *ordre public* it is fruitful to discuss the major perceptions of the content in doctrine. The dividing line seems to be whether *ordre public* is actually related or not to a body of positive law.

According to Straus, *ordre public* consists of ‘major principles of the legal order’, and if the exploitation of an invention is allowed by laws and yet found to

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732 T 19/90, V 6/92, V 8/94, G 1/98, T 272/95, T 1374/04, T 1213/05, G 2/06, T 522/04. See also Leland Stanford, where reference was made to the Guidelines. (Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, para 8(49)).
733 It is specifically of interest to note that the issue of the content of the concepts of *ordre public* and morality are absent from the decisions regarding the embryo exclusion in Rule 28(c) EPC. (G 2/06, T 1374/04, T 522/04). In those cases, the Boards of Appeal/EBA goes directly for the interpretation of the embryo exclusion, without trying to define the concepts of *ordre public* or morality. The working definitions provided by the Board in *PGS* are repeated in T 315/03 as well as in the Opposition Division decision of 21.07.2003 (Edinburgh) (but in the latter only in relation to the concept of morality).
734 T 356/93, Reasons for the Decision, para 4. The patent concerned *inter alia* transgenic plants, plant cells as well as processes for their production.
735 Schatz, 161.
be contrary to *ordre public* (or morality) must necessarily imply that the relevant laws are either unconstitutional and/or immoral.736 Schatz contends with this view, and consequently the exploitation of an invention can thus only offend *ordre public* if the invention in question is prohibited by law.737 By such interpretation the concept of *ordre public* is closely tied to (il)legality and points to an understanding of the term as embodied in or stemming from positive law.

Other commentators do not equate the *ordre public* concept with statutory law, but rather with fundamental legal principles enshrined in acts of a higher norm level, such as state constitutions or international conventions. Moufang draws the definition of *ordre public* from its meaning in international private law; as a final option when the application of foreign law would lead to consequences that would be totally unacceptable for the national legal order. Hence, his definition of *ordre public* is construed as referring to the ‘most fundamental rules of the relevant legal order.’738 Such fundamental rules are found in the constitution (for national legislation) and for the EPC, Moufang contends that assistance can be gained from the ECHR.739 Prohibition of an invention by a simple statutory law would thus not make Article 53(a) EPC applicable, which is the main point of disagreement between Moufang on the one hand, and Straus and Schatz on the other hand.740

Further interpretations of the concept are centred on the broader concept of ‘public order’, or taking the Rule of Law perspective.741 Beyleveld and Brownsword argue that *ordre public* refers to the ‘structure of social relations governed by the Rule of Law itself, to the foundations of civil government as such.’742 This implies inclusion of the concept of ‘public morality’ into the *ordre public* term and refers to ‘the common good’ or ‘the general will’.743 From this angle the prohibition by law or regulation in the Contracting states is neither a sufficient reason, nor a necessary criterion, to reject a patent application on the basis of *ordre public*, because under the Rule of Law perspective law or regulation are irrelevant for such purpose.744 The concept of *ordre public* functions instead as an identifier of law or regulation in accordance with the Rule of Law, i.e. validating the legal regime. *Ordre public*, by such interpretation, becomes a ques-

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736 Straus 1995, 930-932.
737 Schatz, 162.
738 Moufang 1994, 71.
739 Moufang 1994, 71 and 1998, 503. All Contracting and Extension states of the European Patent Organisation are Member States of the Council of Europe and thereby also to the ECHR.
740 Sterckx and Cockbain argue for the same conclusion as Moufang, namely that illegality is neither a necessary nor a sufficient condition for the finding that something is contrary to *ordre public*, and chooses the point of view as expressed in case law, namely that the EPO Divisions and Boards of Appeal must themselves create the normative contents of the concepts. Sterckx and Cockbain, 298.
741 See Beyleveld and Brownsword, 54 ff. and Section 5.1.
742 Beyleveld and Brownsword, 62.
743 Id., fn. 83.
744 Id., 77-78.
tion of whether the invention would threaten the Rule of Law itself, something that would never or very rarely be an issue.

By contrast, the EPO has interpreted the concept of *ordre public* (and morality) in a fashion which detaches the concept from possible foundations in national (and also to an extent international) law, i.e. a body of positive legal and ethical norms. As mentioned, the PGS decision is the most authoritarian decision because it contains express definitions of the concepts of *ordre public* and morality. The Board issued the following general definition of *ordre public*.

It is generally accepted that the concept of "ordre public" covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to "ordre public".

The PGS definition includes the protection of public security and physical integrity of individuals, which points to an interpretation of the *ordre public* concept as a protective measure for threats against society, including individuals and the environment. This view should be compared to the concept of *ordre public* as used in a number of international treaties, where it has been held that its general meaning is ‘public policy’. The meaning of *ordre public* in the EPC context is by comparison narrower. But the TBA refrained from an interpretation in which the concept of *ordre public* is tied to legislation, at least national legislation, with reference to the proviso that ‘approval or disapproval of the exploitation by national law(s) or regulation(s) does not constitute per se a sufficient criterion for the purposes of examination under Article 53(a) EPC’. Thus, this has been interpreted as meaning that illegality is neither a necessary nor sufficient condition for something to be contrary to *ordre public*.

Straus has criticised this interpretation, because it treats the concept in the EPO setting as completely detached from the notion of *ordre public* as laid down in the constitutions and laws of the Contracting states. Schatz has rightly pointed out that by such definition ‘the EPO has to define by itself the norma-

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745 The PGS definitions were repeated in T 315/03 and the Opposition Division decision of 21.07.2003 (Edinburgh) (for the latter only in relation to the concept of morality), and referred to in T 866/01.
747 See Section 12.5 and 12.5.1.
748 Gold and Gallochat, 358.
749 T 356/93, Reasons for the Decision, para 7.
750 Sterckx and Cockbain, 298.
751 Straus 1995, 931-932.
tive contents of these concepts and then apply them. [...] [T]he EPO combines the role of both legislator and judge.\textsuperscript{752}

In \textit{Euthanasia compositions}, the Board relied partly on \textit{PGS}, and partly on definitions from legal doctrine. It found that \textit{ordre public} 'is formed by the ethically based constitutional or other rules, usually backed up by penal provisions, that reflect the basic values prevailing in society or trade.'\textsuperscript{753} The definition provided by this particular Board differs from \textit{PGS}, in that it clearly ties the \textit{ordre public} standard to existing rules, constitutional or other, which indicates a discrepancy between the Boards with regard to the relation of \textit{ordre public} to positive law. In this context it is also important to highlight the disparity provided in the EPO decisions. The concepts are either treated as synonyms and thereby representing one single standard, or the concepts are not defined at all. In either situation, the decisions fail to provide a proper basis regarding \textit{ordre public}.\textsuperscript{754}

\subsection*{13.5.3.2 Morality}

The English expression ‘morality’ has its equivalents in the French and German expressions of \textit{bonne mœurs} and \textit{gute Sitten}. Whilst the discussion with regard to the \textit{ordre public} concept has centred around the definition of the concept in relation to legislation, the discussions regarding the definition of the morality concept is by comparison far more elusive.

If Straus equates \textit{ordre public} with positive (national) law, morality is in his view found rather in the ‘ethical foundations of a given legal order as reflected primarily in the constitutional provisions and their implementing laws’, thus still reflecting principles contained in legislation but of a higher legal order.\textsuperscript{755} From the point of view of national patent law, Schatz agrees with Straus in the reflection of ethical principles in legislation, but also argues for an acceptability standard, perhaps equivalent to cultural morality\textsuperscript{756}, where morality is construed by a body of ethical norms, generally accepted by those concerned with these norms. For instance, such norms could consist in deontology, principles for research ethics and codes of conduct.\textsuperscript{757} In the same vein, Moufang refers to ‘ethically-established norm[s] of vital significance, the binding force of which is generally accepted.’\textsuperscript{758} Moufang, however, seems to rely on the notion that the moral principles must be contained in legislation but also accepted socially, thus indicating (in contrast to Straus) that just because something is legally permissible does not make it morally permissible. Morality in this context comprises

\begin{footnotesize}
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\item \textsuperscript{752} Schatz, 162.
\item \textsuperscript{753} T 866/01, Reasons for the Decision, para 6.9.
\item \textsuperscript{754} See Warren-Jones 2008:1, 641 ff.
\item \textsuperscript{755} Straus 1995, 932.
\item \textsuperscript{756} Cultural morality is defined as ‘the most widespread and influential standards of moral permissibility within a specific community’. Beyleveld and Brownsword, 57.
\item \textsuperscript{757} Schatz 161.
\item \textsuperscript{758} Moufang 1994, 503.
\end{itemize}
\end{footnotesize}
ethical minimum standards, thus embracing only ‘high-ranking and generally accepted ethical principles’.759

The definition of morality by Beyleveld and Brownsword is necessarily dependent upon their delimitation of the concept of ordre public under the Rule of Law. Since both morality and ordre public both fall into the concept of public morality, morality becomes such matters of public morality ‘that are not directly implicated within the idea of Rule of Law itself’.760 The preferred norm is what Beyleveld and Brownsword label as ‘European critical cultural morality’.761 Their argumentation is based upon the notion that the EPC operates within the sphere of not only the European patent system but also the European legal-moral order, in which the ECHR has a central constitutional position.762 The moral requirements that must be employed are substantial in character and part of the constitutional arrangements of a single legal community.763 Beyleveld and Brownsword further argue that the standard employed by such ‘critical cultural morality’ is the one of ‘right-thinking’ persons within the community constituted by the EPC Contracting states. The EPO cannot, therefore, discretionally employ the criteria of their choice when applying the morality standard. Beyleveld and Brownsword reject particularly the standard of cultural morality in the Contracting states as a criterion, i.e. moral permissibility based upon general acceptance within a community, as well as other specified philosophical theories of morality (utilitarianism, Kantian, Hegelian, Rawlsian, or Gewerthian ethical theory).764

Most commentators agree with the definition of morality provided by Schatz as ‘a body of ethical norms which are generally accepted by those concerned with these norms’, e.g. ethical principles generally recognised in the different branches of the medical profession or codes of conduct observed in industry and business.765 Such principles are usually binding on the basis of conduct.766 A conflict with morality (or its counterparts) has been held to only occur when ethical minimum standards are violated, thereby indicating that morality in Article 53(a) EPC should be interpreted as embracing only ‘high-ranking and generally accepted ethical principles’.767 Such principles refer to extra-legal principles, but form also part of the legal order. It is advocated that the value standards represented in the morality concept must therefore, in order to be effective

760 Beyleveld and Brownsword, 62.
761 Id., 73.
762 Id., 70, 127.
763 Id., 68.
764 Id., 64 ff. Cf. Sterckx and Cockbain, 295-296 for a similar critique of cultural morality, and advocating utilitarianism and human dignity in the morality assessment.
765 Schatz, 161.
766 Beyleveld and Brownsword, 56.
in a single case, be anchored in the general legal order. Moreover, morality principles not anchored in such a manner could still, in exceptional cases, justify exceptions from patentability, provided that they are ‘essentially generally recognized as obligatory and have to be limited to elementary rules’. Thus, such a stance recognizes both principles indirectly recognized in subject-specific legislation, e.g. the principle of the inviolability of the human being, as well as directly recognized principles, e.g. permissive commercialization of hESC. Against this is argued, e.g. by Moufang, that moral principles operate on a higher norm-level than legislation and require social acceptability to be recognized. Thus, even if some specific inventions would be permissible by law their exploitation could still be regarded as being contrary to morality.

Turning now to the EPO’s definition of morality, it is clear that the TBA has outlined cultural morality as a criterion in a definition that could only be described as procedural:

The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilization. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.

The reference to the ‘totality of the accepted norms’ and the ‘conventionally-accepted standards of conduct’ that pertain to the ‘culture inherent in European society and civilization’ clearly points to an understanding of the concept as embracing a common morality standard for the whole of the European society and civilization in relation to the invention in question. Thus, the concept of morality as defined by the Board in PGS embraces standards of conduct or norms that are shared by one society, i.e. the European. This implies the recognition of such non-legal norms as argued by e.g. Schatz and Moufang. But the definition is clearly focused on finding a common morality by measuring the general acceptance on the part of the public. By such a definition the EPO rather creates a methodology for its own findings of the normative contents of

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768 Straus 2013, 27.
769 Id.
the concepts (also in line with the method for *ordre public*), in addition to the task of applying them to a particular invention.\(^{771}\) However, later decisions indicate a slightly different view, closer to the notion argued by Strauss of anchoring moral principles in the general legal order. The definition provided in *Euthanasia compositions* also mentions ‘legal systems’ in plural, which moves the definition of morality closer to national views:

Morality is an old legal concept. It was adopted in western legal systems from Roman law as "boni mores". Morality is one of the fundamentals of our legal system and at the same time forms the basis for the inclusion of extra-legal principles of ethics in the law. The legal approach based on morality for the EPC can be found in the concepts of the European cultural and legal systems. Morality constitutes actual ethically-based norms of behaviour that have become socially binding through being generally accepted. The exploitation of an invention only infringes morality if it is regarded as reprehensible by society in general or at least by the trade concerned.\(^{772}\)

By means of this commentary, the Board recognizes that Europe consists of a plurality of cultural and legal systems, and it is also noted that morality is only infringed if it is regarded as reprehensible by society in general or at least by the trade concerned. Still, it is evident from both definitions that the EPO Boards consider morality to be something collective and shared throughout Europe – a unitary European standard, based on cultural morality. In addition, despite the somewhat different definitions it is still uncertain how the EPO views the relation between legislation (constitutional or other rules) and the *ordre public* and morality concept respectively.

The statements by the Boards are of a very general character and do not solve the question of how and where morality should be found and assessed, i.e. what sources are relevant and on what level. The morality concept has therefore proven very difficult to establish, a truth also recognized (and accepted) by the Boards:

[M]orality is not a criterion to be determined by the patent authorities. No single definition of morality based on e.g. socio-ethic, economic or religious principles represents an accepted standard in European culture.\(^{773}\)

As evidenced by further statements, the Boards do not seem convinced that such a common standard is actually possible to find. The Board of Appeal in *Oncomouse II* held in this respect:

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\(^{771}\) See the critique by Sterckx and Cockbain in that the morality definition reduced ethics to sociology, since a socially binding norm does not equate a morally binding norm. Sterckx and Cockbain, 295.

\(^{772}\) T 866/01, Reasons for the Decision, para 6.12.

\(^{773}\) Id.
The many bases (economic, religious, etc) for definitions of morality suggested by the appellants are of no assistance since no single such basis represents an accepted standard in European culture.774

From this perspective it is interesting to read the Opposition Division decision related to the so-called Edinburgh patent covering hESC. Despite citing Article 53(a) EPC in its entirety the discussion is centred exclusively on the morality concept. The assessment of whether or not the invention is contrary to morality is conducted by recourse to national legislation and regulation in relation to hESCs in Europe, as well as the unacceptability standard. The Division subsequently held that:

Neither the evaluation of the national legislation nor the assessment of the conventionally accepted standards of conduct of European culture has revealed a uniform approach with regard to human ES cells, and according to T356/93 as cited above even a uniform estimation of the situation for all contracting states of the EPC would not automatically be a criterion for the purposes of examination under Article 53(a) EPC. Therefore, a different approach has to be followed in order to assess the patentability criteria of morality in this specific case.775

It would be tempting to conclude from this reasoning that national legislation equals ordre public since ‘conventionally accepted standards of conduct’ clearly represents the morality standard. Still, the decision has been criticised on several grounds and its status and legal implications should not be exaggerated.

The decisions of the EPO (perhaps with the exception for the Edinburgh decision) shows a tendency to completely detach the interpretation of the concepts from national and European law, even if Euthanasia compositions could be read to signal a more permissive approach. This inclination is actually the cause of the major difficulties in establishing the contents of the morality and ordre public concepts and thereby creating a proper, transparent and reliable standard for the application of Article 53(a) EPC.

13.5.3.3 Elusive Sources

Although the question of whether principles in general legislation form part of the ordre public as well as morality concept is contentious, there seems to be consensus in legal doctrine that ethical principles constituting the concept of morality is definitely anchored in rules of constitutional status, or even a higher ranking, such as the ECHR. However, the acceptability of relevant moral standards within a group or community concerned, i.e. cultural morality, is still a contentious criterion in legal doctrine, at least where such morality is based on

774 T 315/03 Harvard Oncomouse, Reasons for the Decision, para 10.10.
775 Opposition Division decision of 21.07.2003 (Edinburgh), Reasons for the Decision, para 2.5.3.
quantitative criteria alone, and lacking qualitative assessments. Furthermore, the question of whether ethical principles also form part of the legal order, and thereby relate to national legislation, is another point of disagreement.

There is consequently a distinction between the way the concepts have traditionally been interpreted in national law (and even European law) and the way the Board of Appeals treat the concepts, with its decisions having a basis in the PGS decision. As advocated by some commentators, *ordre public* has traditionally, in national laws, referred to a body of positive law and morality to a body of positive ethical norms, e.g. prevailing in a relevant profession or social group.\(^76\) If the commercial exploitation of the invention does not breach any of these laws or norms, then the patent office need not assess the potential hazards involved with the invention, since such is the exclusive task of special authorities, and not the patent offices.\(^77\)

The EPO, on the other hand, does not refer to the body of positive legal or ethical norms, and has shown reluctance to tie the application of (especially) *ordre public* to existing legal rules. In the light of the forming of the European Patent Organisation and the views of influence by national states this is not surprising. However, already when formulating the concept of morality, the Board circumvents the task of creating a proper European definition. By stating that the EPC founders had difficulties finding a common European concept of morality and then proceeding to refer to ‘the totality of the accepted norms which are deeply rooted in [the European] culture’, the Board in PGS is actually referring to something that in later decisions has been stated to be non-existent, at least with regard to the suggestion of economic, religious or socio-ethic bases for the concept.\(^78\) If the statement in PGS is to be interpreted as precluding the existence of a general, all-embracing European morality it would perhaps make sense. However, since the founders also held that the task of finding the European morality lies with the European institutions, the Board has no other option than to refer to a European unitary standard. But the referral to a unitary bundle of accepted norms would prove as difficult to the Board as to the EPC founders to establish, not least in view of the following decisions on hESC inventions.

In essence, the definitions provided by the Boards are difficult to apply. For morality, the definition creates a method for decision-making in accordance with Article 53(a) EPC, i.e. the search for a unitary standard. For *ordre public*, the autonomous position in relation to principles and legislation found in national law is understandable against the historical background of a foreseen unitary patent. The enumeration of interests to protect lends more substance to the

\(^{76}\) Schatz, 162.  
\(^{77}\) Id.  
\(^{78}\) T 866/01, Reasons for the Decision, para 6.12 and T 315/03 Harvard Oncomouse, Reasons for the Decision, para 10.10.
ordre public concept (in comparison to the definition of morality), but it is far from clear what actually constitutes the concepts of ordre public, or rather, what constitutes potential sources for the finding. The EPO has not been as vocal in identifying sources for identification as have commentators.

13.5.4 Separate Concepts?

The difficulties regarding the definitions of the ordre public and morality concepts also concern their interrelation. An important question in this respect is whether the concepts of ordre public and morality are independent from each other or interlinked. Although the Boards of Appeal has stated that the concepts represent two standards, it is not evident that they are always treated so. For instance, the EPO Guidelines do not separate or define the concepts of ordre public or morality, but treat the purpose of the exception rather than its contents. The TBA in Oncomouse I did not separate the concepts either, but treated them as representing one single assessment. It is of interest to note that in many cases the Examining Division or Opposition Division have likewise treated the concepts of ordre public and morality as representing one single standard – the morality assessment.

It has therefore been argued that there is a disparity within the EPO, where the Examining as well as Opposition Divisions have generally used a conjunctive construction of the morality provision in which ordre public represents a borderline clarification of the wider concept of morality. Ordre public would in such a construction be included within the morality concept. This view is also to a certain extent advocated by Beyleveld and Brownsword in their promotion of the ‘public morality’ concept. In contrast, in the majority of the decisions of the Board of Appeals the concepts are treated as disjunctive, where ordre public and morality form repetitious terms, or in some instances both terms are present in the same objection. The combining of the two concepts into one single basis was for instance not advocated by the TBA in Oncomouse II:

Those definitions confirm the view, which appears from the words of Article 53(a) EPC itself, that "ordre public" and morality may form the basis of two separate objections either or both of which can be raised in a particular case (and are both raised in the present case).

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780 T 19/90, Reasons for the Decision, para 5.
783 Id., 643.
784 See Beyleveld and Brownsword, 61 ff.
786 T 315/03, Reasons for the Decisions, para 10.2.
The clarification in *Oncomouse II* was further upheld in *Euthanasia Compositions*.\(^787\) If any conclusion can be drawn from this it is that the lower Divisions’ habit of treating the concepts as one single standard has not gained support in the Boards of Appeal of the EPO. Many commentators conclude that the provision contains two alternative concepts.\(^788\) The separate definitions further strengthen the view that according to Article 53(a) EPC, objections could be based either on *ordre public* or morality concerns, or possibly both.

Still, the question remains of whether not the *ordre public* concept can be held to exist within the morality term, which evidently has a broader scope. This is especially true if *ordre public* exists in not only the legal rules as such, but in legal principles underlying the society. In particular the *ordre public* factors of protection of the environment and the protection of physical integrity of the individual have been said to fall under the broader morality concept, whilst disruption of the social order and disruptions of public peace or public safety are captured by the *ordre public* term.\(^789\) The treatment of the concepts as being two different entities is clearly signalled by the EPO Boards, but it is also true that lower divisions have had a tendency to treat the two concepts in a synonymous fashion, thereby blurring the lines between them in the more practical handling of patent applications.

As advocated above the prevailing definitions by the Boards of Appeal, as expressed most clearly in *PGS* and *Euthanasia compositions*, rather create a method for establishing *ordre public* and morality than defining the actual content of the concepts. In addition, there is a difference in the methodology assigned to the respective concepts. For *ordre public*, the Boards enumerate the protection of interests to take into account, interests generally based on positive law, but not restricted to the prevailing principles of national or even European law. Dependent on the formulation of the *ordre public* concept in question, the approach could be narrow or broad. A broader approach includes identifying ethically based rules of conduct, perhaps implying the inclusion of *ordre public* into the broader issue of morality. For morality, a search for a unitary European standard of norms regarding the exploitation of the invention is endorsed. Whereas a discussion of these different points of view is interesting, the real effect of treating the concepts as separate is more questionable, especially considering the non-precedential status of decisions by the Examining Divisions and Opposition Divisions. Of more interest is the actual assessment of the application of Article 53(a) EPC, which shows a tendency by the EPO Divisions and

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\(^787\) T 315/03, Reasons for the Decision, para 10.7 and T 866/01, Reasons for the Decision, para 6.9.

\(^788\) See in particular Moufang 1994, 503, Warren-Jones 2008:1, 645 ff. and Sterckx and Cockbain, 292 ff., as well as the discussion by Beyleved and Brownsword, 61 ff. Many commentators do not address this particular issue.

\(^789\) Sterckx and Cockbain illustrate this division by an exemplification of inventions which would contravene *ordre public* (only, and not morality): so-called ‘boom boxes’; clothing that reveals the wearer’s genitalia; and speed trap detectors. Sterckx and Cockbain, 292.
Boards to revert to various standards of measurement of morality and *ordre public*, and the creation of different tests in the execution of the assessments. The variants of standards and tests naturally draw their fundaments from the different definitions, and perhaps the lack of a fundamental definition is the reason for the lack of consistency in the assessment of Article 53(a) EPC on the part of EPO Divisions and Boards.

13.6 EPO’s Methodology

13.6.1 Introduction

Decision-making processes need to be transparent and validated, especially where they also concern third parties. When considering issues of ethics and morality, this function is even more important. The operation of the morality clause therefore necessitates an interpretation which is generally applicable and transparent. To fulfill these requirements it is of crucial importance to adhere to a method for making the assessment, a standard against which the method is measured, and take into consideration what kind of evidence is needed to substantiate the findings of an application of the said method.

In relation to the standard for making the assessment in relation to Article 53(a) EPC, there are already indications of the use such standards found in the definitions by the Boards and Divisions, at least in relation to the morality definition. In the EPO decisions rendered so far, at least two distinct standards have emerged from the Divisions and Boards of Appeal – the *abhorrence* standard and the *unacceptability* standard.\(^790\) As mentioned, the procedural definitions rather open up for a standard against which morality (and to a certain extent also *ordre public*) is assessed by employing different types of tests. Thus, the method for assessing whether or not the standard(s) are fulfilled is represented by recourse to different types of tests. The standards and tests employed in EPO practice are outlined in Sections 13.6.2 (standards) and 13.6.3 (tests), with a discussion in following Sections 13.6.4-13.6.7.

13.6.2 The Standards

13.6.2.1 Establishing Standards

The *abhorrence* standard originates from the EPO Guidelines, where it should be considered ‘whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be incon-

\(^790\) See the discussions on abhorrence and unacceptability in Gitter, 21 ff.
ceivable. If it is clear that this is the case, objection should be raised under Art. 53(a); otherwise not.” It is also stated that ‘the purpose of Art. 53(a) is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour. Traditional examples of such subject matter are letter bombs and anti-personnel mines.”

The standard built into such an assessment is thus the ‘public in general’, which would regard the invention as so ‘abhorrent’ that it would be ‘inconceivable’ for the patent authority to grant a patent right. Nothing is stated about the method to reach such a conclusion, other than that it is a test based on probability. The examiner should assess, not the real effects on the public of the characteristics of the invention, but rather the probability of the reaction of the public in general to the invention, and that such a reaction would have to be one of abhorrence. As a standard, it sets an extremely high threshold for denial of patentability on morality and ordre public grounds, since it would affect only those very rare inventions of a particularly detestable nature.

The unacceptability standard is closely tied to the PGS morality definition and is used in a number of EPO decisions. The basis of this standard is the assessment of whether behaviour is acceptable or unacceptable, based on public perception. In PGS, the unacceptability standard was used in relation to the assessment of the morality criterion, where none of the products or activities of the patent were considered to be ‘wrong as such in the light of conventionally accepted standards of conduct of European culture.” In G 1/98 (Transgenic plant/NOVARTIS II), the objections to patentability under Article 53(a) EPC were found to fall outside the scope of the referred questions, but the EBA nevertheless held that ‘there is no consensus in the Contracting States condemning genetic engineering in the development of plants under the above criteria [whether publication or exploitation of the invention is contrary to ordre public or morality].” In Leland Stanford the use of donated human material was found to be ‘widely accepted’ [provided consent was given] and that ‘[t]here is at present no consensus in Europe [sic] society about the desirability or otherwise of this technology [xenotransplantation].” Likewise in Oncomouse II the TBA tested objections based on the morality concept against the unacceptability standard (‘moral disapproval in European culture”). The standard of unacceptability was further used in Euthanasia compositions with regard to the morality

792 Id.
793 T 356/93, Reasons for the Decision, para 17.3.
795 Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, paras 8(50-51). Leland Stanford is interesting because although the unacceptability standard was referred to in the Reasons, the Opposition Division nevertheless reached the conclusion of patentability (patent maintained in an amended form) with reference to the abhorrence standard.
796 T 315/03, Reasons for the Decision, paras 13.2.10, 13.2.21.
assessment. In contrast to the other decisions where the standard was measured from the point of view of unacceptable, the Board instead used acceptability as the norm, and concluded that the practice of euthanizing animals was considered ‘as their [veterinarians’] moral obligation based on generally accepted ethics and norms which the board accepts are deeply rooted in the culture inherent in European society and civilization.’

It is however of interest to note that the assessment of alleged breach of *ordre public* in *Euthanasia compositions* was conducted with a mentioning of general acceptance, which indicates a similar adherence to unacceptability also with regard to *ordre public*.

The abhorrence standard has been used in a number of lower division decisions, most notably in *Relaxin*, where the Opposition Division stated that ‘[t]he function of this article has to be seen as a measure to ensure that patents would not be granted for inventions which would universally be regarded as outrageous’, and followed up by repeating the wording of the Guidelines. The reasoning is similar to *Leland Stanford* in the incorporation of references such as ‘widely-accepted standards of behavior’ and ‘clear consensus’ on the part of the public/society, thereby indicating unacceptability. The final decision, however, is set up as requiring reliance on an abhorrence standard, both in the introductory part of the decision and with regard to the objection based on a general assertion on the alleged intrinsic immorality of patenting human genes. However, in discussing the arguments posed by the opponents, the Opposition Division continuously utilizes language referring to an unacceptability standard. For instance, the opponent’s assertion that the use of human tissue in the development of the invention was rejected with reference to the isolation procedure (provided prior informed consent was in place) being acceptable and even welcomed by the vast majority of the public.

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797 T 866/01, Reasons for the Decision, para 6.13.
798 ‘There is clear evidence on file that the unequivocal, generally accepted and exclusive meaning and scope in the field of veterinary medicine and practice for the expression “euthanasia” is the humane killing or mercy killing of animals by trained personnel.’ (emphasis added) T 866/01, Reasons for the Decision, para 6.10.
800 ‘[T]he function of this article has to be seen as a measure to ensure that patents would not be granted for inventions which would universally be regarded as outrageous.’ The Opposition Division then quoted the relevant ‘abhorrence’-passage of the Guidelines. V 8/94, Reasons for the Decision, para 6.2.1.
801 V 8/94, Reasons for the Decision, para 6.4.3.
802 In fact, the Opposition Division also relied on the explicit approval of uses of human body parts in Article 13 of the (then) Draft Bioethics Convention as a counterargument to the opponent’s objection. The methods utilized by the Opposition Division and Boards of Appeal for overriding objections posed by the opponents are analysed by Warren-Jones in Warren-Jones 2008:2, 198-203.
803 V 8/94, Reasons for the Decision, para 6.3.1.
be excluded from patentability under Article 53(a). [...] In conclusion, neither
does the opposed patent offend against widely-accepted standards of behavior
 [...] nor is there a clear consensus amongst members of the public in the con-
tracting states that patenting human genes [...] is immoral.\footnote{V 8/94, Reasons for the Decision, paras 6.5-6.6.}
The reference to ‘widely-accepted standards of behavior’ clearly signals an unacceptability stan-
dard, whilst the ‘clear consensus’ in relation to the concept of immorality could
perhaps be sorted under an abhorrence approach, but this is all depending on
the significance attached to the concept of ‘immorality’. The language simply
indicates a breach of the requirements in Article 53(a) EPC, but says very little
of the standard, or level required to reach the outcome of the case.

It is clearly so that the EPO Boards and Divisions have used, on separate
occasions, both standards, although the unacceptability standard seems to pre-
vail in the Boards of Appeal decisions.\footnote{See Warren-Jones 2007, 837, especially fn. 24-25.}
However, the problem with the unac-
ceptability standard is that its definition ultimately stems from the morality
definition as stated in PGS which is a procedural assessment of public perception.
The assessment of \textit{ordre public} objections is more difficult to sort in under unacceptability, since it is not as clear from the decisions what kind of standard
is used. For instance, serious prejudice to the environment is a core criterion
under \textit{ordre public}, often referred to in the decisions.\footnote{See e.g. T 356/93, Reasons for the Decision, para 18 ff. and T 866/01, Reasons for the Decision, para 6.11.}
Where the morality and \textit{ordre public} concepts are treated as two different criteria, unacceptability is al-
most exclusively referred to in relation to morality, but not to \textit{ordre public}. There,
enumeration of the interests to protect and assessment of breach of those in-
terests is the common way of handling objections.

This leads to two observations. \textit{First}, it seems as if the use of standards is
preferred for morality assessments, and there are no decisions where a pure
\textit{ordre public} assessment has consisted of evaluation against (any of) the standards. \textit{Second}, the conclusion may be dependent on the fact that the separation of the
criteria of \textit{ordre public} and morality is not strictly upheld, which leads to a spill-
over effect of the unacceptability standard from morality to \textit{ordre public} even if
that is not explicitly stated in the decisions.\footnote{See the reasoning in Warren-Jones 2008:1, 645.}
It seems as if these overlaps are
neither explicitly nor implicitly recognized. But if neither unacceptability nor
abhorrence is used, what type of standard is then used in \textit{ordre public} cases?

If the content of the \textit{ordre public} concept is considered from the available
sources, it can be concluded that from the definition in PGS factors such as the
protection of public security and the physical integrity of individuals as part of
society, as well as breach of public peace or social order or to seriously prej-
dice the environment, are considered to be \textit{ordre public}. The assessment con-
ducted by the TBA in *PGS* focused on serious prejudice to the environment and found the evidence for such risks lacking in substance.\(^{808}\) In *Euthanasia compositions*, *ordre public* was considered to consist of the violation of ethically based constitutional or other rules, or even jeopardize public peace or social order or seriously prejudice the environment. As mentioned, this definition seems more tied to establishing a breach of existing rules of higher value, but the same factors as in *PGS* remain, namely the protection of public peace or social order and to seriously prejudice the environment. This concurs with the definition provided by e.g. Moufang, where *ordre public* consists of ‘one of the fundamental principles of the legal system’.\(^{809}\) There are thus overlaps between the definitions in references to public peace or social order, but also differences in the form of whether or not the *ordre public* standard is actually tied to existing legislation or not.\(^{810}\) From such reasoning the *ordre public* concept seems more material or substantive in character (breach of enumerated principles), whilst the approach to morality is procedural (general acceptability).

From the point of view of substantiation of facts in support of arguments, both morality and *ordre public* seem equally difficult to establish. In *Euthanasia compositions* the Board held that the appellant had not provided any evidence that euthanasia of lower animals ‘would obviate any ethically based constitutional or other rules’\(^{811}\), including public peace, social order or seriously prejudice the environment. The conclusion of the Board was thus that, in the absence of relevant evidence to substantiate facts, no assessment could be made. The same is true for *PGS*, where the Board held that since the arguments that the invention was a serious risk for prejudice to the environment were unsubstantiated by relevant facts, no assessment could be made as to whether the exploitation of the invention was contrary to *ordre public*.

By the reasoning of the Boards, it seems as if the issue was – and is – a substantiation of facts by relevant evidence. If relevant evidence would have been presented it would have supported the argument of prejudice to the environment risks caused by the invention in suit. In such cases the Boards have to assess these risks in relation to something, and the next question is therefore in relation to what? If subsumed under morality would it consist of assessing, in the view of such risks, whether the exploitation of the invention would be unacceptable to the public in general considering the negative consequences that may follow from its use? Or would it consist of something else? Perhaps a method for weighing the substantiated risks against the (equally substantiated) benefits stemming from the invention? From this reasoning the next question,

\(^{808}\) T 356/93, Reasons for the Decision, para 18.8.
\(^{809}\) Moufang 1994, 503.
\(^{810}\) See the reasoning in Opposition Division decision of 21.07.2003 (Edinburgh), Reasons for the Decision, para 2.5.3., where national legislation is investigated.
\(^{811}\) T 866/01, Reasons for the Decision, para 6.11.
namely the methodology according to which the assessment should be made, becomes relevant. For *ordre public*, the question of standard still remains but as will be shown, the problem has been solved by the EPO by creating a test for assessing such risks, at least in relation to genetically modified animal inventions.

13.6.2.2 Moving from Standards to Tests

Thus, at the moment two standards are definitely used in relation to the assessment of *ordre public* or morality. First, the abhorrence standard, the operation of which seem to require neither definitions of *ordre public* or morality nor the separation of two concepts. The definition of abhorrence also seems to relate to public perception, because according to the Guidelines, it is a matter of perceptions of the public in general. Second, the unacceptability standard which seems closely tied to the definition of morality. This standard rests on an assessment of what the public in general considers acceptable or unacceptable based on (sociologically) binding standards of behaviour in European culture or society. For such a standard the assessment is necessarily procedural because it includes an element of measuring public perception. It is also unclear from the EPO decisions whether the unacceptability standard is used in relation to *ordre public* objections, or if possibly a third standard is developed in such cases? Or perhaps the solution is the recourse to the envisaged tests.

The reasoning in *Oncomouse II* may shed some light on the issue at hand. In the envisaged method for assessment for application of Article 53(a) EPC, the Board enumerated ‘social order, environmental risk and accepted standards of behavior in European culture’ as factors to take into account. This brings us to the next step in the operation of the provision, namely the methodology according to which the assessment is conducted. As concluded, the standards, abhorrence and unacceptability, and possibly a third standard, thus set the principles against which the assessment of application of Article 53(a) EPC is conducted. The envisaged methods for assessment created by the EPO Divisions and Boards are the so-called ‘balancing test(s)’ and the ‘rebuttable presumption test’.

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813 See Section 13.6.3.
814 T 315/03, Reasons for the Decision, para 10.5.
815 Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, para 8(51). Likewise tests are absent from V 8/94, T 272/95, T 866/01, T 1213/05, Opposition Division decision of 21.07.2003 (Edinburgh), T 1374/04, G 2/06 and T 522/04.
13.6.3 The Tests

The standards indicated in the case law of the EPO necessitate recourse to two types of methods, or tests, which are used to indicate whether the commercial exploitation of the invention is contrary to *ordre public* or morality. These tests are the balancing test and the rebuttable presumption test. The balancing test occurs in two different variations, the *T 19/90 test* and the *Rule 28(d) test*. Section 13.6.3.1 outlines the balancing tests and Section 13.6.3.2 describes the rebuttable presumption test.

13.6.3.1 The Balancing Tests

The method of balancing of interests at stake was first developed by the Board in *Oncomouse I*, where the TBA stated that:

> [P]recisely in a case of this kind there are compelling reasons to consider the implications of Article 53(a) EPC in relation to the question of patentability. [...] The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention’s usefulness to mankind on the other.

The statement by the Board had probably two purposes. The first one addressing the Examining Division’s conclusion that patent law was not the right tool for regulating problems arising in connection with the genetic manipulation of animals. The second purpose was to create a method for dealing with objections and assessing the application of Article 53(a) EPC in decisions concerning the genetic manipulation of mammalian animals.

This test, labelled as the *T 19/90 test*, of balancing the suffering of animals and possible risks to the environment against the invention’s usefulness to mankind, was followed in later decisions concerning genetically modified animals (*Oncomouse II*) and chimeric animals (*Leland Stanford*, where the Opposition Division recommended the use of ‘balancing act’-test for all patents concerning animals, whether genetically modified or not). In *PGS*, concerning genetically

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816 T 19/90, Reasons for the Decision, para 5.
817 When the decision of patenting in *Oncomouse I* was remitted from the TBA to the Examining Division, the patent was subsequently granted on the ground that in the overall balance the interest of mankind to remedy widespread or dangerous diseases outweighed the risks to the environment of the uncontrolled dissemination of unwanted genes and suffering in the form of cruelty to animals (which was found to be reduced by the use of the invention, resulting in a lower number of test animals). V 6/92, Reasons for the Decision, para 4.
818 The case number of the Board of Appeal *Oncomouse I* decision (T 19/90 (Onmoouse/HARVARD)).
819 T 315/03, Reasons for the Decision, paras 10.5-10.8, Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, para 8(46). Although the test in the latter decision was based mainly on Rule 28(d) EPC (then Rule 23d(d) EPC), the statements have bearing on the use of balancing acts in general. The final decision in *Leland Stanford* was however not made on the basis of
modified plants, the TBA investigated the use of the technology in relation to accepted standards of conduct (i.e. unacceptability standard), as well as possible risks to the environment associated with the invention, but without conducting a balancing of interests. The Board pointed out that the use of a balancing exercise could be more relevant in situations where an actual damage or disadvantage exists. It was therefore more a matter of substantiating the factors to be used in the balancing exercise, than a rejection of the test as such in relation to plant inventions.

Following the adoption of the Biotech Directive’s rules in the EPO Implementing Regulations, a slightly different balancing test was introduced in Rule 28(d) EPC (the Rule 28(d) test), namely the exclusion from patentability for:

- Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

This balancing test weighs the suffering of animals against the substantial medical benefits to man or animal, and is by its formulation narrower in scope. Its application was thoroughly discussed in Oncomouse II, where the Board stated that the Rule 28(d) test takes precedence over the T 19/90 test with regard to the point in time to apply the test. If Rule 28(d) EPC does not apply, then an assessment in relation to Article 53(a) EPC can take place, i.e. the T 19/90 test. The nature of the Rule 28(d) test is also clear – it is a balancing test where the likelihood of suffering (no more than likelihood is needed to trigger the operation of the Rule) must be weighed against the substantial medical benefit to man or animal (where the substantial medical benefit has to be substantiated).

In Leland Stanford, the Opposition Division identified the factors in Rule 28(d) (ex Rule 23(d)) EPC, as the medical benefits associated with the invention, the animal suffering and the potential risks of xenotransplantation (which was the envisaged process) as important for the assessment of patentability. The Opposition Division seemed willing to apply both tests, even though the animals of the invention were not genetically modified, thereby precluding a proper Rule 28(d) test. Despite this (envisaged) broad application of the tests, the resulting assessment was however not conducted by a proper balancing of the identified interests at stake according to either test, and the Division did not strictly define which factors belonged to which test (Rule 28(d) or T 19/90 test). The Opposition Division rather applied a reasoning which resulted in an appli-
cation of the abhorrence standard, and concluded that the present invention did not by their estimation fall under this category, thus not using the envisaged balancing test(s) at all. Likewise in Non-invasive localization the Board applied the Rule 28(d) test despite the fact that the invention in suit did not consist of a process for genetically modifying an animal, but a process to be performed on an already genetically modified mouse. However, the fact that the animal in question was already genetically modified, although not in terms of the invention, made the Rule 28(d) test applicable, at least according to this Board of Appeal. A certain liberty is indeed applied in these cases for the application of the Rule 28(d) test.

In the view of the TBA in Oncomouse II, the T 19/90 test is sufficiently broad and can be used in cases where arguments regarding ordre public and morality issues respectively and exclusively form the basis of the objections, as well as in cases where the issues concern both concepts. By such reasoning it has been argued that the balancing tests are measured against the standard of unacceptability, thereby indirectly supporting a notion where the morality definition spills over into the ordre public concept. By gathering together different factors such as environmental concerns, suffering of animals, benefit to mankind and also envisaging additional factors, the test offers a method for conducting the assessment of application for Article 53(a) EPC with a rather broad scope.

The purpose of the balancing tests envisaged by the EPO is to function as the appropriate standard of morality or ordre public in decisions concerning at least genetically modified animals but also plants. The type of facts as well as the level of substantiation of such facts required for proof of evidence for the different elements is set out by the Boards. The balancing test is held to function only in relation to the unacceptability standard, because it is not possible to balance competing factors to the point of abhorrence. For instance, Warren-Jones argues that abhorrence is an ultimate point which cannot be reached through a weighing of interests. A different kind of tests is needed to reach the level of abhorrence, namely the rebuttable presumption test.

823 Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, paras 8(47-53).
824 T 1262/04, Reasons for the Decision, para 17.
825 T 1262/04, Reasons for the Decision, para 17.
826 T 315/03, Reasons for the Decision, para 10.5.
828 See the reasoning in T 315/03, Reasons for the Decision, para 10.10 and T 356/93, Reasons for the Decision, para 18.8.
829 Warren-Jones 2008:1, 653.
13.6.3.2 The Rebuttable Presumption Test

The balancing tests are not the only way of reaching a decision under Article 53(a) EPC. The second test, labelled the ‘rebuttable presumption test’ is described as follows:

[W]here the presence of moral aspects raises a favourable presumption, which the immoral aspects can only rebut where they are so significant that a favourable decision would be untenable (a ‘rebuttable presumption’).

The use of the rebuttable presumption test is not clearly advocated by the EPO, but the reasoning of the Divisions and Boards nevertheless points in the direction of such a test in some cases. A problem is that objections that may have been well-suited for a rebuttable presumption test are nearly always found to be unsubstantiated by evidence. Failure to reach a decision by use of such a test therefore usually depends on a lack of evidence. Even though some of the decisions show the adherence to a rebuttable presumption test, the demarcation between this test and the balancing tests is presently unclear.

As mentioned, in Relaxin and Leland Stanford, the Opposition Division preferred a standard of abhorrence. The tests used to measure the respective invention’s patentability is therefore of interest. In Leland Stanford the Opposition Division envisaged a ‘balancing act’ test for all patents concerning animals, but the resulting assessment was not conducted as a true balancing test with the factors used in either the T 19/09 test or the Rule 28(d) test. The Opposition Division simply held that there were enormous medical benefits associated with the invention and that the advantages of the invention were thus sufficiently clear and substantiated.

The disadvantages argued by opponents were rejected. The Opposition Division held that the ‘hypothetical potential risks associated with xenotransplantation [the technology used]’ were not a ground for denying patentability because, first, such hazards were possible and not conclusively documented, and second, the EPO was not the correct authority to monitor and estimate such risks. Evidently, the argument concerning risks was not considered appropriate because it was not based in substantiated facts, and it was not correct in the view of the role of the EPO. Likewise, arguments relating to the effects of the patent were rejected due to the fact that the role of the EPO did not allow for the taking into account of the economic effects of the grant of patents in specific areas. The use of donated human material for research was furthermore considered as ‘widely accepted’ (i.e. unacceptability standard evoked) on the

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831 Warren-Jones 2007, 834.
basis of regulatory law and authority. The technology as such (xenotransplantation) was considered by the Opposition Division as giving rise to intense discussions but no consensus was established in European society on the desirability or otherwise of the technology. This argument, therefore, did not hold any value. After considering these arguments, always in relation to the medical benefit factor, the Opposition simply stated that ‘the present invention does not in the estimation of the OD fall under [the abhorrence] category.’

Although the underlying considerations by the Board in *Leland Stanford* could be seen as adhering to a sort of balancing exercise, with the deficiency being unsubstantiated disadvantages, the arguments posed by the opponents were nevertheless not used in a proper balancing test (as outlined in the *T 19/90* and *Rule 28(d) tests*). The conclusion is that the Opposition Division rather made an intuitive estimation of the abhorrence of the invention, definitely in the light of the arguments posed, but the ground for arriving at their conclusion is not entirely clear. It is therefore difficult to actually define the assessment in terms of a particular test. In sum, the Opposition Division found that the arguments of the opponents were not substantiated enough to warrant merit, or were not strong enough to counter the medical benefit case, not in the form of a true balancing test but rather of a free comparison between moral and immoral perceptions, based on the unacceptability standard in the reasoning but using the abhorrence standard in the final stage of decision-making.

As mentioned in Section 13.6.2, it is quite unclear how the findings of the Opposition Division in *Relaxin* are substantiated in terms of what standard is actually adhered to in the material part of the decision. It is also not evident what type of test is used to reach the decision of patentability. Relying on the fact that the abhorrence standard was clearly envisaged in the introduction, perhaps the conclusion is not far-fetched and that this is actually the standard employed by the Opposition Division. Opposing such a conclusion are the references to the unacceptability standard that are perhaps not frequent but yet occur in the decision, which in turn leads to the effect that the basis for the findings are both unacceptability and abhorrence standards.

The method used to corroborate the findings in *Relaxin* is clearly not a balancing test. Perhaps it is a rebuttable presumption test since the Opposition Division reverted to testing the arguments of the opponents in order to determine which of them held (against the facts, presented or commonly known). In support of a rebuttable presumption approach the conclusion can be drawn that the immoral aspects were not substantiated in the majority of the objections, and where substantiated they nevertheless did not reach the level of abhorrence.

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832 Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, para 8(51).
Where the Boards are not using the balancing tests the question is whether the rebuttable presumption test is used as an alternative in these situations. However, the reasoning of the Boards does not clearly permit such a conclusion. Even though (at least the) T 19/90 test is sufficiently broad so as to take additional considerations into account, some objections need to be handled outside the framework of this test. But it is not clear whether these external factors should be assessed through a balancing test or some other type of assessment.

In Oncomouse II, arguments relating to an alleged threat to evolution, alleged increased trade in genetically manipulated animals and alleged moral unacceptability of such manipulation were examples of factors that, according to the Board, could be deployed as part of the T 19/90 test. However, in the end, the test was not used but rather another type of assessment. In the substantive assessment of the factors in Oncomouse II, the Board first conducted the Rule 28(d) test in relation to the factors identified by Rule 28(d) EPC (i.e. animal suffering and substantial medical benefit to man). Second, using the T 19/90 test, the factors originally identified by the TBA in Oncomouse I were employed (animal suffering, possible risks to the environment and the invention’s usefulness to mankind) in addition to new ones (the possibility of using non-animal alternatives to achieve the same aims as the patent in suit). The most prominent issue of concern in the assessment was, however, that the objections were not substantiated by evidence. This was particularly evident in relation to the so-called remaining considerations (alleged threat to evolution, alleged increased trade in genetically manipulated animals and alleged moral unacceptability of such manipulation). These were considered to be outside the framework of the tests, but whether the failure to deploy them as factors in the T 19/90 test was due to their unsubstantiated character or due to the fact that they were considered to fall outside the framework of the test is not apparent from the reasoning of the Board. It is interesting that the T 19/90 test was not used, against the background that the Board specifically mentioned in the general part that such factors could be a part of that test. It is furthermore clear that the Board regarded the arguments as being wholly dedicated to morality, as none of them appeared to suggest anything contrary to ordre public.

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833 T 315/03, Reasons for the Decision, paras 10.7-10.8.
835 Id., paras 10.5-10.8, 12.2.5, 13.2.5-13.2.9. The degree of animal suffering was rejected as a factor in the test, whereas the possibility of using non-animal alternatives was considered and resulted in tilting the balance in favour of the patentee. (13.2.8)
836 They could not have been considered under the Rule 28(d) test because they did not fall within any of those categories.
837 T 315/03, Reasons for the Decision, para 13.2.10.
The first two of the *remaining considerations* (alleged threat to evolution and fear of increased use of transgenic mice in cancer research and increased trade in animals generally) were treated as questions of argument, but the apparent lack of evidence resulted in the Board finding that they could not apply at all.\(^{838}\) The remaining issue of alleged moral unacceptability of the genetic manipulation at hand became a question mainly of public perception arguments and what types of evidence that qualified for substantiating findings in that regard.\(^{839}\) The findings supported by evidence were on the one hand, that ‘care and concern for the well-being of animals is an accepted tenet of European culture’\(^{840}\) whereas on the other hand, ‘the use of animals in medical and scientific research […] is also an established feature of European culture.’\(^{841}\) The resulting conclusion was that this dichotomy may give rise to ‘unease’ on the part of the public, but nothing in the case before the Board served to elevate such unease to the status of ‘moral disapproval in European culture of the use of animals for medical research, let alone moral disapproval of the use of mice in cancer research – i.e. moral disapproval of the exploitation of the present invention.’\(^{842}\)

From *Oncomouse II* it can be deduced that the *T 19/90 test* is broad and flexible enough to allow for additional considerations and not only the original ones (i.e. animal suffering, possible risks to the environment, the inventions’ usefulness to mankind) and that matters can also be considered outside the framework of the *T 19/90 test* (but whether such factors would be assessed through a similar balancing exercise or through a rebuttable presumption is not clear from the reasoning of the Board). The assessment of the remaining considerations is not, however, conducted by a balancing test, i.e. the considerations were not (as envisaged) taken into account as additional aspects under the main *T 19/90 test*. The findings that were substantiated, namely concern for the well-being of animals and the use of animals in research were not of such a nature so as to be used in a balancing test (according to the Board), where positive and negative factors are weighed against each other, i.e. where the disadvantages to society are greater than the advantages. It was rather so that there was not enough evidence to conclude that the requirement of ‘unease’ on the part of the general public was fulfilled.

The question then remains regarding what kind of considerations the Board took into account when concluding that these objections did not fulfil the requirement of moral disapproval in European culture. It was clearly not a balancing test, but rather a finding of substantiation in relation to premises based on the definition of morality as defined in the unacceptability standard. The

\(^{838}\) T 315/03, Reasons for the Decision, paras 13.2.11-13.2.12.
\(^{839}\) T 315/03, Reasons for the Decision, paras 13.2.13-13.2.21.
\(^{840}\) Id., para 13.2.17.
\(^{841}\) Id., para 13.2.18.
\(^{842}\) Id., para 13.2.21.
conclusion that the presence of the premises of care for the well-being of animals in relation to the use of animals in research did not create unease on the part of the general public, and thereby the use of animals in research was not considered as being unacceptable – but rather acceptable.

The balancing tests were not used by the Board in *Euthanasia compositions*, although the standard applied was clearly one of unacceptability. Considering that the invention in question was a chemical compound and not related to animals, it is perhaps not surprising. In the assessment of whether the publication or exploitation of the invention was contrary to *ordre public* or morality, the TBA held in relation to *ordre public* that the meaning and scope of the term ‘euthanasia’ in the field of veterinary medicine and practice is the human killing or mercy killing of animals by trained personnel, and that the aim of this practice is to alleviate the suffering of animals.\cite{844}

The unacceptability standard was used in relation to the *ordre public* assessment, which is quite interesting.\cite{845} Merely mentioned in passing, the main assessment was made in relation to whether the exploitation of the invention ‘would breach or even jeopardize public peace or social order or seriously prejudice the environment.’\cite{846}

The TBA based its reasoning on the closest prior art document in relation to the patent application, a textbook in the field of veterinary medicine, pharmacology and therapeutics.\cite{847} Continuing its reasoning, the TBA held that the appellant had not provided any evidence that euthanasia of lower animals ‘would obviate any ethically based constitutional or other rules’ including public peace, social order or seriously prejudice the environment. Had that been the case, the handling of the objections by the TBA would have been very interesting.

The reasoning of the Board in this particular decision is based on the identification of interests, i.e. the alleviating of suffering of lower animals, which could perhaps form one part of a balancing exercise, should evidence of any competing interests been found and substantiated. This lends further support to the notion that *ordre public* concerns may form the basis of the method of a balancing exercise, provided that the factors to be balanced are sufficiently substantiated. On the issue of morality, the Board concluded after investigating the evidence that ‘euthanasia is considered as a moral obligation based on gen-

\begin{footnotes}
\footnote{The assessment was made with regard to the wording of 1973 Article 53(a) EPC.}{845}
\footnote{There is clear evidence on file that the unequivocal, generally accepted and exclusive meaning and scope in the field of veterinary medicine and practice for the expression “euthanasia” is the humane killing or mercy killing of animals by trained personnel.’ (emphasis added) T 866/01, Reasons for the Decision, para 6.10.}{844}
\footnote{According to the TBA, ‘its content reflects the common general knowledge and state of the art before the priority date of the patent’. T 866/91, Reasons for the Decision, para 4.3.}{846}
\end{footnotes}
erally accepted ethics and norms which the board accepts are deeply rooted in European society and civilization." The conclusion was therefore one of acceptability on the part of the general public. Now, the actual outcome of *Euthanasia compositions* mirrors the outcome in *PGS*, namely that evidence to support the disadvantages (prejudice to the environment, obviation of ethically-based constitutional or other rules) was lacking, precluding a proper assessment and leaving us with the question of what kind of consideration, or test, would have been used if all the necessary evidence had been presented. Perhaps a balancing exercise would have been the preferred method, although it is difficult to predict, especially in view of the subject matter not being animal inventions, but rather plants (*PGS*) and chemical compounds (*Euthanasia compositions*). The question still remains whether such an assessment would consist of a balancing exercise or some other type of test.

13.6.5 Navigating the Archipelago of Tests and Standards

Despite the EPO Boards and Divisions’ diverse use of standards and tests, opinions in doctrine advocate a uniform use of a specific standard in relation to a specific kind of test. Gitter, who identified the use of different tests in EPO case law already in 2001, clearly regards the outcome of the balancing test as adhering to an unacceptability standard, although she labels it as an ‘unacceptability test’ (as opposed to an ‘abhorrence test’). The use of a balancing method (weighing the disadvantages of the patent to society against the advantages) is equated to the qualification of whether the grant of the patent ‘would be unacceptable in light of the conventionally accepted standards of conduct of European culture’ on the basis of the reasoning in the *PGS* decision. Warren-Jones, concurring with Gitter, argues that the balancing test(s) must always be judged in relation to an unacceptability standard, and that the standard of abhorrence requires a rebuttable presumption approach. The resulting methodology according to Warren-Jones therefore consists of a linking of the unacceptability standard to the balancing tests(s) and the derivation of abhorrence is only possible by the use of a rebuttable presumption test.

The main difference between the balancing test and the rebuttable presumption test is that the first test allows directly competing factors to be assessed, whilst the second test investigates objections to determine whether or not any of them reaches the level of ‘abhorrence’. The incorporation of issues is also

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850 Gitter refers exclusively to the *T 19/90 test*. Gitter, 26 ff.
851 See Gitter, 21, 26 ff. Gitter uses the notion ‘tests’ in relation to unacceptability and abhorrence, and equates the unacceptability test with a balancing exercise.
different between the tests, since under the balancing test all relevant issues contribute to reaching a decision; under the rebuttable presumption approach the decision will naturally rest upon one factor, i.e. the single factor that will have the most influence on whether or not the level of abhorrence is reached.854

The methodology proposed by Warren-Jones is undoubtedly theoretically logical; nevertheless it is not possible to read in an absolute adherence to an unacceptability standard in relation to the balancing test from the EPO decisions. The decisions of Oncomouse II, Euthanasia compositions, PGS, Relaxin and Leland Stanford do not follow such a strict categorization.855 If one takes the point of view that it is simply not possible to balance competing factors to the point of ‘abhorrence’, then the logical conclusion is that the unacceptability standard is the only one that remains, at least with regard to the methodology of the EPO where the balancing tests are advocated also outside the domain of inventions regarding genetically modified animals.856 Such a conclusion is unfortunately not in conformity with the reasoning of the Boards and Divisions in the EPO decisions. Rather, a mixing of tests and standards is demonstrated, of which the only certain conclusion is that the Boards of Appeal tend to rely on unacceptability, no matter what tests are used, whereas the Opposition and Examining Divisions have on occasion used the abhorrence standard.

The procedure in the EPO may be a reason for this distinction in standards, because it is on appeal that the argumentation may be developed and considered in its entirety.857

Other commentators do not support a methodology where the unacceptability standard is equated with the balancing test. Sterckx and Cockbain argue that the balancing approach (which they consider to be substantive, rather than procedural) concerns assessment under the morality (and not ordre public) criterion, and the outcome of such test is in their view not dependent upon an unacceptability standard, in that its conclusion is ‘not based upon the perceptions of the invention on behalf of the majority of the public’.858 Sterckx and Cockbain are critical of the procedural definition of acceptability because there is a difference between norms being socially binding (accepted by the majority) and norms being morally binding. As far as the morality clause is concerned, the issue is clearly one of moral standards, not social ones (which may be relevant within sociology or politics). According to Sterckx and Cockbain, the public perception argument (i.e. what people consider to be contrary to morality)

854 Warren-Jones 2008:1, 653.
855 In T 272/95 and T 1213/05 tests are not even mentioned.
856 See e.g. T 356/93 para 18.8 and T 315/03 para 10.8.
857 See the Guidelines for Examination in the European Patent Office (November 2014), e.g. D-V, C-VIII. Whilst the initial examination is conducted by three technical examiners, the addition of a legally qualified examiner is possible if the nature of the decision so requires. This possibility is explicitly recognised in relation to Article 53(a) EPC, see Guidelines G-II, 4.1 and C-VIII, 7. See also Holtz, 74 ff.
858 Sterckx and Cockbain, 296.
can never establish whether something is actually contrary to morality (in accordance with ethics). The unacceptability standard, as described by Warren-Jones and Gitter, clearly relates to the public perception of accepted norms (cultural morality). Sterckx and Cockbain prefer the balancing test over any test based on acceptability, because the outcome of such a test, in their opinion, measures morality in a fashion superior to the unacceptability standard, which is simply erroneous according to their perception. The balancing approach is, in their view, not entirely suitable for the assessment of morality, because it is too limited to “capture” what matters with regard to morality. Sterckx and Cockbain rather prefer a so-called principle-based, or ‘deontological approach’ to morality, ‘according to which certain things may be contrary to morality even if they would produce more benefits than disadvantages’, but they nevertheless advocate both an consequentialist and a deontological approach in the application of Article 53(a).

Sterckx’s and Cockbain’s arguments are consequently different from Gitter and Warren-Jones, who conclude that the balancing exercise requires an unacceptability standard. Sterckx and Cockbain seem to find the basis for the unacceptability and abhorrence standards in the definitions of morality provided in EPO decisions and the Guidelines. From such a perspective the basis for both standards is the perception of the majority or totality of society, and the difference between the standards is actually the level of moral concern: unacceptance or abhorrence on the part of the general public. Warren-Jones instead regards the methodologies (balancing exercise or rebuttable presumption approach) as clearly following from the moral standard adopted. Her arguments are quite convincing – it is not logically possible to weigh competing issues to the point of ‘abhorrence’ as is done under the unacceptability standard.

Consequently, the unacceptability standard permits a wider range of issues, and the standard required for findings of non-patentability on the basis of morality and ordre public concerns with regard to unacceptability is not only lower than at the level of abhorrence, it is also more difficult to predict. The methodology resting upon a rebuttable presumption approach necessitates a single immorality or breach of ordre public of a nature so repugnant that it is probable that the public in general would find the invention abhorrent. The rebuttable presumption approach is more a method of identifying the strongest factor (in the view of public perception), which could be either moral ( patentable) or immoral (unpatentable). Logically, the effect of such a narrower test and a higher standard would lead to a more foreseeable situation in comparison to

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859 Sterckx and Cockbain, 296.
860 Id.
861 Id.
862 Id., 297.
the unacceptability standard and balancing test but also the effect that fewer inventions would be considered unpatentable on the basis of Article 53(a) EPC compared to the unacceptability test, which arguably employs a lower standard and broader foundation for assessment. The question as to how the level of abhorrence would be achieved is still open, and encounters the same difficulties as to the unacceptability standard as to how the assessment should be conducted. Perhaps this is the major problem in this regard. These conclusions are furthermore based on the use of the balancing test in relation to the unacceptability standard and the rebuttable presumption test in relation to the abhorrence standard.

Against the background of the opposing views represented by commentators, what is then the prevailing view of the EPO Divisions and Boards of Appeal? It is clear that the EPO has adopted the balancing tests with regard to decisions regarding genetically modified animals, and as evidenced by Leland Stanford and Non-invasive localization also in relation animals that were not genetically modified but rather used in procedures of xenotransplantation.864 The TBA has also opened up for the use of the balancing test in relation to plants in PGS.865 Due to the issue of unsubstantiated facts to support the objections we cannot know if the test would have been used if the arguments had been substantiated. The Board clearly stated that the test was not the only means of arriving at a conclusion regarding the application of Article 53(a) EPC. Oncomouse II referred to the ‘conventionally accepted standards of conduct in European society’ merely in passing, and it is quite unclear whether this is actually the standard applied to the balancing test. Although the matter of Article 53(a) was not considered substantively in G 1/98 (Transgenic plant/NOVARTIS II), the EBA nevertheless held that no consensus could be found among the Contracting states condemning genetic engineering in the development of plants, thus indicating the basis of the application of Article 53(a) EPC being one of consensus, but not at what level (i.e. standard) such consensus must reach.866 In Relaxin and Leland Stanford the standard of abhorrence was used, thereby requiring a rebuttable presumption test in terms of the proposed methodology. Unfortunately it is not possible to read in such a test in the reasoning of the Divisions in these two decisions. Neither is a rebuttable presumption test easily identified in the other decisions. The use of this test must therefore be characterised as elusive. It is also of interest to note that the Board in Breast and ovarian cancer totally dismissed the objections as not relating to the legal requisites of

864 See generally T 19/90, V 6/92, Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), T 315/03 and T 1262/04.
865 T 356/93, Reasons for the Decision, para 10.8.
‘publication or exploitation’ of the invention being contrary to *ordre public* or morality.  

A tentative conclusion in relation to the standards set by the EPO Divisions and Boards of Appeal is rather that the interests recognised in connection with the *ordre public* test points to the use of a balancing exercise similar to the ones recognised as the *Rule 28(d)* and *T 19/90 tests*, but with other interests involved. The application of such a balancing exercise however presupposes that the actual benefits and disadvantages to be balanced are properly identified and sufficiently substantiated. On the issue of *ordre public* the Board in *PGS* concentrated the analysis on whether the exploitation of the invention in the patent in suit was likely to seriously prejudice the environment. In this respect, the Board held that the potential risks associated to the exploitation of a certain invention were difficult to anticipate merely on the basis of the disclosure of the invention in the patent specification. The issue was thus regarded as a question of substantiation of the perceived threat to the environment by the invention in the patent application. It was therefore reduced to a question of evidence. The *ordre public* assessment was therefore focused on assessing the evidence brought forward by the appellants and discussing their value as substantiating the existence of a threat to the environment caused by the invention.

But if the risks to the environments would have been substantiated, would the Board have used a balancing exercise in the assessment? And which factors would have been assessed in the balance? It is difficult to predict, but since only one interest was focused upon, it is difficult to imagine a balancing exercise taking place in relation to only one factor. Although a comparative factor against the risks in such case could be the benefits to mankind (following the logic of the animal balancing tests), this was neither recognized nor discussed by the Board. It is thus conceivable that some other method would have to be applied in such case.

For morality, the unacceptability standard is indicated already in the definitions as provided in *PGS* and *Euthanasia compositions*. For instance, the considerations with regard to morality in *PGS* were directed to the question of the dominion that was sought to be exercised by man over the natural world by the use of plant engineering techniques, and whether the invention consisted of a misuse or destructive use of the technology. The Board held that plant breeding techniques as such were simply tools, and it was the use of such a tool that should be judged in relation to Article 53(a) EPC, i.e. it would be contrary to
morality to propose a misuse or a destructive use of these techniques. After examining the claims of the patent in suit the Board came to the conclusion that none of the claims referred to subject matter which related to a misuse or a destructive use of plant biotechnological techniques because ‘they concern activities […] and products […] which cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture.’ The TBA concluded that against the unacceptability (or rather, acceptability) standard, ‘no single definition of morality based on e.g. socio-ethnic, economic or religious principles’ represents such a standard in Europe. Again, it is clear that the unacceptability standard was used, but the question remains what kind of assessment the Board used when coming to the conclusion that the invention was patentable. It is evidently not a balancing exercise.

*Oncomouse II* provides for interesting input in the discussion because the Board is very detailed in its argumentation and aims at providing guidance to the solution of the questions at hand, i.e. the patentability of the Oncomouse invention under the morality clause, including Rule 28(d) EPC. Despite this purpose, the problems encountered by the Board in defining the prevailing moral attitudes in relation to animal patenting in general and more specifically the genetic manipulation of animals are overwhelming, and not least due to difficulties to properly characterise and handle the content of the substantive objections. The objections in relation to the morality exclusion did not hold general acceptance (according to the Board) and were in some cases contradictory. For instance, the definition of morality was held by the opponents to be found in economic criteria, religious creeds, legislation (or rather the fact that legislation was a poor guide to morality), constitutions, norms deeply rooted in a particular culture, or the deeply-rooted norm that animals were not akin to inanimate objects. Disregarding opinion poll evidence, the Board settled for an assessment of the application of Article 53(a) EPC consisting of the *T 19/90 test*.

The Board advocated the use of this test as a means sufficiently flexible to allow for the current views as to ‘social order, environmental risk and accepted standards of behavior in European culture’, indicating standards related to both *ordre public* and morality.

From the reasoning in *Oncomouse II* it is apparent that the Board found a solution to the problem of defining the morality and *ordre public* concepts by aiming for a sufficiently narrow test related to the issue of animal patenting. It is also apparent that the Board had problems taking the different objections in

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872 *T 356/93, Reasons for the Decision, para 17.1.
873 *T 356/93, Reasons for the Decision, para 17.3.
874 *T 866/01, Reasons for the Decision, para 6.12.
875 *T 315/03, Reasons for the Decision, para 10.3.
876 Id., para 10.5.
877 Id.
relation to Article 53(a) EPC seriously. Basing its argumentation on the broad definitions provided by *PGS*, and adding examples of arguments that in the view of the Board could form the basis of an Article 53(a) EPC objection outside the area of animal patenting, the scope of relevant factors to be taken into account was clearly broadened but unfortunately the content of the morality and *ordre public* concepts were not particularly elucidated. The main conclusion to be drawn from *Oncomouse II* is thus that a broad range of issues can be brought up in an Article 53(a) EPC assessment, but the real problem (at least so far) is not the content of such objections but how they are substantiated. From this point of view the contentious issue is rather the evidence of the arguments raised, and it remains difficult to clearly tie a specific test to a specific standard.

13.6.6 Relating Tests to Standards

In *Oncomouse I* the Board remitted the patent application for the Oncomouse to the Examining Division, which executed the *T 19/90 test* in relation to the unacceptability standard. In *PGS*, the unacceptability standard was applied by the TBA but without the use of a balancing test. In the appealed decision the use of a balancing exercise in the assessment of patentability, as advocated by *Oncomouse I*, had been discarded, and the Opposition Division had instead opted for the abhorrence standard but without use of a specific test. Although their conclusion was followed by the TBA as far as the use of the balancing test is concerned (i.e. that the balancing test can but must not be used), the abhorrence standard was clearly not supported as an alternative to unacceptability. The TBA identified the factors of ‘serious prejudice to the environment’ or ‘contrary to the conventionally accepted standards of conduct of European culture’. The factors were however not balanced against each other.

The first factor, environment, was tested only under the *ordre public* concept. The TBA arrived at the conclusion that it was not possible to use a balancing test since no sufficient evidence of actual disadvantages was adduced and added that it was not the only way of assessing patentability with regard to Article 53(a) EPC. For this part of the assessment the acceptability of the invention was not discussed, perhaps because the objection failed in terms of evidence presented, and the test was not even put into use. Had it been, the standard of unacceptability would perhaps have been used in the balancing exercise to measure the effects of the advantages *vis-à-vis* the disadvantages. With regard to morality, the use of plant biotechnology was discussed and the claims of the patent in suit were assessed against the standard of conventionally accepted

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880 T 356/93, Reasons for the Decision, para 18.8
standards of conduct of European culture. There was no mentioning of a balancing test. Clearly this can be seen as a use of the unacceptability standard, which then rests on the assumption that the use of the balancing test necessitates an unacceptability standard, whereas on the other hand the unacceptability standard can evidently be used without recourse to a balancing test. The conclusion in relation to PGS is that the Board preferred the standard of unacceptability instead of a standard of abhorrence, but without exercise of the balancing test as advocated in Oncomouse I. The main reason for this recourse seems to be the absence of substantiated evidence so that factors could readily be identified and applied. The absence of such substantiated evidence of advantages or disadvantages resulted in the effect that no factors could be used, and hence, no balance could be exercised.

In Oncomouse II the TBA applied the balancing tests both in form of the Rule 28(d) test and the T 19/90 test.881 Despite the thorough analysis of the foundations for the decision, the meticulous handling of the operation of the relevant provisions and their elements, and the comprehensive discussion of the objections raised, very little attention was given to the standard against which the balancing tests should be measured.882 The unacceptability standard was rather used as a criterion, against which the objections which did not fit into the balancing tests were assessed.883 A tentative conclusion is therefore that the TBA views the factors of the balancing tests as pertaining to the ordre public part of the assessment.

In relation to morality in Euthanasia compositions, the TBA based its argumentation on an interpretation of the concept of ‘euthanasia’ (on the basis of the closest prior art, the textbook), finding that although ‘no veterinarian enjoys euthanasing animals […] veterinarians consider it nevertheless as their moral obligation based on generally accepted ethics and norms which the Board accepts are deeply rooted in the culture inherent in European society and civilization’.884 The TBA thus reached its conclusion on the basis of one piece of evidence, representing the total of the moral considerations (‘generally accepted’) in Europe, thereby succeeding in finding a unitary approach. It is interesting that such an approach was found to be in evidence for the morality (as opposed to immorality) of the contested invention.

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881 T 315/03, Reasons for the Decision, para 4.4 (T 19/90 test, in relation to the patentability of animals in general), 10.5 (T 19/90 test as the starting point for a ‘real’ Article 53(a) EPC assessment), and para 6.2 (the Rule 28(d) EPC test).
882 T 315/03, Reasons for the Decision, para 4.6 (with reference to the morality definition in T 356/93), 13.2.10 (labelling the remaining arguments as morality objections) and 13.2.17-13.2.18 (where animal welfare and use of animals in medical and scientific research are found to be equally established features of European culture).
883 T 315/03, Reasons for the Decision, para 13.2.10 ff.
884 T 866/01, Reasons for the Decision, para 6.13.
13.6.7 Moral Approaches Revisited

As identified in the investigation so far, the EPO uses two different tests (balancing test (T 19/90 or Rule 28(d)) or rebuttable presumption test, and two different standards (unacceptability or abhorrence) in the assessment under Article 53(a) EPC. The recourse to available tests and standards is neither cohesive, nor has an express system for choice of application been established. The choices of the Boards and Divisions seem in most decisions quite random.

An important point of divergence between commentators is the actual theoretical framework established by analysis of the EPO case law. Gitter and Warren-Jones emphasizes a structure where the tests and standards are specifically related to each other in that the balancing tests are used in relation to an unacceptability standard and the rebuttable presumption test is used against a standard of abhorrence. Sterckx and Cockbain are the foremost representatives of the opinion that the definition of morality as following from PGS and the Guidelines (both) represents a procedural definition, which is erroneous from the perspective of establishing moral judgments in ethics. What Gitter and Warren-Jones label as standards Sterckx and Cockbain label as procedural definitions. In my opinion they are both correct, since despite the type of concepts used the definitions are in fact procedural. The main difference between the perceptions is instead the construction of the use of the standards and tests.

Sterckx and Cockbain view the balancing test as a means for assessing morality which is alternative to the procedural definitions (standards). They label this test ‘substantive’, and from their point of view the balancing test is not a test to be measured against a certain standard, but an alternative means of assessment which is superior to the (erroneous) procedural definitions since the balancing test is not directed towards measuring public perception. Sterckx and Cockbain also identify a second substantive approach for assessment, namely the so-called ‘principle-based’ or ‘deontological’ approach, ‘according to which certain things may be contrary to morality even if they would produce more benefits than disadvantages’. They use the WARF decision as an example for this approach, concluding that for morality in this particular case the EBA focused on the principles of human dignity and non-commodification.

In essence, what Sterckx and Cockbain describe as substantive approaches of which the outcome is not dependent upon public perception, Gitter and Warren-Jones categorise as different tests which are used to measure public perception, where the outcome of the balancing tests necessitates assessment against the unacceptability standard and the outcome of the rebuttable presumption test is measured against the standard of abhorrence. The main divergence between the commentators is consequently the structure of the frame-

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885 Sterckx and Cockbain, 297.
work with regard to the view of the standards as equalling tests (Sterckx and Cockbain) or a structure where the outcome of the tests establishes whether a certain standard is fulfilled (Gitter and Warren-Jones).

Perhaps an additional approach could provide clarification, namely by addressing the underlying moral approaches which are expressed in the different tests. As Sterckx and Cockbain rightly point out there are in fact two moral approaches distinguishable in the decisions, namely the utilitarian approach (balancing test) and the deontological approach (rebuttable presumption test).

The utilitarian approach, consisting of a weighing of probable benefits against harms in reaching a result where one set of factors outweighs the other in relation to the total set of consequences, is represented by the balancing tests. The use of the two balancing tests, the narrower Rule 28(d) test and the broader T 19/90 test respectively, is consequently utilitarian in approach. As the Boards have pointed out, the factors related to (transgenic) animal inventions enumerated in legislation (i.e. animal suffering and substantial medical benefit to man) and in case law (i.e. animal suffering, environmental risks and usefulness to mankind), are not limited, at least not with regard to the T 19/90 test. Consequently, such a test could – theoretically – be used for other types of inventions besides transgenic animals. The reasoning in PGS and Euthanasia compositions does not provide clear answers to the question of whether the fact that the balancing test was not used in these decisions depended on a failure to substantiate the arguments (factors), or whether the test was not suitable for the inventions concerned. It seems as if the EPO is positive towards using utilitarian-based tests, most clearly with regard to animal, plants and chemical compound inventions. There is, however, no express characterisation of the balancing tests as utilitarian in nature. It is also interesting to note that the use of the balancing test is not advocated in any of the decisions concerning material of human origin.

The second moral approach, the so-called deontological approach, would from the perspective of tests, represent the rebuttable presumption approach. Where such a consideration is represented by the principle of human dignity and the principles of non-instrumentalisation or non-commodification of the human body, it is apparent that the approach taken is one of a rebuttable presumption. Any action or practice that compromises these principles is non-

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886 Rule 28(c) EPC.
887 T 19/90, Reasons for the Decision, para 5.
888 T 315/03, Reasons for the Decision, para 10.
889 See the reasoning of the TBA in T 356/93, Reasons for the Decision, para 18.8 and T 866/01, Reasons for the decision, paras 6.10-6.11.
890 See V 8/94, Reasons for the Decision, para 6.2.1 ff. In T 1213/05, none of the objections were tried in substance. See T 1213/05, Reasons for the Decision, para 46 ff., especially para 56. The hESC decisions concerned Rule 28(c) EPC and the assessment was focused on the specific criteria contained therein. See generally Opposition Division decision of 21.07.03 (Edinburgh), T 1374/04, G 2/06 and T 522/04.
rebuttably, because they cannot be outweighed by other factors. But the approach represented by Warren-Jones, that the test is tied to a standard of abhorrence, is not evident from the decisions. To compromise human dignity, e.g. by making the human embryo or body a source of financial gain, could perhaps result in an abhorrent situation. But the standard of abhorrent nevertheless has a high threshold, and the use of this standard (also in connection to human dignity) has been criticised.\textsuperscript{891} The standard of unacceptability would in most cases suffice for a finding of a violation of human dignity.\textsuperscript{892}

13.7 The Scope of Invention\textsuperscript{893}

After the conclusions reached in relation to the concepts of ordre public and morality it is crucial to treat the remaining requisites of Article 53(a) EPC, namely the concepts of invention in Section 13.7 and commercial exploitation in Section 13.8, in order to be able to weigh the different requirements in relation to each other with regard to the operation of the morality exclusion.

Before entering into the discussion of commercial exploitation, it is crucial to define the scope of the term ‘invention’ in Article 53(a) EPC, and more specifically, what exactly is considered to fall within that concept in the context of an Article 53(a) EPC assessment, i.e. exactly how is the subject matter under scrutiny defined and delimited.\textsuperscript{894} The connection between the concept of invention and its exploitation is not really elucidated in the case law, and in some decisions there is not even a difference between the technical teaching – equaling the use of the invention – and its exploitation.

From a general patent law perspective, the scope protection awarded to an invention is defined in the patent claims. The patent claims determine the extent of protection conferred by the patent, in which process the descriptions and drawings shall be used to interpret the claims.\textsuperscript{895} Neither a literal meaning of the wording used in the claims nor a use of the claims as mere guidelines is intended, when interpreting the scope of protection of an invention.\textsuperscript{896} The wording of Article 53(a) EPC explicitly refers to the invention and is thus not equated to the scope of protection conferred by the claims.\textsuperscript{897} This statement is

\textsuperscript{891} See Sterckx 2008, 478-479. Cf. V 8/94, Reasons for the Decision, para 6.2.1, where the abhorrence standard is used.

\textsuperscript{892} See e.g. Opposition Division decision of 21.07.03 (Edinburgh), Reasons for the Decision, para 2.5.3.

\textsuperscript{893} The term invention in this context denotes the scope of the subject matter under scrutiny, and not the definition of invention in Article 52 EPC.

\textsuperscript{894} A connecting issue is whether this delimitation of the subject matter is consistent with its treatment in relation to other patentability criteria. The scope of this thesis does not allow for a comparison in that sense.

\textsuperscript{895} Article 69 EPC.

\textsuperscript{896} Protocol on the Interpretation of Article 69 EPC of 5 October 1973 as revised by the Act revising the EPC of 29 November 2000.

\textsuperscript{897} T 866/01, Reasons for the Decision, paras 5.9-6.
important since the purpose of the invention as indicated in the patent in accordance with the invention is the main criterion towards which an *ordre public* or morality assessment is made, i.e. the commercial exploitation. Nevertheless, the statement is only found in one case and is made by a Board of Appeal. Naturally the purpose is subject to interpretation, but this view is connected to the principle that the exclusion is only applicable where the use of the invention is exclusively immoral. That an invention may have one, or several, immoral uses is not enough to render it excluded from patentability, if it has at least one moral purpose. Thus, it is the ‘normally intended use’ of the patented product or process and not the possibility of misuse that is the focal point of the assessment.\(^\text{898}\) Thus, the full scope of protection of an invention is not a criterion when assessing patentability with regard to Article 53(a) EPC.

In respect of Article 53(b) EPC and the exclusion from patent for plant varieties, one of the questions referred to the EBA in G 1/98 (Transgenic plant/NOVARTIS II) was whether claims comprising but not individually claiming plant varieties were excluded.\(^\text{899}\) The EBA stated that ‘it is not the wording but the substance of a claim which is decisive in assessing the subject matter to which the claim is directed.’\(^\text{900}\) A purely literal approach to claim interpretation was thus disregarded by the EBA. But the scope of the claim is not necessarily equated with the subject matter of a claim. An important task is to identify the *underlying invention*. The underlying invention needs to be deduced from the claimed invention, and in this sense, how generic or specific the claimed invention is, is relevant:

An inventor who has invented fastening means characterised in that they consist of a specific material has invented neither a nail, nor a screw, nor a bolt. Rather his invention is directed to fastening means generally. This is not a question of form but of substance: the applicant may claim his invention in the broadest possible form, ie the most general form for which all patentability requirements are fulfilled. If he has made an invention of general applicability, a generic claim is not the consequence of the verbal skill of the attorney […] but of the breadth of the application of the invention.\(^\text{901}\)

The principle as applied to Article 53(b) EPC considerations should be equally correct for an Article 53(a) EPC assessment from the aspect of the interpretation of the term ‘invention’. However, in the Article 53(a) EPC decisions a number of different terms are used. In *Relaxin*, the Opposition Division refers to the ‘patent teaching’ and the ‘subject-matter of the patent’ before drawing

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\(^{898}\) Straus 1995, 933.

\(^{899}\) G 1/98, Reasons for the Decision, para 3.1.

\(^{900}\) Id.

\(^{901}\) Id.
the conclusion that ‘the patent is not considered to offend against Article 53(a) EPC’. In the appealed decision, the Board used only the terms ‘claims’ and ‘product claims’ and assessed their patentability with regard to Article 53(a) EPC. In PGS, the Board repeatedly used the terms ‘claimed subject-matter’, ‘claimed invention’ and ‘the claims of the patent in suit’ before concluding that ‘none of the claims of the patent in suit comprises subject-matter the exploitation of which would be contrary to “ordre public” or morality’. In Oncomouse I and II the Examining and Opposition Divisions exclusively used the term ‘invention’ or ‘the subject-matter of the patent in suit’, however, the Boards of Appeal repeatedly referred to the ‘oncomouse’ or the ‘mouse’ as the object of the invention. In Breast and ovarian cancer, the Board consistently used the term ‘claimed subject-matter’.

In WARF, the term used was ‘the present invention’, which included the claims, the description as well as the rest of the application. The EBA held that ‘[w]hat needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed.’ The Board was adamant of the fact that it is not only the claims that are decisive for the application of the prohibition (in this case Rule 28(c) EPC), and stated that there is no possibility of avoiding the prohibition by clever and skilful drafting of claims. As in G 1/98 (Transgenic plant/NOV-ARTIS II) the matter was clearly not one of literal claim interpretation but a search to define the underlying invention. The question is, however, whether not the EBA goes a step further in WARF, when stating that ‘the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos[…]’. The EBA held that the use of the starting material (hESC cultures) for the invention (a cell culture comprising primate ESCs with certain characteristics) presupposed the making of said material (although not claimed). This reasoning leads to a number of interesting conclusions.

903 See T 356/93 generally paras 3-19.
904 T 19/90, para 5 and T 315/03, generally. See also the Examining Division’s decision V 6/92, where the term ‘invention’ was equally used.
905 T 1213/05, generally.
906 G 2/06, Reasons for the Decision, para 22.
907 Id. This reasoning was signalled already by the referring Board of Appeal, which investigated the drafting of Article 6(2)(c) of the Biotech Directive and concluded that ‘[…]the wording of Article 6.2.(c) appears to have been essentially determined by the politically responsible legislative bodies which cannot be presumed to be thinking in terms of patent claim categories […] but whose aim was to safeguard that technologies making use of human embryos for a purpose that was regarded as being ethically unacceptable […]should be excluded from patentability as such.’ (T 1374/04, Reasons for the Decision, para 46). Furthermore, with reference to G 1/98, the Board held that ‘it appears to be a generally accepted principle that the meaning of a legal provision is not limited to the specific cases the legislator had in mind when drafting the provision’ (T 1374/04, Reasons for the Decision, para 51).
908 G 2/06, Reasons for the Decision, para 22. The broad interpretation is especially relevant for the concept of commercial exploitation.
The substance of a claim is not the same thing as the scope of a claim. The wording of the claim (the skill of the patent attorney) should not be decisive in a literal sense, but rather the generic character of the invention should be decisive, i.e. the breadth of application of the invention. In G 1/98 (Transgenic plant/NOVARTIS II), the focus of the reasoning was directed towards the breadth of application of the invention. The excluded subject matter, plant varieties, was not found to be the object of the invention in a situation where the claim embraced a larger plant grouping, which could include plant varieties. In this case, there was already a present definition to adhere to (i.e. the definition of plant variety), as well as the analysis which showed that the invention under scrutiny was not restricted to the modification of individual varieties, nor was the resulting product restricted to individual varieties. In the WARF decision, the analysis focused on the question of whether the invention required the use of human embryos. Even though embryos were not part of the claims, or even the object of the invention, the EBA found that the invention required the use of embryos, because they provided material (stem cells) which was indispensable for the working of the invention, i.e. the technical teaching.

To this end it seems as if the vast spectrum of terms used by the Boards of Appeal in relation to the interpretation of Article 53(a) EPC was indicative of the fact that they are all part of the broader concept of underlying invention, irrespective of the fact that such a broad concept may have separate individual contents (claims, description, etc.). A further question is also whether the concept of technical teaching overlaps with the underlying invention, or if the former is narrower in scope. For this analysis it suffices to conclude that the EPO uses the terms in an interchangeable manner.

Thus, the concept of invention includes not only the claims or the claimed subject matter but also the rest of the patent application as well, subject to a non-literal interpretation by the relevant Board. There is still room for diverse interpretations on a case by case basis, but the question is whether or not the

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910 The definition of a plant variety is developed and defined within the field of plant breeder’s rights. Article 1(vi) of the International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991 (UPOV) states that “variety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder’s right are fully met, can be - defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, - distinguished from any other plant grouping by the expression of at least one of the said characteristics and - considered as a unit with regard to its suitability for being propagated unchanged. The corresponding (and identical) EU definition is found in Article 5(2) of the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.
911 By considering the invention in its entirety, including all aspects making it available to the public, the EBA took a holistic consideration in relation to the inventive process. The moral assessment is profoundly broader than previously demonstrated by the EPO, and extends to general instrumentalisation of the embryo/human body. It lacks a moral discussion and hence fails in providing proper guidelines as to standards, methodology and evidence for future decisions to come. See Harmon 2006:1, 659.
interpretation in *WARF* is a breach of established principles, considering the earlier approach to the scope of the claim as demonstrated by the EBA, for instance in relation to Article 53(b) EPC. The only conclusion of such an apparent contraposition in practice is that the EBA considers Article 53(a), including Rule 28(c) EPC, to contain both a broader scope as well as overriding function compared to Article 53(b). The appropriateness of such an interpretation is both interesting and important, but this is not the problem with the decision. Rather, the lack of clarity on behalf of the EBA when interpreting the rule is the foremost problem in this regard. It is impossible to draw any relevant conclusions from the reasoning of the EBA in relation to the effects of the broad application, which results in legal uncertainty.

In this respect, attention should be drawn to the concept of commercial exploitation, due to its possible overlap with the concept of invention in terms of how it is defined. It is essentially the commercial exploitation of the invention that should be assessed against the possible breach of the principles of *ordre public* and morality. However, how the invention is defined is important since it has a bearing on the effects of the interpretation, specifically regarding the question whether or not developmental aspects should be taken into account in the assessment of application of Article 53(a) EPC. Such developmental aspects may include the R&D leading up to the invention, or the starting material that the invention uses in order to execute its technical teaching. Depending on how the respective concepts of ‘invention’ and ‘commercial exploitation’ are framed, developmental aspects could be included in both assessments. The principle of commercial exploitation must be dissected, including identifying possible objections that can – or cannot – be raised in relation to Article 53(a) EPC.

13.8 The Scope of Commercial Exploitation

13.8.1 Categories of Moral Objections

It is advocated that the concept of ‘commercial exploitation’ is crucial for the assessment of the application of Article 53(a) EPC, because it is the ultimate decisive factor in the delimitation of the scope of application of the exclusion and consequently defines the subject matter to be assessed according to the methodology outlined by the EPO as analysed in previous Section 13.6. The importance attributed to the commercial exploitation concept is evident first and foremost from the text of the morality clause, i.e. whether the commercial

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912 Even if this interpretation is in relation to Article 53(b) EPC, the statements contained therein are nevertheless relevant for the general EPO approach to claim scope interpretation in general. G 1/98, Reasons for the Decision, paras 3.1, 3.8.
exploitation of the invention is contrary to ordre public or morality that should be assessed. From the treatment of Article 27.2 TRIPS in Section 12.6 it is concluded that the concept of commercial exploitation covers the exercise of the exclusive right in a market setting. But there is a need to consider the concept in more depth and analyse its delimitations in the European setting, against the background of the functioning of the EPC and the legal practice of the EPO. The crucial question is what types of considerations are relevant for an Article 53(a) EPC assessment, considering that the operation of the clause actually rests upon the concept of commercial exploitation.

The aim of this Section is to analyse the EPO decisions in order to determine which sub-categories of the concept of commercial exploitation the Boards of Appeal and Divisions have recognized in their assessments in the application of the morality clause. Of interest is also in which categories the objections to the issuing of a patent may fall, and how these objections have been treated by the EPO. This categorization is dependent on the types of objections recognized, or rejected by the Boards. The delimitation in the operation of the morality clause is evident from an assessment of what types of objections are recognized as relevant and which are rejected as being irrelevant to the test of the clause. It is also apparent from the decisions, in particular the early decisions, that the reasoning of the Board is to a large extent resulted not only from the objections raised by the opponents but also from several instances of clever reformulation of such objections on part of the Divisions and Boards.913

What types of relevant considerations are then to be taken into account under the heading of commercial exploitation? The life span of a (patented) invention could be held to cover a range of activities in different categories according to various points in time in the process. Such a categorisation could for instance consist of the following:

- Research,
- Preparation of patent application,
- Patent application,
- Patent grant (or denial) (putting the patentee in an exclusionary position entailing socio-economic effects),
- Testing,
- Exploitation, and
- Enforcement of the patent (using the exclusionary position in relation to a (potential) infringer).

913 See the internal principles for examination and appeal in the EPO in Section 10.3.1.
If such a categorisation is envisaged it becomes apparent that moral considerations can arise in each category, relative to a specific point in time in the development process or life span of the invention. The relevant question is then which of these categories are subsumed under the concept of ‘commercial exploitation’ in Article 53(a) EPC.

It is possible to divide the argumentation in relation to the scope of ‘commercial exploitation’ into a range of sub-categories. For the treatment of the concept in this Section the categories have been reformulated in accordance with the identification of arguments used and recognised by the Boards, as well as the current jurisprudential discourse. The categories of moral objections recognized in this analysis are: development (including technology per se), socio-economic effects (including patenting, monopoly and access) and exploitation (including use).914

The analysis of the commercial exploitation concept in the EPO case law is structured according to the following. In Section 13.8.1 the categories of moral objections are presented. Section 13.8.2 contains a presentation of three Board of Appeal decisions (Oncomouse II, Euthanasia compositions, Breast and ovarian cancer) in chronological order, representing a narrow interpretation of the concept. The following Section 13.8.3 covers arguments in cases related to a broader interpretation. This Section is structured according to category of argument (development, socio-economic effects, exploitation). These two Sections encompass almost exclusively the arguments found in the EPO decisions. The last Sections 13.8.4 and 13.8.5 gives a broader perspective by analysing the conclusions from EPO case law and the current jurisprudential discourse, and discusses the conclusions.

13.8.1.1 Developmental Aspects

Developmental aspects includes moral objections related to the research and the preparation of the patent application and possibly also (pre-patent) testing of the invention, i.e. the means of arriving at the invention. The main question is whether the different stages of the development of the invention are included, denoting a broad interpretation of ‘commercial exploitation’ (and possibly also a broad interpretation of ‘invention’). Commercial exploitation, from a literal reading, is usually directed towards the use of the invention on the market. The

914 Inspiration for this categorization is drawn from the work by Beyleveld and Brownsword (1993), but has been altered in comparison to their original categorization to conform to the current legal and scientific context. See Beyleveld and Brownsword, 34. Their original categories are: publication, development, use, access and monopolistic questions. The ‘publication’ category covers objections where the information of an invention is of such a nature that it would be immoral to put it into the public domain. The importance of this category has diminished, due to the EPC 2000 revision where the terms ‘publication or exploitation’ in Article 53(a) EPC were replaced by ‘commercial exploitation’. However, earlier case law had to address the publication issue, and moral objections can still fall under this category, although they would be unlikely to be treated seriously.
category of development covers the means of arriving at the invention, i.e. the development of and particular research leading up to the invention. Developmental aspects in the narrow sense may include the means of arriving at the invention, including its starting material, as included in the technical teaching based on how broad or narrow the concept of ‘invention’ is interpreted. The definition of invention has a bearing on the developmental aspects in this sense, and there are also overlaps with reasoning regarding the immorality of the invention per se. Developmental aspects in a broader sense include the R&D process regardless of how the concept of invention is interpreted, i.e. usually such aspects are not part of the invention concept, thereby denoting events not included in the technical teaching or not even in the concept of underlying invention. Acts performed in the development process of the invention will from the point of view of this broader sense still be included in the assessment according to Article 53(a) EPC, thereby requiring a very broad reading of the concept of commercial exploitation.

When discussing the arguments for including developmental aspects in the concept of commercial exploitation, some additional questions arise. One important question is the issue of moral complicity, where the patent applicant has not committed the morally dubious acts but instead they were conducted by someone else, possibly without any connection to the applicant. The connection in material, time and location would have to be substantiated and perhaps also the intent or knowledge of the patent applicant in encouraging the morally dubious acts.915 This is not something that has been discussed in the decisions, but the recent judicial developments in relation to hESC inventions nevertheless necessitate such a discussion.

The treatment of developmental issues in the EPO Boards of Appeal and Opposition Divisions is contradictory. In the majority of cases the Boards of Appeal have dealt with developmental objections in a material fashion. The objections have been dissected and tried with argumentation at a material level, with the aim of testing whether or not the opponents have succeeded in substantiating their arguments. Three decisions contain theoretical discussions on whether developmental aspects are outside the scope of application of the concept of commercial exploitation. But very seldom have the Boards’ objections related to the activities during the making or development of the invention on the basis that such arguments are not an issue to be raised under the exclusion of Article 53(a) EPC.916 Sometimes the Boards have stated that it is the (commercial) exploitation of the invention that is at stake, but have still tried the arguments in a substantive fashion.917 The Boards of Appeal and Divisions have

915 See Sterckx and Cockbain, 302 ff.
916 Explicitly only in T 866/01 and implicitly in T 315/03 and T 1213/05.
917 See e.g. T 356/93, Reasons for the Decision, para 11.
even independently used argumentation based on developmental aspects to corroborate their findings that the invention falls outside the scope of Article 53(a) EPC.

The category of development also includes objections related to the *technology per se*, i.e. where the assessment is directed towards the technology in general, in contrast to the specific technical teaching or function that the invention performs.

### 13.8.1.2 Socio-economic Effects

The category of *socio-economic effects* includes the sub-categories of patenting, monopoly and access. The argument in relation to *patenting* is that the act of granting a patent in terms of putting the patentee in an exclusionary position is contrary to Article 53(a) EPC. The objections relate to the actual act of providing the patent applicant exclusionary protection for his or her invention, something that in itself could be regarded as immoral according to which the act of granting a patent is in itself immoral i.e. goes against established ethical principles. The arguments relating to *monopoly* reside in the fact that the patentee is entrusted with exclusive rights by the patent authority (representing society), and thereby has the chance of making a profit out of the invention.\(^{918}\) One particular aspect of the monopoly category that must be mentioned is the fact that the right granted by a patent is actually one of exclusivity and not of monopoly.\(^{919}\) The immorality residing in the larger category of patenting is, however, different from the monopolistic. Where the immorality of the acts of patenting is perceived as resting with the patent authority, the immorality of the monopolistic category lies with the patentee. The *access* category consist of argumentation to the end that exclusion of third parties from using the invention is immoral. The potential users may be hindered from access by the patentee’s actions, e.g. due to the fact that the patent is suppressed, or that the invention is marketed but the price is too high.

### 13.8.1.3 Exploitation

The *exploitation* category is the narrowest one and denotes the actual literal meaning of Article 53(a) EPC. The concept of *use* of the invention is very close to the concept of exploitation of the invention, illustrated by the fact that the reasoning on exploitation often includes arguments related to the invention per se. Although these may sometimes overlap, exploitation is by definition nar-
rower. Arguments related to exploitation often spill over into a reasoning regarding the invention \textit{per se}, which is hence placed within this category. This includes a discussion on the claimed products (compositions), methods, processes and the uses to which the invention will be put, subsequent to the grant of a patent.

13.8.2 A Narrow Interpretation

Of the total amount of decisions, three Board of Appeal decisions stand out as being very detailed as well as clear on the issue of delimitation of the concept of commercial exploitation. The decisions in \textit{Oncomouse II}, \textit{Euthanasia compositions} and \textit{Breast and ovarian cancer} represent a narrow view of the concept of commercial exploitation.

13.8.2.1 Oncomouse II

The analysis by the TBA in \textit{Oncomouse II} with regard to the application of Article 53(a) EPC to the invention under scrutiny is very detailed and thorough. First of all, the Board held that:

It is, in the Board’s opinion, only possible to read the words “contrary to “ordre public” or morality” as qualifying “publication or exploitation”. [...] Accordingly, the Article [53(a) EPC] raises no question of the morality of that invention \textit{per se}. [T]his case is concerned neither with the morality of genetically manipulating a mouse nor with the morality of the oncomouse thereby produced nor with the morality of patenting either the oncomouse or the genetic manipulation method but only with the morality of publication or exploitation of the oncomouse or that method.\footnote{T 315/03, Reasons for the Decision, para 4.2.}

By means of such a statement the Board delimits the application of the morality clause to the use, equalling exploitation of the invention under scrutiny. The morality of the invention \textit{per se} (the oncomouse), whether it is the product or process, including the technology in general (genetically manipulating a mouse), is not at issue. Neither is the morality of the act of patenting included in the Article 53(a) EPC assessment.

The Board continued by referring specifically to the \textit{ordre public} concept, and held that:

Indeed, that Article 53(a) EPC is only concerned with the morality of publication or exploitation is confirmed by considering “ordre public”. Neither the making of an invention (which by definition must occur in private if there is to be any
chance of a patent) nor the process of patenting an invention (conducted within a patent office) can be seen as contrary to “ordre public”.921

The reference to confirmation of the proviso of ‘exploitation’ by referring to ordre public is interesting. The Board seems to imply that the making of an invention and the patenting of an invention as such cannot amount to a breach of ordre public. For the concept of ordre public the Board relied (later in the decision) on the definition from PGS.922 The conclusion is further strengthened by that the act of patenting (as opposed to the invention) can never be a breach of ordre public, and thereby can never be a part of the concept of commercial exploitation. This latter statement is clearly directed to the inclusion of developmental aspects in the Article 53(a) EPC assessment, and the Board is very determined regarding the fact that the making of an invention in private is not part of the concept of exploitation, which is quite natural.

The actual assessment of whether the exploitation of the invention in question would be contrary to ordre public or morality is done by the use of the balancing tests envisaged in Oncomouse I and Rule 28(d) EPC (then Rule 23d(d) EPC). The Board stated that in addition to the tests, other considerations may be taken into account either under the tests or by way of considering other matters outside the framework of the test.923 Such arguments included (in the present case) an alleged threat to evolution, alleged increased trade in genetically manipulated animals and alleged moral unacceptability of such manipulation.924 According to the Board, such arguments could well be deployed under the T 19/90 test, and in cases concerning subject matter other than the genetic manipulation of animals, ‘such arguments would form the core of any Article 53(a) EPC objection’.925

When the Board applied the test in Oncomouse II to the invention in question, they did so by investigating the patent in suit, i.e. first, the invention, and second, its commercial exploitation with respect to the factors envisaged by both tests – the Rule 28(d) and T 19/90 test. Such factors include suffering of the animals, likelihood of substantial medical benefit to man or animal (28(d) EPC), and usefulness to mankind (T 19/90).926 The main request, concerning rodents, failed due to presence of animal suffering and no substantiation of either substantial medical benefit to man or animal or usefulness to mankind. The evidence consisted of the patent itself for substantiating the likelihood of suffering (established as an inevitable consequence of the purpose of the patent), but the likelihood of substantial medical benefit to man or animal/usefulness to man-

921 T 315/03, Reasons for the Decision, para 4.2.
922 Id., para 10.2.
923 Id., para 10.7.
924 Id.
925 Id., para 10.8.
926 Id., paras 12.2.1-13.2.9.
kind could not be inferred from the patent and there was no other evidence presented.\textsuperscript{927} The established suffering did not correspond to any prospect of benefit, and therefore the patent could not be granted on the terms of the main request.

In relation to the first auxiliary request, concerning mice (instead of rodents), the outcome was more successful for the patentee. The Board found, in contrast to the main request, that the likelihood of substantial medical benefit could be inferred from the patent itself, consisting in the purpose of the method and the resulting oncomice of further cancer research.\textsuperscript{928} In addition there was also evidence on file, consisting of declarations and post-published documents, demonstrating actual medical benefits achieved using exactly oncomice obtained by the claimed process.\textsuperscript{929} The medical benefits consisted of the usefulness of using particularly oncomice models in research. The medical benefit demonstrated was also found to substantiate the finding of usefulness to mankind, under the broader \textit{T 19/90 test}.

In addition, the Board had to assess two further arguments raised in relation to the second test, namely the ‘degree’ of animal suffering (as opposed to ‘existence’ in the \textit{Rule 28(d) test}) as well as the possibility of using non-animal alternatives to achieve the same aims as the patent in suit. The Board held that there cannot be a distinction between ‘acceptable suffering’ and ‘unacceptable suffering’ and that such distinction would not assist in deciding cases of this kind.\textsuperscript{930} The argument for non-animal alternatives was rebutted by the respondent (the patentee) by providing evidence of the advantages the use of oncomice had over other non-animal alternatives. The Board added this matter to the balancing test and concluded that it tilted the balance in favour of the respondent.\textsuperscript{931} Lastly the Board considered the environmental risks as balanced against usefulness to mankind and the risks consisting of the escape or deliberate release of oncomice into the wild. The threats to environment were hypothetical and not established by evidence, and although the Board reasoned around possible effects to the environment they nevertheless concluded that the environmental risks were at the most of neutral effect to the case.\textsuperscript{932}

Despite the lack of evidence present, the Board nevertheless considered the issues as questions of argument.\textsuperscript{933} An alternative method could have been to simply reject them on the basis that they were not substantiated, or that they fell outside an Article 53(a) EPC-assessment. The prevailing attitude of the Board in this particular case is very accommodating and thorough in its analysis.

\textsuperscript{927} T 315/03, Reasons for the Decision, paras 12.2.1-12.2.4.
\textsuperscript{928} T 315/03, Reasons for the Decision, para 13.2.2.
\textsuperscript{929} Id.
\textsuperscript{930} Id., para 13.2.6.
\textsuperscript{931} Id., para 13.2.8.
\textsuperscript{932} Id., paras 13.2.8-13.2.9.
\textsuperscript{933} Id., para 13.2.11.
of every possible argument in relation to the invention at issue. There are no stones left unturned in the reasoning of the Board. During the exercise of the balancing test for the main and auxiliary requests the Board did not discuss the concept of exploitation or the difference between the patent in suit or the technology as such. The reasoning focused on the invention, both in terms of evidence but also in terms of the envisaged use. Even when discussing the environmental risks there was nothing in the decision to indicate that the Board took issues into account that were confined to factors external to the invention as defined in the patent. On the other hand, the Board did not mention the exploitation of the invention in this particular line of argumentation. Rather, they discussed ‘the use of the patent’, and in relation to environmental risks, ‘the release’ of oncomice as such into the wild. Thus, although the concept of exploitation was not explicitly discussed it is clear that the issue dealt with by the Board in conducting the balancing exercise were strictly limited to the envisaged use, thereby equalling exploitation, of the invention in the patent in suit.

When the Board discussed the last arguments raised by the appellants (objections to the patent), which concerned the fears of increased use of transgenic mice in cancer research and the increased trade in animals generally, they pointed out that it was the morality of the exploitation of the oncomouse invention, and not the morality of animal patents, which was at issue. The Board interpreted the appellants’ arguments as amounting to the suggestion that allowing a patent will increase the use of modified mice. This reformulation of the objection on behalf of the Board resulted in the conclusion that, against the background of the nature of a patent, there was no evidence to suggest that a patent would increase the use of modified mice. In addition, the Board relied on evidence from the respondent (patentee) on the ‘remarkably unprofitable’ nature of the invention, which in the Board’s view negated the unsupported allegations of the appellants.

In conclusion, this decision is very thorough and provides detailed guidance on every aspect of the questions under scrutiny. The decision is regarded as authoritative not least with regard to the relation between Rule 28 and Article 53(a) EPC. The objections handled by the Board covered aspects of every sub-categorisation of commercial exploitation, and it is clear that they focus on exploitation/use of the invention. Developmental aspects are not included in the Board’s view of commercial exploitation and neither are socio-economic effects or aspects related exclusively to the invention as such.

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934 T 315/03, Reasons for the Decision, para 13.12.2.
935 Id., para 13.2.12.
13.8.2.2 Euthanasia Compositions

In *Euthanasia compositions* the Board was eloquent in delimiting the application of Article 53(a) EPC to the publication or exploitation\(^{936}\) of the invention, and to the question of whether these objective facts would ‘contribute causally to the infringement of the fundamental principles of “ordre public” and morality.’\(^{937}\) In accordance with this statement, the Board held that the application of Article 53(a) EPC raised no questions of the breach of the principles of *ordre public* or morality by the following:

- the invention *per se* (i.e. the claimed composition *per se* or their preparation),
- the act of granting the patent,
- the making of the present invention as such or the inventor’s activities during making or development of his invention or the development of the present invention as such.\(^{938}\)

Thus, it is clear from this listing that this TBA considered no developmental aspects (making etc.), neither the granting of a patent to be included in the concept of commercial exploitation. As to the concept of invention, the Board held that exploitation equals the ‘normal avowed use indicated in the patent (’bestimmungsgemäßer Gebrauch’) of the invention’s teaching’.\(^{939}\) The designated interpretation of the concepts of commercial exploitation and invention is thus quite restricted and does not include developmental aspects or the making of the invention. It is the use of the invention as indicated in the patent that should be assessed in relation to infringement of *ordre public* or morality. Such immoral use must constitute the only way to exploit the invention, since the mere possibility of abuse, for instance if alternative uses are possible, is not sufficient to deny patent protection under Article 53(a) EPC.\(^{940}\)

On the basis of the Board’s interpretation of exploitation in Article 53(a) EPC, the following arguments were rejected without being considered as to their material aspects:

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\(^{936}\) The decision was made before the EPC 2000 revision.

\(^{937}\) T 866/01, Reasons for the Decision, para 5.6.

\(^{938}\) Id., para 5.6 a)-c).

\(^{939}\) Id., para 5.7.

\(^{940}\) Id., para 5.8. One objection posed by the opponents to the patent was that the exploitation or avowed use indicated in the patent included the arbitrary or intended termination of life (killing) or termination of life on demand (euthanasia) of all kinds of animals, including human beings. Citing the text of patent, the Board refuted the arguments by stating that the sole purpose of the patent was to produce humane death in lower animals and that a different interpretation ‘is entirely excluded and in no way derivable from the patent description.’ T 866/01, Reasons for the Decision, para 6.7.
that the intended exploitation or publication of the present invention includes the arbitrary or intended killing or euthanasia of all kinds of living beings other than lower animals (e.g. human beings),
- that the animal experiments (carried out during the making or development of the invention) reported in the patent were contrary to morality or *ordre public*,
- that the claimed compositions per se and the grant of a patent for such compositions represented an infringement, or risk thereof, of certain basic principles of *ordre public*, in particular the protection of right to life enshrined in Article 2 of the ECHR.  

The Boards’ rejection of the arguments without substantive consideration signals a clear demarcation of the concept of exploitation compared to other decisions. The rejection confirmed that the definition of the term invention is focused on the technical teaching, and the assessment under the morality clause is directed upon the exploitation of the invention. The development and making of the invention does not form part of the assessment, and neither does the invention *per se* or the socio-economic effects of the patent.

The substantive assessment by the Board with regard to the possibility of a breach of the *ordre public* concept of Article 53(a) EPC focused on the question of whether use of the euthanasia compositions in general, evidenced by information in a veterinary handbook, would obviate any ‘ethically based constitutional or other rules’. With regard to the term morality, the Board held that euthanasia is considered by veterinarians as their moral obligation based on ‘generally accepted ethics and norms which the board accepts are deeply rooted in the culture inherent in European society and civilisation’. Thus the TBA found no established unitary immorality in Europe towards euthanasia in lower animals. On the contrary, such unity was instead established by the Board in the support of the use of euthanasia compositions and methods. This was done on the basis of evidence consisting of a textbook on veterinary practice and medicine. The Board also concluded that no convincing argument or evidence to the contrary had been presented, thereby indicating that a different outcome would have been at least hypothetically possible but in the absence of evidence to the contrary, there was not even an assessment on argument.

*Euthanasia compositions* is perhaps the TBA decision which express the delimitation of the operation of the morality clause most clearly in relation to the significance to the concept of the commercial exploitation as such, and accord-

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941 T 866/01, Reasons for the Decision, para 6.8 a)–c).
942 Id., para 6.11.
943 Id., para 6.13.
ing to this, TBA categories other than commercial exploitation are definitely excluded from its scope.

13.8.2.3 Breast and Ovarian Cancer

The invention in Breast and ovarian cancer related to the so-called BRCA1 gene, which predisposes for breast cancer. A large portion of the objections to the patent application centred on the issue of (lack of) prior informed consent to the use of the cells that formed part of the process of development and research resulting in the present invention. The Board refuted this argumentation on procedural grounds, stating that the absence of a formalised procedure for the verification of such consent made such monitoring a matter for national states and not the EPO.945

Socio-economic consequences of the patenting of the claimed subject matter were also raised by the opponents, which argued that ethical issues were associated with the effects of the patent. The patenting as such, of this particular invention, would result in increased costs for patients as well as being detrimental to the organization of diagnosis and research in Europe. The opponents argued that the dependence of breast cancer patients, or those suspected of carrying a predisposition to breast cancer, on the patent proprietor for diagnosis and research was contrary to human dignity.946 The Board refuted these arguments by stating that Article 53(a) EPC refers not to the ‘exploitation of the patent’ but to the ‘exploitation of the invention’.

The opponents’ arguments were simply rejected on the basis that they fell outside the scope of application of Article 53(a) EPC, as demarcated by this particular Board, which stated in this respect that ‘the EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas and restricting the field of patentable subject-matter accordingly’.947 The fears raised by the opponents with regard to the effects of the patent were rather conferred to the exploitation of any patent, and the Board saw no ground for differing between technical fields in this respect.948

Despite the formal rejection of many arguments, the Board nevertheless analysed the content of the objections relating to first, national legislation in France and Germany949 and second, the European Parliament resolution of 26 October 2005 on ‘Patents on biotechnological inventions’. The first objection was rejected on the basis that national legislation does not form part of the

945 T 1213/05, Reasons for the Decision, paras 46-51.
946 Id., para 52.
947 Id., para 53.
948 Id.
949 Legislation related to the implementation of Article 5 of the Biotech Directive with regard to the patentability of and scope of protection for inventions concerning human gene sequences.
EPC legal order and is irrelevant for the interpretation of the EPC. The second objection reflected the opponent’s purpose of referring to the Resolution, which was the inclusion of socio-economic effects in the patent granting procedure. The EPO refuted this argument as well, on the basis of the reasoning that, as already stated, such factors fell outside the scope of Article 53(a) EPC but in addition the Board further underlined the fact that it is the publication or exploitation of the claimed products that should be contrary to ordre public or morality.

13.8.3 A Broader View

13.8.3.1 Developmental Aspects

As demonstrated in the previous Section, the decisions *Oncomouse II*, *Euthanasia compositions* and *Breast and ovarian cancer* contain theoretical discussions concerning the concept of commercial exploitation which becomes decisive for the decision-making process of the Boards. In contrast, the rest of the EPO decisions are not entirely clear on the delimitation of the concept of commercial exploitation with regard to different types of objections related to developmental aspects on the invention. The majority of the developmental aspects can be sorted under two categories of objections related to: (1) human dignity and human rights, especially the right to autonomy expressed by the principle of prior informed consent, and (2) technology *per se*. Even though the category of technology *per se* is broader and could be held to also include objections related to human dignity and human rights, in the sense that such objections could be framed as directed towards the technology *per se*, the analysis will nevertheless start with the first category.

13.8.3.1.1 Human Dignity and Prior Informed Consent

An often raised objection regards the (presence or absence of) prior informed consent to the use of donated human biological material, when such material form the basis for the research leading up to a patent application, or the basis for the invention as such. The principle of informed consent is often tied to the principles of human dignity and the right to autonomy/self-determination, but has also been conveyed by the EPO to lend support for the argument that an invention is patentable and falls outside the scope of the morality clause.

The first case to address such objections, and in some ways also referring to them, is the Opposition Division decision of *Relaxin*. The patent in dispute in

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950 T 1213/05, Reasons for the Decision, para 55.
951 T 1213/05, Reasons for the Decision, para 56.
the Relaxin case covered *inter alia* a DNA fragment encoding for the human protein H2-relaxin.953 Human H2-relaxin is a hormone produced during pregnancy which facilitates the birth process. Typical claims of the granted patent were directed to the DNA fragment as such but also directed towards variants of the synthetic human H2-relaxin as well as the polypeptide chain of the protein. The main point of argumentation of the opponents was that the taking of tissue from pregnant women, in accordance with the teaching of the patent, was immoral.954 The basis for the first argument was the breach of the principle of human dignity, since they claimed that it constituted an offence against human dignity to make use of a particular female condition (pregnancy) for a technical process oriented towards profit.955 The second line of argumentation referred to the principle of the human right to self-determination.956 The opponents held that the patenting of human genes, such as the DNA fragment coding for human H2-relaxin, amounted to a form of human slavery since it involved the dismemberment of women and their piecemeal sale to enterprises.

The moral objections are clearly developmental in character, in that they relate to the processes leading up to the invention, the first by referring to the act of isolation; the second by referring to the dismemberment of women. The objections focused on the starting materials and the effects of ownership or exclusive rights over material derived there from.

In relation to the first objection, the Opposition Division likewise referred to developmental aspects in their own argumentation, by using the findings that the (lawful and informed) consent given by the women to the act of isolation of the tissue actually countered the objections raised in this regard.957 The Opposition Division also held that human tissue or other material has been widely used for many years as a source of useful products, and that many life-saving substances are isolated in this way of which many have been patented. To counter the opponent’s arguments, the Opposition Division stated that ‘every evidence indicates that this practice is perfectly acceptable and even welcomed by the vast majority of the public.’958 The existence of prior informed consent actually served the purpose of morally justifying the objected procedures.959

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953 EP1121491.
954 The starting material of the invention comprised cell cultured ovarian tissue from a woman with an ectopic pregnancy.
956 Id.
957 The arguments by the Opposition Division relating to the second objection of slavery and dismemberment were instead concentrated on the effects that a patent entails. The Opposition Division drew attention to the fact that a patent such as the one in suit does not confer upon its proprietor any rights to individual human beings. In this context it was also stated that the exploitation of the invention does not involve dismemberment and piecemeal sale of women, and that there is no need to use human beings as the source for the protein. These counter-arguments were therefore related to the effects of a patent, and belong to the category of exploitation. V 8/94, Reasons for the Decision, para 6.3.3.
958 V 8/94, Reasons for the Decision, para 6.3.1.
959 Id., para 6.3.
Opposition Division finally added that the use for other purposes of parts of the human body removed during the course of an intervention is explicitly approved in Article 13 of the Draft Bioethics Convention of the Council of Europe, provided that there are appropriate information and consent procedures. It was also important, according to the Opposition Division, that the isolation procedure need not be repeated in order to carry out the invention.

It is important to realize that the counter-arguments by the Opposition Division were equally centred around the developmental aspects of the invention – the isolation and donation of tissue from pregnant women. The Opposition Division even made an attempt to morally justify the developmental aspects of the invention by referring to the concept of the vast majority of the public, as well as referring to the principles codified by the (then) draft Biomedicine convention.

The matter of prior informed consent was further treated in Breast and ovarian cancer. The opponents argued that no proof existed that the donors of cells which had been critical to identify the invention in suit, the BRCA1 gene, had given a previous informed consent to the use of said cells. The absence of such consent implied that the initial obtaining of these research results involved severe ethical violations, and a violation of ordre public and morality as referred to in Article 53(a) EPC.

The Board stated that since the legislator has not provided for a procedure of verifying the informed consent in the framework of the grant of biotechnological patents under the EPC, patent law is not the appropriate framework for the imposition and monitoring of such a requirement. The statement by the Board implies a more restrictive and literal interpretation of the handling of prior informed consent than previous decisions. Instead of referring to the absence of a procedure for verification the Board could have instead referred to

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961 The question of prior informed consent and its effects on the assessment of patentability was not discussed by the TBA in the appealed decision. The TBA treated the question as a technical issue of the delimitation between invention versus discovery in the field of human biological material, referring to the patentability of isolated material as being explicitly envisaged by the (then) Rule 23(e) EPC. The objection regarding prior informed consent was thus reformulated to a question of patentability on technical grounds and redirected from Article 53(a) to Article 52(2) and Rule 23(e) EPC.

962 V 8/94, Reasons for the Decision, para 6.3.2.

963 T 1213/05 (Breast and ovarian cancer/UNIVERSITY OF UTAH).

964 The opponent even stated that the prior informed consent would have to include an explicit consent to the commercial exploitation of the research results by patents as well as a benefit sharing agreement. T 1213/05, Reasons for the Decision, para 47.

965 T 1213/05, Reasons for the Decision, para 46.

966 Id., para 49. The Board supported its reasoning by referring to passages in the judgment from the CJEU (Case C-377/98 Netherlands v Parliament and Council [2001] ECR I-7079), and the Opinion from the Advocate General Jacobs (Opinion of Advocate General Jacobs, delivered on 14 June 2001, Case C-377/98, Netherlands v Parliament and Council), see paras 50-51.
the non-applicability of developmental aspects under Article 53(a) EPC, in the
vein of Oncomouse II and Euthanasia compositions. The reasoning of the Board
clearly exempts argumentation concerning prior informed consent from the
scope of application of Article 53(a) EPC. The existence and substantiation of
proof of prior informed consent was thus not considered since the objection
was rejected on formal grounds.

Should developmental aspects be included under Article 53(a) EPC, there is
no need for procedural verification, but the issue of prior informed consent
would in such a situation be important as a matter of evidence. Since every case
is judged on its own merits, the principle of prior informed consent need not
be formalised, since it does not have to be included in every patent application.
Still, should the EPO choose to interpret Article 53(a) EPC in a broad fashion,
this principle may become very important, not least since the lack of such con-
sent would probably amount to a breach of at least (national) regulation or
principles of autonomy recognized in European law and international conven-
tions.967

It is interesting to note that the appellant had argued not against the absence
of a procedure, but rather that evidence of prior informed consent to the
commercial exploitation of the research results was lacking in the patent appli-
cation. In the spirit of Recital 26 of the Biotech Directive968 (that the EPO
would have to follow in the terms of Rule 26(1) EPC), this is rather a question
of evidence with regard to findings of subject matter contrary to morality or
ordre public, and the reasoning of the Board would then have had to concentrate
on discussing the required evidence and its status.969

Instead, the Board of Appeal chose to handle the appellant’s line of argu-
mentation by referring to the decision from the CJEU in the Netherlands case,
making it a question of procedure rather than content.970 If Recital 26 would be
interpreted so as to require a verification of informed consent prior to patent-
ing, the task must befall the patent authorities, as they are the only competent
receivers of patent applications. Given the nature and legal status of recitals this
interpretation may attach too much importance to the literal wording of the
statement contained in Recital 26.971 However, if the concept of commercial
exploitation should include also developmental aspects of the invention, the
importance of the principle of free and informed consent can certainly not be

967 See e.g. Chapter II of the Convention for the Protection of Human Rights and Dignity of the Human
Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomed-
968 ‘Whereas if an invention is based on biological material of human origin or if it uses such material, where a
patent application is filed, the person from whose body the material is taken must have had an opportunity of
expressing free and informed consent thereto, in accordance with national law’.
969 See Holtz, 519, distinguishing between the physical use (the taking of the material) and the legal use (the
application for a patent).
970 See T 1213/05, Reasons for the Decision, para 50.
971 See Van Overwalle 2007, 248 f., with further references to Van Overwalle.
overlooked. From such a point of view, the patent authorities are required to accept objections and evaluate evidence relating to this principle in an assessment of patentability of an invention based on material of human origin under the morality clause, regardless of whether an established procedure for verification of informed consent exists.972

Furthermore, the Board’s reliance on the reasoning of the CJEU in the Netherlands case is liable to criticism on the basis that the statements by the Court were made in relation to the violation of the principle of self-determination, and not to a possible objection under Article 6(1) of the Biotech Directive (corresponding to Article 53(a) EPC). Objections regarding the principle of informed consent raised under Article 6(1) could perhaps have given a different outcome, as the line of argumentation before the CJEU was not the same as before the Board of Appeal.

The issue of prior informed consent to the donation of human material for research was brought up by the opponents in Leland Stanford. The Opposition Division, contrary to Breast and ovarian cancer but reflecting the view in Relaxin, held that the use of such material for research ‘is widely accepted provided that consent was given, which there is no reason to doubt in the present case.’973 The Division thus handled the objection by recourse to substantive arguments relating to the presence of consent, but without entering into a reasoning regarding the verification of the said consent or what exactly the given consent had related to (research, commercialization, patenting). The principle of prior informed consent had a bearing on the assessment of patentability in the sense that the existence of such consent was a reason for the acceptability of the development of the invention and hence the practice of the invention. Developmental aspects were thus both present and had an effect on the decision to grant the patent. The legality of the conducted research (under the principle of prior informed consent), in connection with the medical benefits associated with the invention, served the purpose of not denying a patent on ethical grounds.

13.8.3.1.2 Technology per se

Although objections relating to the immorality of the technology per se are more the rule than the exception in cases regarding biotechnological inventions, the Boards and Divisions have chosen to treat them differently. From Section 13.8.2 it is concluded that in at least three of the decisions, the Boards of Appeal have simply rejected the inclusion of such arguments under the concept of commercial exploitation in Article 53(a) EPC, or reformulated the objections to make them applicable and possible to examine substantively. Still, the PGS

972 See Odell-West, 380-382.
973 Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, para 8(50).
decision stands out as a decision where the objections relating to the technology per se were either treated substantively or reformulated. The discussions in PGS, compared with the reasoning of the Board in Euthanasia compositions, also expose an interesting delimitation between the concept of underlying invention and the concept of commercial exploitation.

As mentioned, the moral objections in PGS related to the development of the invention focused primarily on the technology per se. The invention consisted of processes for controlling the action in plant cells and the production of herbicide-resistant plants as well as the resulting herbicide-resistant plant cells and plants as such. The moral objections raised by the opponents concerned inter alia the dominion that was sought to be exercised by man over the natural world by the use of plant genetic engineering techniques. It was claimed that plant genetic resources were the heritage of mankind, and they had to remain available to all without further restriction and to be preserved intact for future generations. Permitting patent protection for the products of such technology, i.e. genetically engineered plants, was against these principles. Although the objections seem to provide the patentee with greater expectations of the effects of the patent (i.e. dominion over the natural world) than what ever could be provided by the exclusive right, the objections relate to the technology as such, and whether the use of such technology should be pursued or not. This point of view is confirmed from the way the Board handled the issue.

The Board compared plant biotechnology with traditional selective breeding, and concluded that since they both share the same motivation (changing the property of a plant in order to obtain a new and possibly improved plant) the former cannot be regarded as being more contrary to morality than the latter. In this respect the Board assessed the morality of the technology per se. The Board further held that, ‘like any other tool, plant genetic engineering techniques can be used for constructive or destructive purposes.’ When considering the purpose of the present invention, focus was placed on the aim of the invention, as disclosed in the patent claims. The assessment by the Board must therefore be regarded as being an assessment of the nature of the technology as such, with the specific aspects as present in the invention in question. It is the

974 Cf. T 19/90, Reasons for the Decision, para 5.
975 T 356/93, Summary of Facts and Submissions, para IX and Reasons for the Decision, para 17.1.
976 Similar reasoning is found in Leland Stanford. The Opposition Division referred to the technology underlying the present invention, and concluded that at present there was no consensus in European society about the desirability of the technology as such. Considerations of the making of the invention and the morality/desirability of the technology per se were made, and contributed to the decision of not applying Article 53(a) EPC to the present invention. Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, para 8(44) ff.
977 T 356/93, Reasons for the Decision, para 17.1.
978 See also the reasoning by the Opposition Division in the Lubrizol Genetics Inc. decision, where the objection of 'common heritage' was raised and handled in a similar fashion as in PGS. Opposition Division Decision of 5.6.1992 (Lubrizol Genetics Inc.)(unreported). Cf. Warren-Jones, 2008:2, 200-201.
use of the technology in general terms that poses the alleged threat to the heritage of mankind, according to the opponents, but following a reformulation of the issue at hand, it is the use of the invention that was assessed by the Board. The focus on the aim or use of the invention lends support to the conclusion that, in fact, the result of the argumentation used by the TBA focused on the exploitation of the invention. The inclusion of the use of the technology in a case regarding transgenic inventions is not uncommon, depending on type of invention as well as the claims. For transgenic plant and animal inventions, the method of production of such plants and animals are usually included in the claims. It is thus correct to assume that the technology, to the extent that the production method of the transgenic subject matter equals use of a general technology, is included in the use of the invention. Consequently it is also included the concept of commercial exploitation, provided that the assessment with regard to morality and ordre public is conducted in relation to the purpose indicated in the patent. It is a natural effect of the character of the subject matter of the invention.

For other types of inventions, the connection between production method and technology as such is not as relevant or automatic. This is demonstrated for instance in Euthanasia compositions, where the disclosure of the invention was limited to the use of the claimed compositions for providing humane death in lower mammals, and not to the use of such compositions for the intended or arbitrary termination of life in all kinds of living beings, including humans.979 The claims were predominantly product and use claims980, thus excluding an intended exploitation where production and technology interacted, i.e. excluding any reference to technology in general.

Furthermore, the invention under scrutiny in Euthanasia compositions was a traditional compound invention, which is different from the transgenic modification inventions in that the former consist of a chemical mixture of salts and/or other entities and the claims were predominantly product and use claims. The process claims in PGS are comparatively closer to claiming the actual use of a technology (albeit with a specific purpose). Despite this fact, the conclusion of the Board in PGS that it is the use (equalling exploitation) of the invention that is assessed is correct. The invention in PGS evidently contains aspects of technology use that could be regarded as belonging to the category of technology per se. But due to a broad understanding on behalf of the Board of the concept of underlying invention in this particular situation, coupled with a

979 T 866/01, Reasons for the Decision, para 6.8.
980 In two states (Spain and Greece) the claims were instead directed to the method: ‘1. A method for preparing a composition which comprises an aqueous solution comprising formulating (a) a cardiototoxic compound selected from the group consisting of a quinacrine salt and a chloroquine salt in a cardiotoxic amount; and (b) embutramide in a lethally anesthetic amount. 14. The method according to any of claims 1 to 13 wherein the composition is prepared for providing euthanasia in a lower mammal’. (Also dependent method claims.)
clever reformulation of the objection on the part of the Board, the resulting discussion focused on the use, equalling exploitation in a narrow sense. The opponents’ argument (the alleged threat to the heritage of mankind) was clearly focused on the technology per se, but the handling by the Board of the objection as well as the focus on the concept of underlying invention changed the focus to the use of the invention instead of technology per se (with regard to this particular objection, that is).

The handling of this particular developmental objection in PGS can be contrasted to a situation where the assessment of developmental aspects is clearly outside the scope of the concept of underlying invention, thereby denoting developmental aspects in a broader sense. This was specifically the situation in Euthanasia compositions where it was argued by the opponents that the animal experiments reported in the patent contravened morality and ordre public, and the framing of the objection invited an assessment of technology per se. The arguments were however not tried in substance but rejected on the ground that they fell outside the scope of application for Article 53(a) EPC. In other words, the Board clearly demarcated the scope of application as excluding developmental aspects and applied a narrow interpretation of the concept of commercial exploitation.

Another discussion in PGS related to the use of genetic engineering techniques on plants and whether the potential of such techniques would lead to a dominion gained by man over the natural world. This argument is also related more to the question of the underlying technology than the actual invention, and must therefore belong to the category of developmental issues rather than commercial exploitation in a narrower sense. The argumentation of the Board follows the developmental line, in that the Board stated that a misuse or destructive use of the technology would undoubtedly be against ordre public or morality, but that it has to be established whether the invention in the present case related to such uses. In relation to morality, the Board held that:

In the Board’s judgement, none of the claims of the patent in suit refer to subject-matter which relates to a misuse or destructive use of plant biotechnological techniques because they concern activities (production of plants and seeds, protection of plants from weeds or fungal diseases) and products (plant cells, plants, seeds) which cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture.

981 T 866/01, Summary of Facts and Submissions, para XIII [14].
982 T 356/93, Reasons for the Decision, paras 17.1-17.2.
983 Id., para 17.3.
By reference to the claims of the patent in suit the Board indicated that the question at issue was not the technology as such, but rather the use of the technology envisaged by the invention’s technical teaching.

13.8.3.1.3 Excluding Developmental Aspects?

From the investigation in previous Sections it is evident that developmental arguments are common objections in cases involving Article 53(a) EPC. The Boards of Appeal have addressed the theoretical issues related to the concept of commercial exploitation in only three cases, and these represent a narrow interpretation focusing on exploitation or use per se, excluding developmental aspects from the scope of application of Article 53(a) EPC. In the rest of the decisions where developmental aspects have been raised, the objections have been either met (and rejected) by material argumentation, or been subject to reformulation on behalf of the Boards. Thus, the Boards and Divisions seem to apply different strategies with regard to the handling of developmental aspects. If regard is given to theoretical reasoning and eloquence, the prevailing position of the Boards of Appeal must be characterized as excluding developmental aspects from the scope of the concept of commercial exploitation and consequently from the scope of application of the exclusion in Article 53(a) EPC.

13.8.3.2 Socio-economic Effects

In contrast to the position with regard to developmental objections, there seems to be a general consensus in the EPO that the socio-economic effects (i.e. patenting, monopoly and access) of the grant of a patent in a specific field are not something that the EPO can take into account; not under Article 53(a) EPC or any other Article of the Convention. The main argument is based on a literal reading of Article 53(a) EPC, which refers to the ‘commercial exploitation of the invention’, not the ‘commercial exploitation of the patent’. The Boards of Appeal have stated that socio-economic consequences of the patenting of a subject matter fall outside the scope of application of Article 53(a) EPC. The result of including such considerations would be an unduly restriction of the field of patentable subject matter.

Despite the clear statements by the Boards of Appeal with regard to objections focusing on socio-economic effects, such discussions are nevertheless found in EPO case law. The final argument conveyed by the opponents in Relaxin referred to the immorality inherent in the act of patenting human life. This argument (relating to an otherwise, in the present situation, obscure objec-

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984 The most common objections to the economic effects of a patent have been raised in connection with biomedical inventions concerning genes or other parts of the human body. See e.g. T 1213/05 (Breast and ovarian cancer/UNIVERSITY OF UTAH).
985 See T 866/01, T 315/03 and T 1213/05.
tion to the patenting of human life) is difficult to characterise due to the mis-
understanding of patent law on behalf of the opponents. Nevertheless, it seems
fit to relate this objection to the act of patenting, rather than to any of the other
categories. This objection was met by the Opposition Division with arguments
about the character of the material being patented; they held that DNA is not
life, but a chemical substance which carries genetic information and can be used
as an intermediate for the production of proteins. The reasoning of the Oppo-
sition Division was focused upon the relation between human genes and hu-
man beings. They also held that no moral distinction can be seen in principle
between the patenting of genes on the one hand and other human substances
on the other. By meeting the objections with argumentation of this kind, in-
stead of rejecting them on the basis that Article 53(a) EPC is not concerned
with the morality of patenting, confirms the theory that in its early case law, the
EPO was less strict in following the actual criteria set up in the morality clause,
namely to focus on the ‘exploitation’ of the invention instead of the act of pa-
tenting.986

The issue of immorality of patenting vested in the act of granting a patent is
nevertheless still contentious, not least with regard to gene patents. The devel-
opments with regard to the US patents on breast cancer genes BRCA1 and
BRCA2 prove that the objections to this type of patenting are not simply ab-
stract topics of discussion without practical effects, but rather has been found
by at least one judge to possess substantive value and contributed to the revok-
ing of the patent.987 It is difficult to speculate to what extent of the socio-
economic factors actually influenced the decision, which was delivered on legal-
technical grounds concerning the patentability of the subject matter of the in-
vention (human genes). Still, the socio-economic arguments were given plenty
of room in the judgment, were discussed to a great extent and should therefore
not be overlooked, not least from a point of view of the political discussions.

The corresponding European patent came under scrutiny by the EPO in the
decision Breast and ovarian cancer. The European patent at issue covered the is-
olated nucleic acid (the so-called BRCA1 gene) which predisposed for breast
cancer.988 The opponents argued that the socio-economic consequences of this
particular invention concerned ethical issues. The patenting of the claimed sub-
ject matter would not only result in increased costs for patients, but would also
influence the way in which diagnosis and research would be organized in Eu-
rope, clearly to the detriment of patients and doctors.989 The EPO Board of

986 See the reasoning by Schatz, 160.
987 See Supreme Court of the United States, No. 12–398, Association for Molecular Pathology et al v Myriad Genetics
et al. Argued April 15, 2013—Decided June 13, 2013, 569 US (2013). See also United States District Court,
Southern District of New York, Association for Molecular Pathology, et al. v. United States Patent and Trademark
988 T 1213/05, Summary of Facts and Submissions, VII ff.
989 T 1213/05, Reasons for the Decision, para 52.
Appeal considered these consequences to be a perfect example of issues that are directed to the consequences of the exploitation of the patent, not the invention, and concluded that the objections raised fell outside of the scope of Article 53(a) EPC.990

The result of the taking into account of the economic or social consequences of a patent would force the EPO Boards to restrict the field of patentable subject matter according to its effect. This would inevitably lead to technology-specific decisions, since inventions would be distinguished based on their respective technical field and the economic or social effects for that particular field. Instead, the possible consequences of exploitation of the patent are the result of the exclusionary nature of the rights granted by a patent, i.e. the right to stop competitors from using the invention. The exclusionary nature of private property rights are the same for all patents. Without any legal basis in the EPC, the EPO cannot change the application of the technology neutral rules.991

The question of whether the act of granting the patent may be regarded as an infringement of ethical principles is clearly outside the scope of Article 53(a) EPC, as confirmed by the EPO decisions. But this is regularly, and perhaps not unintentionally, overseen in the public discussion. In addition, prominent commentators argue for an application of Article 53(a) EPC as an assessment of the immorality of putting the patentee in an exclusionary position.992 Even so, according to the Boards of Appeal this question falls outside the scope of application of Article 53(a) EPC as long as the exploitation itself does not infringe the principles of morality or ordre public.

13.8.3.3 Exploitation

This category includes objections based on the premise that the exploitation of the invention (or use) is contrary to ordre public or morality. This basis is literally in line with the wording of Article 53(a) EPC, except for the qualification that the exploitation in question must be ‘commercial’.

The term exploitation is, in addition to morality and ordre public, of crucial importance to the understanding of Article 53(a) EPC. From several EPO cases it can be deduced that the category of exploitation refers to a literal exploitation of the patent, in terms of the use of the invention, as described in the patent and the patent claims. This is also the prevailing doctrinal opinion.993 In the words of Margaret Llewelyn, exploitation equals use:

990 T 1213/05, Reasons for the Decision, para 53.
991 This includes the fact that national legislation may take such factors into account, e.g. the French patent legislation with regard to genetic inventions. The content of national legislation is irrelevant to the issue of how the EPC should be interpreted. See the reasoning of the Board, T 1213/05, Reasons for the Decision, paras 53-54.
992 See e.g. Beyleveld, Brownsword and Llewelyn, 164.
993 Schatz, 161.
The use of the word ‘exploitation’ in relation to the invention shows clearly that it is the use of the invention which has to be looked at when assessing the question of immorality.\textsuperscript{994}

If conceivable, this use is the use of the invention on the market. The term exploitation may also cover production or distribution.\textsuperscript{995} The extent of the use claimed seems to serve as the indicator for the exploitation of the invention. But how is this use to be determined? Plomer asserts that the making of the invention need not involve any industrial or commercial exploitation, and gives examples of the thousands of gene patents that have not resulted in commercial or industrial applications.\textsuperscript{996} The act of commercial exploitation indicates the marketing and sale of the invention (for a profit). The act of use is in this sense narrower.

In \textit{Euthanasia compositions} the Board stated that ‘\textit{[t]he exploitation of the invention within the meaning of Article 53(a) EPC is to be construed as the normal avowed use indicated in the patent (“bestimmungsgemäßer Gebrauch”) of the invention’s teaching.’\textsuperscript{997} This avowed use of the invention needs to infringe \textit{ordre public} or morality if patent protection is to be denied. In this case, the Board used the terms exploitation and use in an interchangeable manner, and the exemplification focused on the content of the claims. A similar view that the use represents the content of the claims has been expressed by the EBA.\textsuperscript{998}

The claims of a patent may cover many conceivable exploitations or uses of an invention’s teaching. For the application of Article 53(a) EPC, it is not sufficient that the invention can be exploited generally in a manner contrary to \textit{ordre public} or morality.\textsuperscript{999} It is merely the indicated exploitation that is of interest. The fact that the invention may be abused and used in a manner which would breach the principles of \textit{ordre public} or morality is not sufficient to render the whole invention unpatrientable. Conversely, an invention can only be denied patent protection where the indicated use, or perhaps every use of the invention is contrary to morality or \textit{ordre public}. In practice, it will be a matter of interpretation of the patent application, most importantly the claims.\textsuperscript{1000}

The examination of the embodiments of the claims in a patent application is necessarily adapted to the purpose of the particular stage of the examination. In order to examine the criteria of novelty and inventive step, all embodiments within the claims must (theoretically) be examined and every single embodi-
ment should fulfil the requirements of being novel and inventive. In contrast to the general patentability criteria, Article 53 is directed towards the exclusion of non-patentable subject matter and subject to the principle of narrow interpretation, although there is room for deviations from that principle if required in individual cases. Thus, the fulfilment of the requirements for non-patentability in relation to specific embodiments covered by a claim does not render the whole invention non-patentable, if the general claim is otherwise patentable.

A practical example is the application of certain inventions covering living beings. A broad teaching would probably use the term ‘mammals’, which includes human beings. Many inventions would be perfectly legitimate for domestic animals but contrary to morality or ordre public if applied to humans, e.g. the avoidance of offspring which are unwanted due to certain properties (sex, colour, health etc.). In such cases, the general claims usually cover specific embodiments. In these situations it is necessary to include the disclaimer ‘non-human’ in respect of living beings. The disclaimer has, however, nothing to do with the technical teaching in the application. It excludes beings to which this teaching should never have been applied anyway (although they would be theoretically workable).

The reasoning of the EBA in G 1/98 (Transgenic plant/NOVARTIS II) focused on the effects of claim construction in relation to the exclusion for plant varieties in Article 53(b) EPC and the question of whether the exclusion applied when a claim covered plant varieties but did not define a single variety, i.e. the result when embodiments are covered by a claim, but not individually claimed. Would the purpose of these further features be immoral or contrary to ordre public then the claimed invention would in fact cover an embodiment considered to fall under Article 53(a) EPC, but, held the EBA, the invention as claimed would not be excluded since its improved features could be used for many acceptable purposes. Likewise, a similar situation is found in case law on biotechnological inventions and the requirement of sufficient disclosure in Article 83 EPC. A claim directed to the use of a whole class of micro-organisms could be granted, although some specific (and particularly effective) strands comprised in this class were not available to the public. The fact that specific

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1001 G 1/98, Reasons for the Decision, para 3.3.
1002 G 1/03, Reasons for the Decision, para 2.4.1.
1003 The conclusion from G 1/98 is that a patent shall not be granted for a single plant variety but can be granted if varieties fall within the scope of its claims. If specific plant varieties are not individually claimed, the subject matter of the claimed invention is not regarded as directed to a plant variety or varieties within the meaning of Article 53(b) EPC. G 1/98, Reasons for the Decision, para 3 (see para 3.10).
1004 G 1/98, Reasons for the Decision, para 3.3.3.
embodiments covered by the claim could not be carried out did not affect the admissibility of the claim as a whole.\textsuperscript{1005} The interpretation of the exclusion in Article 53(a) EPC, especially with regard to the claim scope, focuses on the invention and its exploitation, and whether such exploitation is contrary to \textit{ordre public} or morality. The wording of the provision does not refer to the scope of protection conferred by the claims.\textsuperscript{1006} This distinction is crucial but also quite natural since the aim of the provision is to settle the question whether the exploitation of the invention is exclusively contrary to morality or \textit{ordre public}. In this situation, it is necessary to establish the intended uses of the invention, but not the whole breadth of the claim scope.

It is only the content of the patent that determines the extent of disclosure and information regarding the invention. The disclosed use of an invention is therefore found in the text of the patent, mainly in the description and the claims. For instance, the claims of the invention in \textit{Euthanasia compositions} were directed to a composition and its use for preparing a medicament for providing euthanasia in a lower mammal.\textsuperscript{1007} In the contested patent description the explanation was given that ‘it is the object of the present invention to provide improved euthanasia compositions which rapidly eliminate the presence of noticeable heart beat and the stiffening encountered with ‘T-61'[...]'\textsuperscript{1008} The opponents had asserted that the exploitation or the avowed use indicated in the patent included the arbitrary or intended termination of life (killing) or termination of life on demand (euthanasia) of all kinds of animals, including human beings. The opponents also declared that the patent contained references to toxicity levels of human beings.\textsuperscript{1009} The Board did not share the opponent’s views and held by interpretation of the text and statements in the patent that the ‘avowed use of exploitation of the euthanasia compositions disclosed in the patent for any other conceivable purpose than for the sole intended purpose indicated in the patent in accordance with the present invention, i.e. for producing humane death (mercy killing) in lower animals, has neither been indicated nor contemplated nor foreshadowed at all in the present patent.’\textsuperscript{1010}

One important objection against an invention which is likely to be contrary to \textit{ordre public} consist of the fact that the exploitation of the invention is likely to seriously prejudice the environment. It is conceivable that objections may be raised that claim developmental aspects in this regard, i.e. that the technology \textit{per se} or the means of arriving at the invention would be likely to seriously prej-
udice the environment. In PGS, however, the issue was actually the exploitation of the invention, although the Board also made statements with regard to the morality of the technology *per se*. The Board held that the exploitation of the invention claimed in the patent may only take place within the framework defined by national laws and regulations regarding the use of the said invention. With the emphasis on use, it is clear that the Board envisioned the use of the invention when put on the market, in society. In this regard, the Board described the patent offices as being placed at the crossroads between science and public policy, and stated that:

>[A]t this crossroads patent offices are not alone, but find themselves side-by-side with an increasing number of other authorities and bodies, in particular regulatory authorities and bodies, whose function is inter alia to ensure that the exploitation of a given technology, regardless of whether it is protected by a patent or not, takes place within the regulatory framework provided by laws, international treaties, administrative provisions, etc.

The Board pointed out that the assessment of the hazards stemming from the exploitation of a given technology is one of the important duties of such regulatory authorities and bodies other than the patent offices.

This is a very important statement from the Board. It focuses on the real difficulty with the concept of exploitation, namely that it is scarcely possible for a patent office to make a correct assessment of various effects of the exploitation of an invention at the time of patent examination. In PGS, this problem was illustrated with the example of chemical compounds with a pharmaceutical use. The actual approval or disapproval by the competent authorities of the exploitation of pharmaceutical products is often obtained only after the grant of the patent. A realistic assessment of the therapeutical operability of such a product requires a lengthy, expensive and comprehensive process, often including clinical trials, to make sure that the product is safe and efficient. At the time of patent grant, the exploitation of the product is most likely to be in an initial phase, where risk and safety assessments are not yet completed or even initiated. It is impossible for the patent office to assess the potential risks in relation to the exploitation of a given invention merely on the basis of the disclosure of the invention in the patent application. This reasoning can be applied to nearly all inventions that require approval from competent authorities before exploitation on the market, e.g. pharmaceuticals, GMOs, herbicides, insecticides, tissue, cells, fluids or other material for therapeutic use etc. The main problem with

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1011 T 356/93, Reasons for the Decision, para 18.2.
1012 Id., para 18.3.
1013 Id., para 18.4.
1014 Genetically modified organisms.
such products is that not enough information on the future exploitation is available at the time of patent examination and grant.

If, on the other hand, information is available, the patent office needs to assess what constitutes the commercial exploitation under Article 53(a) EPC. This requires that sufficiently substantiated evidence can be presented at the time the decision to revoke the patent application is taken by the patent office. Such a view is also consistent with the requirement that exceptions to patentability under Article 53(a) EPC have to be narrowly construed.\textsuperscript{1015}

Inventions are checked during the examination procedure to establish that no patents are granted for subject matter whose commercial exploitation would be contrary to \textit{ordre public} or morality. In addition, prior to publication, the patent applications are checked to ensure that elements or drawings which may be contrary to \textit{ordre public} or morality are omitted at the time of publication.\textsuperscript{1016}

A distinction is necessary between the technical teaching or use of an invention indicated in the patent, and the commercial exploitation of that invention. The right to commercially exploit a patent is not unconditional. Neither is the commercial exploitation of an invention a matter for the patent authorities, whose task it is to grant or deny a patent applicant patent protection. The invention claimed in the patent may only be exploited within the framework defined by national laws or regulations in the state where the invention is used. Many claim that patent authorities are placed in the crossroads between science and public policy, and that the assessment of whether the commercial exploitation of an invention is contrary to \textit{ordre public} or morality is therefore a suitable task for the patent authority. It is often claimed that patent authorities should operate within the realm of the norms in the society, even though the actual exploitation of the invention is not something that the patent authority may have a direct influence over.

The EPO has, on the other hand, held that patent authorities find themselves side-by-side with regulatory authorities and bodies, as well as other authorities. It is the task of particularly such regulatory authorities to ensure that the exploitation of a given technology, regardless of whether it is protected by a patent or not, takes place within the regulatory framework provided by laws, international treaties, administrative provisions, etc. The task of assessing the

\textsuperscript{1015} T 356/93, Reasons for the Decision, para 18.5.
\textsuperscript{1016} According to Rule 48(1)(a) of the Implementing Regulations to the EPC, the European patent application shall not contain ‘statements or other matter contrary to "ordre public" or morality’. If the application contains such prohibited matter, the European Patent Office may omit such matter from the application as published, indicating the place and number of words or drawings omitted (Rule 48(2) EPC). The omission from the publication of the application is mandatory for the category of matter contrary to \textit{ordre public} or morality. Examples of the kind of matter falling in this category are incitement to acts of disorder; incitement to criminal acts; racial, religious or similar discriminatory propaganda; and grossly obscene matter (Guidelines for the Examination in the European Patent Office (November 2014), A-III, 8.1). The check is usually carried out by the formalities officer in the Receiving Section. The examination of the substantive part of the patent application is performed by the Examining Division.
hazards stemming from the exploitation of a given technology is important and lies with these regulatory bodies. But if the patent authority is to assess the effects of the commercial exploitation of an invention in relation to the question of whether such exploitation would be contrary to ordre public or morality, it is nevertheless necessary that such effects are identified, substantiated and form part of the assessment. The remaining question is then, what types of effects should the patent authority take into account and on what grounds?

13.8.4 Expanding the Scope?

Of the total amount of the EPO decisions, three Boards of Appeal decisions stand out, not only for treating the concept of commercial exploitation in a narrow fashion but also for providing a well-reasoned and detailed argumentation focusing on the legal requirements of the morality exclusion. The rest of the decisions either contain legal reasoning that denotes a broader view of the concept of commercial exploitation, or simply does not treat that specific question.

If the operation of the morality clause is constructed upon a foundation incorporating arguments in relation to development, technology per se, the patent grant or socio-economic effects, then, the scope and content of the term commercial exploitation would need to be as broad as possible, taking into account not only future commercial exploitation of the invention but necessitating also an assessment of past actions connected to the invention. From this point of view developmental aspects, including R&D of the invention is clearly incorporated into the commercial exploitation of the invention. Such inclusion would necessitate a discussion of moral complicity on the part of the patentee, as well as some kind of estimation of how far upstream a morally dubious act can defile a future patent application.

These aspects are crucial to manoeuvre in a manner necessarily in line with not only the construction of the morality clause in terms of legal precedent and legal interpretation, but also in relation to the function of the European Patent Organisation. It may be so that there are differences in how the morality clause can be – and is – handled by the EU legal system and the European Patent Organisation respectively. The framework for the operation of the provision is hence essential.

1017 See e.g. T 356/93, Reasons for the Decision, para 18.3.
1018 See Crespi, 173-175.
13.8.5 Discussions in Doctrine

Commentators support different views on the proper scope and understanding of the concept of commercial exploitation in Article 53(a) EPC. The conflicts are mainly centred on two aspects of its interpretation.

The *first* aspect is the focus on developmental aspects of the invention, namely whether an invention that rests on an ethically dubious research procedure could be granted a patent. The *second* aspect centres on the situation where it is not the exploitation, or use, of the invention that generates a conflict in relation to *ordre public* or morality, but rather the act of granting a patent, including the economic exclusionary position granted to the patentee. Is this a legitimate objection under the concept of commercial exploitation?

Sterckx and Cockbain view the exclusion in Article 53(a) EPC as ‘aimed at ensuring that the state does not encourage the commercial exploitation for inventions if this would imply violations of *ordre public* and/or morality’. From this point of departure they identify three ways in which the provision must operate in order to have effect.

The *first* situation is the case where the commercial performance of the invention (the operation of the invention in a commercial context, excluding its R&D phases) would be contrary to *ordre public* or morality, for instance due to the violation of human dignity.

The *second* situation is where the monopolisation of the invention would be contrary to *ordre public* or morality, as discussed also by Moufang. Due to the intention of commercialization that is necessarily linked to a patent application, the disapproval targets the economic exclusionary position afforded by the patent with regard to the particular invention. Such interpretation, argue Sterckx and Cockbain, would only be applied in specific areas, such as inventions concerning parts of the human body. This proposed dimension does not, however, include the immorality of socio-economic effects of the patent as for instance the limitation of access to medicines.

The *third* way in which Sterckx and Cockbain see a necessary operation of Art 53(a) EPC is where developmental acts would be contrary to *ordre public* or morality. Thus, a violation of morality, including moral complicity of behalf of the patent applicant occurring at a stage preceding the patent application should lead to rejection under Article 53(a) EPC. Sterckx and Cockbain thus include both developmental aspects as well as monopolisation in the concept of

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1020 Sterckx and Cockbain, 300.
1021 Moufang 1994, 504.
1022 An example of such moral complicity would be to use human material accessed by the violation of fundamental human rights, e.g. the principle of autonomy.
commercial exploitation, in addition to the narrow view of exploitation which they label as ‘commercial performance’ of the invention.

Beyleveld, Brownsword and Llewelyn argue that developmental aspects must necessarily be a part of the morality assessment, but they also admit that the drafting of the provision signals a narrower approach, which they label as a ‘distorted reading’. Their reasoning is expressed in relation to Article 6(1) of the Biotech Directive but it has equal weight in the analysis of Article 53(a) EPC:

[T]he moral test, although framed in terms of commercial exploitation, must be read as looking backwards as well as forwards. […] It is implicit that the commercial exploitation of an invention can be judged to be immoral, because the immoral manner of its development is deemed to taint any future exploitation – no inventor, in other words, should be permitted to profit from his wrong by being put into a monopoly position. Against this interpretation, however, it may be argued that the focus on commercial exploitation […] signals that the manner in which the invention was researched and developed is irrelevant; what matters is simply whether future commercial exploitation (disregard the past) would be immoral. Such an interpretation would involve a distortion of a morality exclusion however drafted – but the danger is that the drafting of Article 6(1) leaves room for such a distorted reading.

Moufang also regards the inclusion of developmental aspects in the assessment as natural, and states that the violation of morality or *ordre public* in pre-patent, or pre-invention stages, should definitely not be rewarded with a monopoly position. The immorality of past actions should therefore have effect on the assessment of whether the commercial exploitation of the invention would be contrary to morality or *ordre public*, despite the fact that the actions perhaps need not be repeated in order to execute the invention.

Crespi views the act of seeking and obtaining patent as separate from the exploitation or enforcement of the right. However, the patent procurement is nevertheless closely related to the development of the invention. If the research is morally objectionable, then there are compelling arguments for preventing the researchers from benefitting from it. But patent law can never act as the sole regulator of science, but rather merely as a first filter against unwanted inventions being put into the public domain, according to Crespi. But such a reasoning accordingly recognizes the problems of disregarding the development of the invention under a narrow reading of Article 53(a) EPC.

Schatz agrees to a certain extent by stating that it is not the permissibility of ‘any kind of technology or any kind of invention as such which is at stake, but

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1023 Beyleveld, Brownsword and Llewelyn, 166, 181 fn 42.
1024 Id., 166.
1025 Moufang 1994, 504-505, Beyleveld, Brownsword and Llewelyn, 166.
1026 Crespi, 174.
the exploitation of it.'1027 Commercial exploitation, according to Schatz, focuses on whether the making or the use of the invented product or process would be contrary to ordre public or morality.1028 The concept of making an invention could include also its development, but it is uncertain if Schatz considers the inclusion also of developmental aspects in the term ‘making of an invention’.

The logic of Moufang, Sterckx, Cockbain, Beyleveld, Brownword, Llewelyn and (to some extent even Crespi’s) reasoning cannot be denied. Should not an exclusion based on morality take into account each and every means of arriving at the invention? To permit a narrower understanding of the morality clause would result in a situation where apparent deviations from moral, and perhaps also legal principles in relation to a particular invention would not be taken into account.

A strong argument against such reasoning is however found in the literal interpretation of the text of Article 53(a) EPC, because the concept of ‘commercial exploitation of an invention’ cannot even in the broadest possible understanding be interpreted as looking backwards to pre-patent stages of development. If such stages are included in the concept of underlying invention, which would consequently also have to be extremely broad, then developmental aspects could come into the assessment without having to stretch the concept of commercial exploitation to include such stages that are definitely not included from a normal reading of the concept. But the concept of underlying invention should not be stretched too far either from the point of view of adhering to established principles of interpretation and legal certainty. It is furthermore apparent from the body of case law of the Boards of Appeal (even though opposing and contradictory argumentation also exist) that developmental aspects should not form part of the assessment in relation to Article 53(a) EPC.

If the converse reasoning is applied, should inventions resulting from morally immaculate research then always be granted patent protection (provided that their commercial exploitation is permitted and that the development of the invention is in accordance to legislation)? The answer to this question is dependent on the weight accorded to the morality assessment and also the scope of the concept of commercial exploitation. If developmental aspects are detached from the assessment then the moral status of the R&D leading up to the invention become irrelevant. On the other hand, if developmental aspects are to be given weight in the considerations according to Article 53(a) EPC, then morally immaculate research should naturally have equal weight in the assessment as morally offensive research would.

In relation to the second aspect in this legal discussion, namely whether it is actually the act of patenting that should be assessed, Beyleveld, Brownword

1027 Schatz, 160.
1028 Id.
and Llewelyn agree with Sterckx and Cockbain in that against the function of a patent as an exclusionary right, a focal question for the morality exclusion is whether "putting the applicant in a monopoly position in relation to the commercial exploitation of a particular invention gives rise to any moral difficulty." From this perspective, it is the morality of granting monopoly control to the applicant that should be targeted by the morality exclusion. The purpose of Article 53(a) EPC is to reject patents for inventions the commercial exploitation of which would be contrary to morality or order public. A formal reading of the provision (centered on a narrow interpretation of commercial exploitation, as recognised by the Boards of Appeal) is evidently criticised, and Beyleveld, Brownsword and Llewelyn argue that the situation may occur where the commercial exploitation of an invention is not immoral, but the grant of a patent may well be considered as immoral. An example of such a situation is where the access to a public good would be impeded by private monopoly control. Thus, the authors argue, that in precisely such a situation, the granting of a patent right would be considered immoral if morality dictates a commercial exploitation free from exclusionary rights.

The arguments related to the negative right that a patent confers upon its holder and consequently that the acts of exploitation and patenting are thereby separated must be scrutinized with regard to this particular aspect of the immorality of the act of patenting. Such an investigation is necessary because the arguments related to inclusion of the act of patenting under the scope of application of Article 53(a) EPC necessitate equating this act to the concept of commercial exploitation. The right to exclude others is distinctively separate from the right to exploit the invention, the latter act being sometimes subject to approval from regulatory authorities. The exploitation of the invention, on the other hand, is obviously independent of whether the invention is patented or not — the exclusive right has no bearing on the regulatory approval whatsoever. Of this the Boards and Divisions have been quite determined. But in practice the link between the act of patenting an invention and its exploitation is often quite strong.

The possibility of patent protection undoubtedly encourages, or is a necessary incentive, to commercialization. Tendencies of commercialization in unregulated areas of R&D, for ethically sensitive (and most often human) material

1029 Beyleveld, Brownsword and Llewelyn, 164 (regarding the corresponding Article 6(1) of the Biotech Directive).
1030 Conversely, they argue that it is not improper to hold that the grant of monopoly control would be immoral if commercial exploitation would be immoral. Beyleveld, Brownsword and Llewelyn, 164.
1031 Beyleveld, Brownsword and Llewelyn, 165.
1032 With the one exception being the reasoning in T 356/93, para 18.2: "A patent confers on its owner(s) for a specified time an exclusive right to exploit the subject-matter of the claims, i.e. to manufacture, use and market it, and to prevent others from doing the same. [T]he right to exploit the invention is unconditional. On the contrary, the invention claimed in a patent may only be exploited within the framework defined by national laws and regulations regarding the use of the said invention."
may be reinforced by the granting of exclusive rights, despite the fact that such rights can never amount to a positive use of an invention in the market. Moufang argues that there should be no parallel between the possibility of obtaining tangible property rights to ethically sensitive material and the granting of patent rights for the same subject matter. The most compelling argument in this respect seems to be that the orientation to industrial use and commercialization is not as prominent in the area of tangible property law, as it is in patent law. Consequently, from this point of view a patent right is inseparable from its commercial implications, and the granting of such a right equals at least intent to use the invention in a commercial or industrial setting.

Crespi disagrees, and states that the act of patenting is not an act of moral significance, because the character of the legal right confined to the applicant is to prevent unauthorised use by others. Such rights may be held or may be exercised, and mere possession cannot be immoral. The exercise of such a right might be immoral if it necessarily entailed an immoral act. But, as Crespi concludes, the exercise of the right can only consist in either restraining unlawful use of the invention or set legally permitted conditions under which the invention may be lawfully used by third parties. Neither of these acts can be judged as immoral. Therefore, to patent an invention cannot be immoral.

Thus, it can be concluded that from the reasoning in legal doctrine that there are compelling arguments for the inclusion also of developmental aspects in the assessment of whether the commercial exploitation would be contrary to ordre public or morality. In relation to the act of patenting, the arguments are not as persuasive and are more elusive, partly because it is difficult to establish the necessary link between the immorality in the act of patenting and the exclusionary position rewarded the patentee and the perceived immorality of the commercial exploitation of the invention on the market.

13.9 The Proviso

An often cited characteristic of a patent is the negative right it entails the patent holder. The negative nature of the patent right is usually exemplified by the fact that the exploitation or use of the invention is subject to legislation other than patent law. The statement in the second sentence of Article 53(a) EPC that ‘such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States’, could be interpreted as enforcing the fact that the patent grant is somehow disconnected to the exploitation of the invention as such.

1033 Moufang 1994, 513.
1034 Id.
1035 Crespi, 175.
From a literal reading of the provision, taking into account the proviso ‘merely’, as well as the *travaux préparatoires* and its relation to Article 4*quater* of the Paris Convention, it serves the purpose of clarifying that the assessment of whether or not a particular subject matter is contrary to *ordre public* or morality is not dependent upon any national laws or regulations. Ordre public and morality principles are not necessarily infringed by the fact that the commercial exploitation of an invention is prohibited by statutory law, a legal prevention or regulation. A patent could thus still be granted even though its exploitation is prevented by regulatory legislation. The reason for such a stance is that if regulatory prohibitions are subsequently removed the inventor should not stand deprived from patent protection. Thus, the existence of a prohibition does not equate an immoral invention, and that precludes a morality assessment as merely based on the existence of national prohibitions. It is also possible to interpret the proviso as introducing a presumption for patentability in a situation where no prohibition exists.

Competing opinions exist on the interpretation of the statement in the second sentence of Article 53(a) EPC and consequently the role of regulatory legislation in the assessment of the morality clause. The influence of such legislation is already a contentious issue with regard to the interpretation of the concepts of *ordre public* and morality. In relation to the effect of the statement it has been held that on the one hand, that the existence of a national prohibition for the invention under scrutiny is a necessary criterion for the application of the morality clause. If no such prohibition exists, the invention should be granted a patent. On the other hand, the proviso could be interpreted to prescribe that the existence of a national prohibition is not a necessary criterion for the application of Article 53(a) EPC is completely detached from the existence of a prohibition or even permission for that matter. This is the prevailing stance of the EPO.

In *PGS*, the Board held that approval or disapproval of the exploitation by national law(s) or regulation(s) does not constitute *per se* a sufficient criterion for the application of Article 53(a) to an invention, but is rather an argument necessary to meet the requirements prescribed. Furthermore, the assessment should not be dependent on any national laws or regulations in the sense that subject matter should not be regarded as complying with the requirements of Article 53(a) EPC merely because its exploitation is *permitted* in some or even all

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1036 As supported by T 356/93, Reasons for the Decision, para 7.
1038 T 356/93, Reasons for the Decision, para 7. See also the Opposition Division decision of 21.07.2003 (Edinburgh), Reasons for the Decision, para 2.5.2, and T 1213/05, Reasons for the Decision, para 55. The issue was not discussed in T 19/90, V 6/92, V 8/94, G 1/98, T 272/95, T 315/03, T 1374/04, T 866/01, or T 522/04. Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal) represented a partly different view.
of the Contracting states. This view was endorsed in the *Edinburgh* decision and in *Breast and ovarian cancer*, which indicates that there is a need for an additional assessment (despite the existence of a permission or prohibition), which is also in line with the independent position EPO has taken in the interpretation of the concepts of morality and *ordre public* as detached from legislation. This assessment may, or may not, take into account the existence – or lack of – a national prohibition on the commercial exploitation of the invention.

It must be noted that in the majority of the cases, except from the mentioned decisions, the EPO Divisions and Boards do not discuss the proviso at all. It is therefore rather interesting to note that in *WARF*, the EBA referred to a decision of the German Federal Patent Court (Bundespatentgericht) in support for the finding that the concern of the EU legislator, when enacting Article 6(2)(c) of the Directive (with impact on the interpretation of Rule 28(c) EPC) was to prevent a misuse ‘in the sense of a commodification of human embryos’. This concern was also apparent from the protection of human dignity being one of the essential objectives of the Directive. The selective policy of the EU in funding stem cell research was also evidence for this concern, and thereby regulation of research, i.e. the selective funding employed within the Community, was used by the EBA as argumentation to corroborate the intention of the legislator for the exclusion from patentability. Furthermore the EBA referred to national definitions of the concept of ‘human embryo’ with the aim of demonstrating that despite the differences in national law the EU legislator had chosen to leave the term undefined in the Directive, thereby opening up for a definition of ‘human embryo’ on a case-by-case basis, in the context of any particular patent application.

Despite the somewhat unorthodox handling of national legislation and court decisions as evidence in *WARF*, the rest of the EPO decisions signal an approach which detaches the assessment of violation of *ordre public* and morality in Article 53(a) EPC from the legal and ethical principles expressed in national legislation, principles which most often, at least considering fundamental values, are founded in European or international legal instruments or conventions. The detachment is understandable and even welcomed if the sole intent is to leave the questions of *ordre public* and morality to the Member States, indicating a narrow (and rare) application of the morality exclusion. Such a free-standing operation of the morality clause is consistent with the findings with regard to *ordre public* and morality on behalf of the EPO, but could be criticised as founded on an improper reading of the proviso in the second sentence of Article 1039–1043.

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1039 T 356/93, Reasons for the Decision, para 7.
1040 G 2/06, Reasons for the Decision, para 18.
1041 Id.
1042 Id.
1043 Id., para 20.
53(a) EPC. In addition, the detachment from legal and ethical principles has currently lead to a situation in which inventions are excluded from patentability despite their use being permitted in national (and EU) law.

A reading of the proviso (as indicating detachment from national law) is in accordance with the opinion of Beyleveld and Brownsword, where prohibition or even permission of the invention under national legislation is neither a sufficient nor a necessary criterion for the operation of the morality clause. Regulation may in their view, under certain circumstances, be of evidential value in the assessment of the morality criterion under the standard of European critical morality. Straus, on the other hand, endorses the view that if society accepts and promotes achievements in a specific technology, the including granting property rights, then patent protection should not be withheld. The fact that patent protection is refused on the basis of morality or ordre public, although the commercial exploitation of the invention is permitted by laws, would imply that such laws would be immoral or against ordre public. The result would be that the invention would be free for anyone to use and exploit legally, which cannot be in line with the aims of the morality clause or even the patent system.

The traditional aim of the proviso (as found in Article 4quater of the Paris Convention) was to not deprive inventors of their rights if the prohibition of the sale is subsequently removed, e.g. as a result of new scientific findings, indicating a presumption for patentability. Such a conclusion is also logical in the view of the concept of ordre public being equal to a body of certain laws, or that the principles of morality are expressed – directly or indirectly – by law. In such cases, the exploitation of an invention can only offend these concepts if prohibited by law.

Depending on the view of the ordre public and morality concepts with regard to their expression or inclusion in national legislation, differing interpretations of ordre public and morality as recognized by e.g. various standards of prohibition or permissibility with regard to a particular invention in the Contracting states has to be handled by the EPO. As recognized, by detaching the interpretation of the concepts from national legislation and principles, the EPO defines

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1044 Since ordre public is a concept which enables the identification of law or regulation in accordance with the Rule of Law, it is irrelevant for the purpose of assessment in this respect. Beyleveld and Brownsword, 78.

1045 ‘[T]he bearing of a non-prohibition (or express permission) will vary from case to case. For example, where the conduct in question has been the subject of serious and prolonged debate within the history of the culture, and non-prohibition or permission is the explicit answer arrived at, this is surely relevant evidence. Similarly, if the conduct has gone unchallenged over a very long period, during which its existence has been common knowledge, there must be some sort of presumption that it is to be judged permissible. On the other hand, if the conduct in question is new, and not well publicised, or publicised in ways that might distort its actual nature, then little or nothing may be read into its non-prohibition or express permission.’ Beyleveld and Brownsword, 81.

1046 Straus 2013, 22-23. See also Moufang 1998, 74.

1047 Straus 1995, 931.


1049 Schatz, 161.
by itself the normative contents of the concepts, without recourse to national or European perceptions expressed in legislation. In addition, it sets the standard against which the assessment of the application of Article 53(a) EPC is judged. EPO endorses such a view in line with the EPC travaux préparatoires, but it must not be disregarded that the relevant working party documentation reflects a phase of the development of the EPC in which a unitary patent, and not a European ‘bundle patent’ was considered. The reference to ‘European institutions’ was thus made under circumstances in which a unification was foreseen (a system in the sense of the forthcoming European patent with unitary effect) whereas the resulting choice of organization resulted in a judiciary with limited powers in relation to national ordre public and morality concerns – they were left to the discretion of the Contracting states.\textsuperscript{1050}

In such a situation, Straus argues that it is not only ultra vires of EPO to disregard the permissibility of exploitation under the laws of the Contracting states, but it would lead to a conflict with the ‘major principles of the legal order’ as laid down in national constitutions as well as EU law. Such competence can only appertain to national constitutional courts or the CJEU.\textsuperscript{1051} In fact, a denial of a European patent would deprive Member states of the possibility to protect inventions in accordance with their national opinions on morality or ordre public. This is not a new issue, and a number of solutions have been proposed to remedy such a situation: to refuse the patent, to grant the patent only for some Member states or to grant the patent in total and let the single Member states that consider the patent immoral to invalidate it in their jurisdictions.\textsuperscript{1052}

The logic behind this reasoning is tied to the inherent nature of a patent or any other exclusionary right. The right holder is only entitled to use his or her invention within the framework of the existing legal system. It is not the patent right that provides the holder with a right to use the invention. The inventor, regardless of patent protection, must respect the current statutory framework including all legal regulations in the territory in which the invention is worked and exploited. Conversely, the refusal of a patent grant does not have any legal effects on the exploitation of the invention, although the loss of an exclusive right will probably entail at least economic consequences for the holder. Thus, patent law is not an instrument capable of averting or preventing abuses or risks associated with the use of a new technology.\textsuperscript{1053}

\textsuperscript{1052} Torremans 2009:1, 159 ff.
\textsuperscript{1053} Singer and Stauder, 87.
If this view of the nature of a patent as a predominantly negative right is scrutinized further, a statement by the Board of Appeal in *PGS* is of interest. The Board held that:

A patent confers on its owner(s) for a specified time an exclusive right to exploit the subject-matter of the claims, i.e. to manufacture, use and market it, and to prevent others from doing the same. [...] However, the right to exploit the invention is not unconditional. On the contrary, the invention claimed in a patent may only be exploited within the framework defined by national laws and regulations regarding the use of the said invention.¹⁰⁵⁴

From the perspective of the Board the patent right contains both a negative part (the right to ‘prevent others’ from exploiting the invention) and a positive part (‘an exclusive right to exploit the subject-matter of the claims’/’the right to exploit the invention is not unconditional’). Such a view indicates a strong link between the act of patenting and the exploitation of the invention; a link which is not otherwise usually accentuated. Of course, it would be strange to treat the act of patenting as not nearly always preceding at least an intended exploitation of the invention. Few would invest the necessary economic resources for obtaining a patent right without at least an intention to exploit the invention commercially, but there are exceptions.¹⁰⁵⁵ The possibility to exclude others from using the invention in a commercial setting would generally be useless if the proprietor did not plan on doing exactly that. This is also one of the frequently cited objectives of the patent system – to encourage investment in R&D by the possibility to commercially reap the fruits of the investments, often under the envisaged situation that without the possibility of patent protection the investments would not be recouped.

If such argumentation is considered then it would be equally strange to, on the other hand, deny the tie between patent and exploitation in other situations. But when the patent eligibility requirements or exclusions are discussed the character of a patent right is cited as being negative and the non-existing relation between patent and regulatory legislation/authorisation is underlined, perhaps due to the principle that patents (or IP in general) are exceptions from the basic principle not to allow monopolies on the market. Alas, the incentive function of the patent system should not be overlooked when treating the impact of

¹⁰⁵⁴ *T 356/93, Reasons for the Decision*, para 18.2.
¹⁰⁵⁵ See e.g. Miyamoto, 152 and Cotropia 2008, 577 (fn. 101), on the discussion on so-called ‘patent trolls’ which exerts a ‘passive’ (as opposed to active) exploitation of the patent rights. Another interesting view of patenting as not primarily focused on exploitation, but rather a way of concealing important aspects on an invention while focusing on other, more news-worthy features have been discussed in relation to the Boeing Company’s high-profile ‘Star Wars’-plasma shield patent (United States Patent 8,981,261 (March 17, 2015) (Method and system for shockwave attenuation via electromagnetic arc)). See e.g. the statements by Anders Larsson, Head of Research at the Swedish Defence Research Agency, at sverigesradio.se/sida/artikel.aspx?programid=415&artikel=6128270.
regulatory law. On the other hand, as mentioned, the granting of a patent does not, in fact, equal commercial exploitation, and there are examples of inventions that, despite patent protection, have not been exploited commercially.\textsuperscript{1056}

In addition, the wording of Article 53(a) EPC as formulated by the EPC working party clearly ties the exploitation of the invention to the patent grant, since if the commercial exploitation of the invention would be contrary to \textit{ordre public} or morality, a patent right shall not be granted. But the content of the requirements of the provision remains debatable, because the EPO Boards and Divisions interpretations tend to focus on different criteria for its application, and the discussions in legal doctrine represents equally different approaches.

So, the fact that the patent does not give the proprietor a positive right to exploit the invention must be treated properly in the context of Article 53(a) EPC since exploitation of the invention is in essence a criterion for the application of the exclusion, which may result in a denial of patentability if such exploitation would be contrary to \textit{ordre public} or morality. Argumentation based on the notion that the patent right does not provide the holder with a right to exploit the invention is therefore quite irrelevant in the light of the wording of the provision.

The remaining question would therefore be how much weight should be put on a national prohibition by law or regulation in the assessment of Article 53(a) EPC. It should then matter on what level the legal prohibition operates. The reason for mentioning ‘national prohibition’ in Article 53(a) EPC is due to the relation between the European Patent Organisation as a collective organization and the interests of the national Contracting states. But in view of the application of the morality clause, this simply means that national prohibitions alone cannot form the basis of an assessment.\textsuperscript{1057} This does not rule out the use of prohibitions of a higher norm level, for instance international or European conventions which are common to the Contracting states. (In this situation, EU legal acts should not be overlooked, although there are EPO Member states which are not part of the EU or even the EEA\textsuperscript{1058} legal system.) Such a particular prohibition must then bring substantial weight to the assessment, even perhaps in itself a sufficient reason for application of the morality clause, despite the opinions of the EPO Boards and Divisions.

If the commercialization of different human material is allowed, then how should patent law treat the issue? One example is the use of human embryos in research, which is allowed in some European states but prohibited in others. There are also possibilities for exploitation of material stemming from human

\textsuperscript{1056} See e.g. Plomer 2009:1, 190.
\textsuperscript{1057} See e.g. Moufang 1994, 503.
\textsuperscript{1058} European Economic Area. The European Economic Area unites the EU Member States and the three EEA EFTA (European Free Trade Association) States (Iceland, Liechtenstein, and Norway) into an Internal Market governed by the same basic rules.
embryo research within the EU. Moufang argues that ‘even if embryo research is permitted to a limited extent, the legal system has to prevent a commercialization of the results obtained through such research. Consequently, the patenting prohibition of Article 53(a) EPC should apply in this respect.’ As the situation is today, Rule 28(c) EPC read in conjunction with the decisions from EPO and the CJEU in this respect makes the embryo exclusion applicable to such research.

Straus disagrees with this reasoning, holding that inventions covering e.g. human material which are legally commercialized should not under the pretext of human dignity be denied patent protection. The only result of upholding such a stance is that researchers can freely not only use and copy the products and processes that are denied patent protection, but also freely commercialize them. Thus, restricting the possibility of patenting under the pretext of guarding principles of human dignity will prevent the granting of patent rights to such inventions, but their use and commercialization in practice will not be hindered. Such restriction will impede the putting of a patentee in a monopoly position, if that is now the aim of the morality clause, but it will not be in line with the further handling of the invention in a commercial setting on the market.

This reasoning is contrary to the findings of the EBA in WARF, since the invention in question was found non-patentable even though its exploitation was generally permitted. But since that decision was decided under Rule 28(c) EPC, and the possibility of treating Article 53(a) EPC was not used, such a conclusion must be treated with caution. The logic behind the reasoning with regard to permitted exploitation is founded on the premise that if the legal framework does not prevent the invention from being exploited, patent protection should not be withheld. To do so would imply that the legal system disapproves not with the use of the invention as such, or even its exploitation, but with the economic exclusionary position awarded to the inventor. This conclusion is supported by prominent commentators but not by the EPO (perhaps with the exception for WARF).

In conclusion, the EPO’s view of the impact of the proviso is currently that, consistent with a literal reading of the provision, the existence of a national or supranational prohibition on the exploitation of an invention is not a sufficient criterion for the denial of patentability under Article 53(a) EPC. The question whether such a prohibition would be a necessary criterion (as argued by e.g. Straus) for the operation of the morality clause is still open, likewise is the im-

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1059 Moufang 1994, 512.
1060 Straus 2013, 49.
1061 See Section 13.12.3.
pact of a permission to exploit an invention on the assessment not treated in case law.

13.10 Evidence

The question of evidence concerns issues of fact. An issue of fact is either a fact (i.e. an issue which has happened, or a hypothetical fact, i.e. an issue which could happen) or a teaching from experience. A fact or teaching from experience may constitute or form the basis of an objection, and it could also form the basis for an argument. But an argument can never be subject to evidence. The question of relevant evidence concerns the basis of the argument, i.e. issues of fact. There is, thus, an important difference between matter of facts and matter of law.

Matters of fact may be the object of evidence, but matters of law are subject to assessment. For instance, the matter of establishing public perception with regard to the unacceptability of the commercial exploitation of an invention is an issue of fact which could be proven by the use of e.g. opinion polls. But the assessment of whether the commercial exploitation of an invention is contrary to morality or *ordre public* is a legal matter which could be assessed on the basis of the fact of the public perception with regard to a specific issue (if sufficiently substantiated).

There seems to be consensus within the EPO Boards and Divisions with regard to the use of some types of evidence in relation to issues of fact, such as the use of opinion polls. The Boards of Appeal has strongly emphasised that surveys and opinion polls cannot be considered as decisive per se when assessing the patentability of a subject matter under Article 53(a) EPC, on the basis of several arguments presented by the Boards. For instance, surveys and opinion polls do not necessarily reflect *ordre public* concerns or moral norms that are deeply rooted in European culture. The results of surveys and opinion polls can fluctuate in an unforeseeable manner within a short time periods and can be very easily influenced and controlled, depending on a number of factors, including the type of questions posed, the choice and the size of the representative sample, etc. Moreover, surveys of particular groups of people (e.g. farmers) tend to reflect their specific interests and/or their biased beliefs. It is scarcely feasible to design opinion polls on an *ad hoc* basis on the specific questions involved in a certain case.\(^{1062}\)

The statements suggest that the opinion polls in question were not executed in a satisfactory manner. The evidential value of an opinion poll is always dependent on its execution with regard to a number of factors. For instance, a

\(^{1062}\) T 356/93, Reasons for the Decision, para 15.
random and representative selection of a certain population is crucial (to ensure the statistical significance), and the character of questions asked should enable objective answers. Against the background of the arguments presented by the Boards of Appeal it seems as if the main problem with the opinion polls was their deficiencies with regard to the presented aspects, which made the opinion polls lack evidential value.

But even if the presented opinion polls would have been executed properly, the statements of the Board of Appeal in PGS indicate an underlying scepticism towards using public perception as a basis for morality, since it was held that the fact that a particular group of people or even the majority of the population of some or all Contracting States opposed the granting of a patent for a specified subject matter could serve as a sufficient criterion for establishing that the said subject matter was contrary to ordre public or morality. From this point of view, it seems as if the concerns of the majority did not reflect a common morality.

The reasoning with regard to opinion polls is indicative of the general principle that the assessment of patentability with regard to Article 53(a) is not dependent upon national laws or regulations. It is thus clear that the assessment necessitates more evidence than public opinion expressed in national legislation. In addition, despite the fact that the EPO has rejected the use of opinion polls in earlier decisions cannot be equated with a general decision in this regard, and the possibility to take such evidence into account in future decisions still exists.

For other categories of evidence, the position is not equally clear. In fact, it seems as if no specific position is adopted by the Boards, which is perhaps natural considering the acknowledgment of the principle of free evaluation of evidence. The EPO Boards seem to be sceptical to issues of fact regarding different forms of scientific evidence (such as opinion polls), and the rejection of insufficiently substantiated empiric evidence has been confirmed in several decisions using a similar reasoning. Instead the Boards have used the basis of expert opinions, current practice, international conventions, legislation, and the submissions of the parties. They have also, on different occa-

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1063 See generally Viken, on opinion polls in trade mark and market law.
1064 T 356/93, Reasons for the Decision, para 15.
1065 This conclusion is interesting for the discussion with regard to critical cultural morality. See Section 13.5.3.2.
1066 Holtz, 448.
1067 See T 356/93, Reasons for the Decision, para 15 and T 315/03, Reasons for the Decision, paras 10.4-10.5.
1068 T 1262/04, Reasons for the Decision, paras 21-22.
1069 See e.g. LELAND STANFORD/Modified Animal, Opposition Division, August 16, 2001, para 8(50) and T 19/90, Reasons for the Decision, para 5.
1070 V 8/94, Reasons for the Decision, para 6.5.
1071 See e.g. LELAND STANFORD/Modified Animal, Opposition Division, August 16, 2001, para 8(45) and T 19/90, Reasons for the Decision, para 5.
sions, rejected the use of opinion polls. On the other hand, the door is not closed on the use of public opinion, but the problem as to how such opinion should be substantiated remains. In some decisions it seems as if the intuitive understanding of the decision maker, i.e. the relevant examiner at the patent authority, suffices to grant the decision its validity.

Another possible source of guidance would be the advice of expert groups. In connection with the morality criterion the EGE would be such a source to consider. The EGE has identified fundamental values and principles common to all European Member states that should guide decisions, including patentability. These values include the respect for human life and human dignity, the relief of human suffering, justice and beneficence, the freedom of research, individual autonomy, and proportionality. The values are simply identified and described, but the EGE is silent as to the sources of these principles, and there is no justification of these values. From the EGE point of view, the respect for human life is a prioritized principle, but as e.g. Viens asserts there is no elucidation of what this respect would entail and why it is a supreme principle, especially within the area of biotech patenting. Furthermore, the EGE makes occasional references to the principle of non-commercialization of the human body, which is notably absent from the listing of fundamental principles referred to.

One particular topic of interest in the discussion regarding the inclusion of developmental aspects in commercial exploitation is the relevance of informed consent to commercial exploitation, including patenting, for inventions developed from human biological material. This issue has bearing not only on the question of developmental aspects, but also on the nature of the evidence required in support of a refusal to patent an invention under Article 53(a) EPC. Physical evidence of different sorts, pertaining mostly to issues regarding breach of *ordre public* are perhaps easily collected and combined, but evidence regarding the breach of moral norms or standards are seen as more difficult due to its intangible and subjective nature.

The issue of prior informed consent was dealt with by the Opposition Division in *Relaxin* and the TBA in *Breast and ovarian cancer*. If a person has not had the opportunity to express free and informed consent (in accordance with national law) not only to the taking and handling of such material in research, but also to the future commercialization, including patenting of said material, would and should this have an effect on the assessment with regard to Article 53(a)

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1072 See e.g. T 356/93, Reasons for the Decision, para 18.6.
1073 See e.g. V 8/94, Reasons for the Decision, para 6.5.
1074 See EGE Opinion n. 12: Ethical aspects of research involving the use of human embryo in the context of the 5th framework programme (23/11/1998) and n. 15: Ethical aspects of human stem cell research and use (14/11/2000).
1075 Viens, 90-91.
1076 Odell-West, 378.
EPC? The ethical status of such research and commercialisation could certainly be regarded as dubious. There is no corresponding provision to the effect of Recital 26 in the EPC. The interpretation of Article 53(a) EPC with regard to informed consent would therefore be dependent on a procedure for verification in the EPC. This is also apparent from the decisions. The importance of such a procedure for verification would be understandable if prior informed consent should be regarded as a requirement for patentability. But if developmental aspects would be included within the concept of commercial exploitation in Article 53(a) EPC, the absence of such consent would definitely have an impact on the assessment of the invention as would any other type of fact related to the process of development of the invention. A different, but important, question is the scope of the consent, i.e. whether consent has to be given also to the act of patenting or only to the research as such.

Another important issue is the impact of the status of national legislation in the process at the EPO. The assessment under Article 53(a) EPC is detached from regulatory law, as advocated by the EPO. This means that an invention could be permitted by legislation or regulation but could still be found to contravene morality or ordre public principles. If, on the other hand, the prohibition by legislation or regulation is a necessary precondition for findings of morality and/or ordre public then the proviso is interpreted as being a necessary, albeit not sufficient criterion for findings of non-patentability. The Guidelines seem to support the latter approach:

Exploitation is not to be deemed to be contrary to "ordre public" or morality merely because it is prohibited by law or regulation in some or all of the Contracting States. One reason for this is that a product could still be manufactured under a European patent for export to States in which its use is not prohibited.¹⁰⁷⁷

This statement indicates that a European patent should be available even if the subject matter in question is prohibited in one state. This leads to the observation that the proviso is addressed to national legislation. The assessment of morality or ordre public based on legislative provisions in national legislation must therefore necessarily be taken into account even under the EPC, at least in the form of evidential proof of morality and ordre public.¹⁰⁷⁸

13.11 The Interface of Patent and Regulatory Law

The strongest general criticism of the morality exclusions in EPC (and the Bio-tech Directive) has come from the EPO, i.e. the Boards of Appeal, Opposition

¹⁰⁷⁸ The extent to which such evidence may be obtained is subject to procedural rules. See Section 10.3.
Divisions and examiners. In several of the decisions, reservations, especially from the Examining or Opposition Divisions, have been voiced about the ability of the EPO to act as a moral gatekeeper. There are several reasons why the EPO finds it difficult to deal with moral aspects in the patenting process. The most compelling reason is the wording of Article 53(a) EPC. The language of the provision refers to the 'commercial exploitation' of the invention, not the immorality of, for instance, granting a monopoly. As seen in Section 13.8.5, it is advocated in legal doctrine that the commercial exploitation should be assessed by including developmental aspects of the invention, as well as by assessing the immorality of the patent grant. The scope of assessment is thus challenged. Other often cited reasons for the difficulty of examiners to assess morality are the fact that moral standards are difficult to ascertain. They change over time and patent authorities lack the expertise to consider questions of ethics and morality. The fact that morality differs among European states is another reason for the difficult situation for the EPO.

In several decisions, especially regarding the use of gene technology to modify the genome of animals or plants, the Boards of Appeal have had to address the question of risk assessment required under the assessment in Article 53(a) EPC. This has been a contentious issue in particular from the point of view of the role and competence of patent authorities vis-à-vis regulatory bodies. For instance, the reasoning of the Board in PGS was based on the exclusive nature of the patent right in the sense that the right to exploit the invention did not stem from the patent and that such right is not unconditional. Still, the Board held that the ‘assessment of the hazards stemming from the exploitation of a given technology is one of the important duties of […] regulatory authorities and bodies’, but still made an assessment of the risks, which resulted in the conclusion that the perceived risks were not substantiated. This decision demonstrates that the Board recognised a duty of risk assessment as part of their mandate under Article 53(a) EPC.

This reasoning touches upon the very core of the justification of the morality clause. What is the purpose of a patent office trying to assess risks involved with a certain technology when this task is not their primary function or even duty and where the means and expertise for making such an assessment may not be fully present at the time of examination? Still, if the purpose of the morality clause is to function as some kind of filter for sorting out inventions that are immoral or contrary to ordre public, the result is that patent authorities find

1079 Enerson, 709.
1080 See e.g. the V 4/89, Reasons for the Decision, para 10.2 and Opposition Division decision of 16.08.2001 (LELAND STANFORD/Modified Animal), Reasons for the Decision, para 8(47) ff.
1081 Even though the Board made an interesting statement regarding the ‘positive right’ a patent entails. See T 356/93, Reasons for the Decision, paras 18.2-3.
1082 T 356/93, Reasons for the Decision, para 18.3.
1083 Cf. Sommer, 69 ff., especially regarding the precautionary principle.
themselves side by side with regulatory authorities, deciding on the same mat-
ters (including risk assessments). That is a result of the functioning of the
morality clause in the light of the methods that the EPO has implemented for
its application. This conclusion leads to the addressing the extent of EPO’s
mandate.

The effect of the focus on risk assessment is that EPO operates side-by-side
with regulatory authorities, which necessarily conduct their authority and make
their decisions (risk assessment etc.) under the framework of national and Eu-
ropean legislation and procedures – the same legislation that the EPO has de-
clared do not necessarily form part of the assessment with regard to Article
53(a) EPC, and at least do not function exclusively as a sufficient or even nec-
essary criterion for assessment. Its status as evidence is also debatable from
the point of view of the EPO.

The EPO has a natural filtering role to play as a first instance to which new
inventions and hence, new technologies appear in public. But this does not
mean that the EPO (or national offices) should make assessments of a nature
that involve considerations of risks (that in most cases have not yet material-
ized) especially where they have no particular means for investigation at their
disposal. Neither do they have a duty to investigate these matters within the
current patent system, apart from the possible effects on morality or ordre public
of the commercial exploitation of an invention.

The Examining Divisions’ premier source of information is the patent appli-
cation (as filed). The EPO is vested with a certain ex officio power in terms of
Article 114 EPC, and third parties may file observations under Article 115
EPC. Still, the nature of the patent granting process is not of the kind that read-
ily accommodates such considerations (at least not in the first stages), already
placed on the regulatory system with its specifically tailored procedures, legisla-
tion and mechanisms to assess and judging risks of new technologies, products
and processes. The operation of the EPO granting and appeal process will per-
haps also invite a different assessment on behalf of higher instances in relation
to Examining Divisions, since it is on appeal that arguments and evidence take
form and properly materialise.

The Boards of Appeal have consistently argued that risks, or hazards, have
to be conclusively documented in order to form part of the assessment. Other-
wise they are rejected as only possible and thereby unsubstantiated. Usually the
argument for this rejection is the negative rights conferred to the patent holder
– that the regulatory system has the ultimate power of granting marketing au-
thorisations and thereby preventing or permitting exploitation of the invention.

1085 The relevant balance of the patent and regulatory system is ultimately a task for the legislator.
1086 See Holtz, 264 ff.
But this stepping aside becomes very illogical when considering the task that the EPO evidently has put upon itself by inviting risk assessment as part of the tests for assessing the application of Article 53(a) EPC. But if the EPO should only deny patent protection in cases where the risks are so properly assessed, that it is quite clear that the invention will never achieve regulatory approval, then the effect of the assessment becomes null. It will also amount to an indirect recognition of the influence of national and European legislation on the patenting process – a fact which does not accord to the stance taken by the EPO in the recognitions of principles for application of the morality clause, namely the detachment from such legislation in the assessment of *ordre public* and morality.\(^{1087}\)

Leaving the EPO’s mandate in relation to risk assessment aside for the moment, a further issue to consider is the role of the EPO to act as moral censors in general.\(^{1088}\) The competence of the Office in this sense, regarding questions based on ethics, has been criticised from different perspectives.\(^{1089}\) In particular, the relevant expertise to evaluate ethical issues is held to be lacking, and the authority of the EPO to act in lieu of regulatory authorities can be questioned.\(^{1090}\) To remedy this alleged lack of relevant expertise, Agovic proposes the creation of a patent ethics committee at the EPO.\(^{1091}\) Agovic also suggests that the methodology for the ethics committee should be based on ethical theories with a common core value, namely, human dignity. Such theories include, but are not limited to, Kantian as well as utilitarian theories. The choice of ethical theory would be at the discretion of the ethics committee, and the decision would be reached through the exercise of a balancing test. The idea of bringing in ethicists as advisers has however not gained general support by commentators.\(^{1092}\) One reason may be the perceived increase in length of the patent application proceedings.\(^{1093}\) Other commentators suggest more transparency, making ethical evaluation a mandatory part of the patent application process, and properly training the examiners in moral thought.\(^{1094}\) It is evident that different moral approaches within patent law have gained in strength, not least due to the Biotech Directive and the focus on human dignity in the process of enactment. It is also apparent that the morality exclusion places patent examiners (and courts) in a position where patent law principles, pro-

\(^{1087}\) Cf. the reasoning of Laurie with regard to informed consent, but the argumentation is relevant in general. Laurie 2007, 223.

\(^{1088}\) The mandate of the EPO must be regarded against the background of the functioning of the European Patent Organisation and the more restrictive character of the harmonising efforts, compared to the EU. See Section 10.1.

\(^{1089}\) See Sommer, 62 ff. and Agovic, 293-294.


\(^{1091}\) Agovic, 306 ff.

\(^{1092}\) See e.g. Crespi, 163.

\(^{1093}\) Id.

\(^{1094}\) See Beyleveld, Brownsworth and Llewelyn, 162.
tection and control mechanisms (regulatory) and philosophy merge. But it is of vital importance to define the assignment given to patent granting authorities. The point of departure regarding the application of the morality clause must be the legal requirements found in the provision as such. The purpose of the exclusion is to prevent the patentability of inventions whose commercial exploitation would be contrary to *ordre public* or morality. The scope of the legal concepts (i.e. *ordre public*, morality, invention and commercial exploitation) necessitates clarification and confirmation of their limits, as evidenced from Sections 13.5-13.8. But the character of the patent granting process places an important role on the parties in the process to present substantiated facts and valid arguments.

A possible solution is to clarify the mandate of the patent system. The scope of application of the morality clause should consequently not be expanded, forcing the assessment into domains which should remain within the scope of competence of the regulatory system. If the morality clause is applied within the correct legal boundaries and with regard to the function of the patent system, then there is no need for recourse to ethics committees or any other types of supplementary bodies. Indeed, the expertise of patent examiners is in fact well suited for deciding issues raised under the morality clause without the need for recourse to moral expertise. The main role of the examiners is essentially to understand the translation of the patent claims into potential products or processes, i.e. how the technology specified in the patent adapts to the market once it evolves into particular subject matter. This expertise is adequate for performing the assessment required by the morality clause, provided that its interpretation is supported by external sources and coordinated in relation to the regulatory system.

13.12 Rule 28(c) EPC

13.12.1 Introduction

The presentation so far has been directed at an analysis of Article 53(a) EPC and the general requirements contained therein. Following the decision to introduce the Biotech Directive’s rules as a ‘supplementary means of interpretation’ to the EPC, the exemplifying list in Article 6(2) of the Directive became part of the EPC. This Section is devoted to the assessment of Rule 28(c) EPC,

1095 In this context, see the possibility of hearing of experts in Rule 117 EPC (Decision on taking of evidence) as well as the possibility of addition of a legally qualified examiner during the initial examination phase. (Guidelines for Examination in the European Patent Office (November 2014), e.g. D-V, C-VIII). This latter possibility is explicitly recognised in relation to Article 53(a) EPC, see Guidelines G-II, 4.1 and C-VIII, 7. See also Holtz, 74 ff.
and the effects of the reasoning in the WARF decision in relation to the general exclusion in Article 53(a) EPC.

Rule 28 of the Implementing Regulations states that:

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

By the nature of its inclusion in the Implementing Regulations and its relation to Article 53(a) EPC, the interpretation of Rule 28 EPC must follow the general principles established in relation to Article 53(a) EPC. The principle of narrow construction may have been abandoned in favour of a case-by-case analysis, but Rule 28 EPC cannot operate on its own but has to be related to the general umbrella created by the requirements found in Article 53(a) EPC. The exclusion in Rule 28(d) EPC has been subject to interpretation in two animal transgenic decisions, and the balancing test contained therein was analysed in connection to the application of Article 53(a).\(^{1097}\) The provision regarding the use of human embryos in Rule 28(c) EPC and its application on inventions concerning hESC caused major concern in two contentious decisions\(^{1098}\) which eventually led to an EBA referral for a final interpretation (WARF).\(^{1099}\) The findings in the normative WARF decision will be scrutinized in the following Section, and the findings of the EBA will be analysed in relation to their effect and impact, especially in relation to the general exclusion in Article 53(a) EPC.

13.12.2 The WARF Decision

First and foremost, the relevant assessment in WARF was exclusively conducted by an interpretation of Rule 28(c) EPC, namely the exception concerning ‘uses of human embryos for industrial or commercial purposes’. The question whether the patenting of the invention also contravened the general morality clause in Article 53(a) was not investigated, mainly due to the formulation of

\(^{1096}\) G 2/06 (Use of embryos/WARF).

\(^{1097}\) See T 315/03 and T 1262/04. The application of Article 28(d) EPC is analysed in Section 13.4.2.

\(^{1098}\) Opposition Division decision of 21.07.03 (Edinburgh) and T 1374/04 (Stem cells/WARF) (referral).

\(^{1099}\) G 2/06.
the questions by the referring Board. Since the EBA found that Rule 28(c) EPC was applicable to the present patent application, it was also – by default – held to be within the scope of Article 53(a) EPC.

The WARF invention stemmed from Thompson’s scientific breakthrough of isolating hESC from a human embryo and culturing the stem cells in vitro. The claims of the invention in WARF covered ‘[a] cell culture comprising primate embryonic stem cells’ (hESC). The use of human embryos was not claimed in the patent application under appeal. But as originally filed, the application contained the use of human embryos as being indispensable, as starting material for the generation of the claimed hESC cultures. This was amended and the application under scrutiny in WARF did only claim the hESC cultures as such.

The questions referred to the EBA read as follows:

1. Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?

2. If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: hESC cultures) which – as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?

3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?

4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: e.g. derivation from available human embryonic cell lines)?

The analysis will start with question two which was focused on the central issue, namely where the embryo exclusion in Rule 28(c) EPC covered also the human embryos not claimed in the application.

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1100 See G 2/06, Reasons for the Decision, para 32. The order and formulation of the questions determined that if an affirmative answer was found to Question 2 (‘[d]oes Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?’), Question 3 (‘If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?’) need not be considered.

1101 The fact that the EBA missed an opportunity to clarify the requirements also under Article 53(a) EPC is regrettable.

1102 See G 2/06, Summary of Facts and Submissions, para III, with reference to the decision of 13 July 2004 of the Examining Division, refusing European patent application No. 96 903 521.1.
The EBA started by defining the present invention as concerning ‘*inter alia* human embryonic stem cell cultures which at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which they are derived, said method not being part of the claims’. The EBA then continued by establishing the relevant sources for the interpretation of Rule 28(c) EPC, namely the Biotech Directive in conjunction with the general rules of the VCLT. Against this background the EBA concluded that it would ‘look at the ordinary meaning to be given to the terms of a provision in its context and in the light of its object and purpose, including the preparatory documents.’

The preparatory documents used by the EBA to interpret the background of Article 6(2)(c) of the Directive (in line with its function as a supplementary means of interpretation) consisted of the Opinion by the Economic and Social Committee of the European Parliament from 11 July 1996 (the Opinion), the amended proposal for the Directive submitted by the Commission in 1997 (the Amended proposal) and the Common Position EC No 19/98 adopted by the Council on 26 February 1998 (the Common Position). The preparatory works were used as a foundation for an interpretation which according to the EBA reflects the concern of the legislator, which in relation to Article 6(2)(c) was to ‘prevent a misuse in the sense of a commodification of human embryos’. Further support for the commodification argument was found in a reference to a decision by the German Bundespatentgericht (BPatG).

It is important to consider this statement in its original context within the Opinion. The EBA explicitly referred to the Amended proposal to specifically exclude the human embryo, which is correct in the sense that no express conclusion was yet made in the proposed Directive. On this issue the Committee stated:

> The human embryo, which is a special case, should be excluded from patentability under Article 3. The present wording of this Article does not in fact appear to offer this guarantee since the notion of the human body can be interpreted as not including the embryo. The Committee considers that it would be preferable to include this exclusion in Article 3 to give a higher political profile to the argument.

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103 G 2/06, Reasons for the Decision, para 15.
104 Id., para 16.
105 Id.
106 Id., para 17.
107 Id.
The purpose of the proposed amendment was thus to clarify the absolute ban on the patentability of the human embryo, which the Committee feared could be interpreted as not falling within the notion of the 'human body'. The only possible conclusion to be drawn from this statement is that the Committee wished to ensure the non-patentability of the human embryo per se.

The next statement of the Opinion specifically mentioned the Committee’s total opposition to the misuse of human embryos (which is the only place in the Opinion where the wording ‘misuse’ appears). This is done not in the context of embryo exclusion but rather concerning the proposed exclusion of eugenic practices seeking to modify the genetic code of the human being. With regard to this particular exclusion, the Committee held that:

The Committee fully approves the ban on the patentability of eugenic practices which seek to modify the genetic code of the human being. In the interests of clarity once again, and to indicate total opposition to practices involving the misuse of the human embryo, the Committee suggests that this sub-paragraph be replaced by the following text: ‘processes for modifying the genetic identity of germ cells of the human being and of future generations, including conception-related products’.

Although the statement ‘indicate total opposition to practices involving the misuse of the human embryo’ points to a perception regarding the protection of the human embryo which could be held to permeate the Opinion, this particular mentioning is made with regard the germ line process exclusion, and not regarding the embryo exclusion. What the Committee expressed in the Opinion was the fear of the non-patentability of the human embryo as such not being specifically regulated, as well as posting clarifying amendments regarding the particular articles in the proposal. The misuse is specifically mentioned only in relation to eugenic practices, and as we will see further in the analysis, it is thus far-fetched to read in a broader issue than that in the statements by the Committee. On the contrary, the specific amendments could be interpreted as clarifying a restrictive interpretation of the patentability of the human embryo only being prohibited per se.

There is not much information to be gleaned from the following Amended proposal either, other than the inclusion of an express exception for ‘methods in which human embryos are used’. But it is interesting that the EBA does not mention in its reference to the preparatory works that the exclusion in the Amended proposal did not come from the Opinion, but from the so-called Rothley report, which was quite vocal regarding the operation of the general

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morality clause (in a sense which restricted its application). 1111 No particular explanation was given as regards the exclusion for ‘methods in which human embryos are used’ though, which makes it difficult to know what specifically was envisioned.

In the following Common Position the exclusion was subject to a narrowing formulation, in that the wording was changed to cover only ‘uses of human embryos for industrial or commercial purposes.’ 1112 This narrowing intention was argued by the Appellant (patentee) in WARF, but the EBA did not concur with this conclusion. Thus, it is important to view the EBA references in its proper context, and to consider alternative possible interpretations drawn from the preparatory works, such as that human embryos per se were never regarded as patentable and also that the legislator only wanted to prevent a misuse of human embryos with regard to certain specified procedures. Further conclusions must be made with caution, especially considering the attitude of the Rothley report, a document not even mentioned by the EBA. 1113

The EBA found further evidence for its commodification argumentation by reference to the selective policy of the EU in the funding of stem cell research. The appellant had argued that the Community funding of stem cell research supports the idea that the legislator did not wish to exclude activities such as those within the present invention, which, according to the EBA, included the use (and destruction) of human embryos. According to the EBA, since Community funding was not available, it did not support the appellant’s argumentation. The EBA came to this conclusion despite the fact that Community funding under the 7th Framework Programme actually was available for research on subsequent steps involving hESCs, but not for the procurement of stem cells by destruction of human embryos. 1114 In the light of this dividing line for funding the EBA’s conclusion does not seem entirely logical. The reason for this must be that already here the EBA sees the destruction of embryos as an integral part of the invention, and not something that is merely a step preceding the actual invention (the stem cells as such).

1114 G 2/06, Reasons for the Decision, para 18, with further reference to the Council press release 11554/06 (Presse 215) of 24 July 2006.
The EBA concluded that the concept of ‘human embryo’ should not be interpreted in a restrictive manner, but that the concept is a ‘question of fact in the context of any particular patent application.’\textsuperscript{1115} The extent of the embryo definition was not a contentious issue in the decision, because it was decided that what was destroyed in the process of creation of the stem cells in the claims of the invention constituted human embryos.

The fact that the human embryos were not claimed in the invention did not affect the application of the exclusion. The EBA stated that Rule 28(c) EPC, as well as its counterpart in the Directive, did not refer to claims but to ‘invention’ in the context of its exploitation. This specific choice of wording entailed that:

What needs to be looked at is not just the specific wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed.\textsuperscript{1116}

In relation to the particular invention in question, the EBA held that:

Before human embryonic stem cell cultures can be used they have to be made. Since in the case referred to the Enlarged Board the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos, this invention falls under the prohibition of Rule 28(c) […] EPC […] To restrict the application of Rule 28(c) […] EPC to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.\textsuperscript{1117}

By confining the technical teaching not only to what is claimed but rather to involve also the making of the cell cultures, the argument by the Appellant that the exclusion goes too far if also steps preceding the invention are considered was refuted. This indicates a broad reading of the concept of invention, including the making of the products in question. In addition, the EBA addressed the concept of commercial exploitation and its effects on the invention.

\textit{13.12.2.2 Commercial Exploitation}

In the context of what should be regarded as ‘industrial or commercial purposes’ in connection the invention, the EBA stated that the making of a product is an integral part of its commercial exploitation:

\textsuperscript{1115} G 2/06, Reasons for the Decision, para 20.
\textsuperscript{1116} Id., para 22.
\textsuperscript{1117} Id.
A claimed new and inventive product must first be made before it can be used. Such making is the ordinary way commercially to exploit the claimed invention and falls within the monopoly granted, as someone having a patent application with a claim directed to this product has on the grant of the patent the right to exclude others from making or using such a product. Making the claimed product remains commercial or industrial application of the invention even where there is an intention to use that product for further research. On the facts which this Board must assume in answering the referred question 2, making the claimed product involves the destruction of human embryos. This use involving destruction is thus an integral and essential part of the industrial or commercial exploitation of the claimed invention, and thus violates the prohibition of Rule 28(c) [\ldots] EPC.1118

The EBA also discussed the possibilities of a narrow reading of the exclusion, as indicated in the process of enactment of the Directive, but concluded that it was not possible to apply such an interpretation in the present case, or at all.1119 Furthermore, it had been suggested that the present reading of the embryo exclusion was beyond the framework of Article 53(a) EPC as well as Article 27.2 TRIPS and therefore ultraviol. Although the EBA refrained from answering Question 31120 and thereby the opportunity to interpret the requirements of Article 53(a), it is apparent from the decision that the EBA did not consider the issue of commercial exploitation of the invention. The EBA directed the scope of the exclusion to a broad view of the invention, including (non-claimed) material as part of its development, but whether such interpretation entails the conclusion that the EBA actually includes developmental aspects under the concept of commercial exploitation is perhaps too far-reaching.

On the relation between Rule 28(c) and Article 53(a) EPC, the EBA indirectly treated the status of the Rule in relation to the question of whether the

1118 G 2/06, Reasons for the Decision, para 25.
1119 ‘However, this Board cannot detect such a narrowing. The reason given in Point 37 of the Common Position for this amendment is that a distinction was wanted between the uses of human embryos for industrial or commercial purposes, which were excluded from patentability, and inventions for therapeutic or diagnostic purposes applied to the human embryo and useful to it, the latter not being excluded from patentability. To clarify this exception from the exception, a new Recital 42 was introduced into the Directive. Thus, if anything, these reasons point in the direction of the opinion of this Board that in the present case human embryos are used for industrial or commercial purposes, since patentability was only considered if the invention was to the benefit of the embryo itself (compare also decision of the BPatG of 5 December 2006, loc. cit., point IV 3). That this is not the case here is evident, since the embryos used to perform the invention are destroyed.’ G 2/06, Reasons for the Decision, para 27. The relation between Article 6(2)(c) and Recital 42 explains the wording chosen in the text. But this does not alter the fact that the expression ‘methods in which human embryos are used’ is broader in application than ‘uses of human embryos for industrial or commercial purposes’, since the former relates to a range of applications with regard to a human embryo. It is difficult to state that ‘methods in which human embryos are used’, indicating a relation between the embryo and the method which allows for an interpretation in which a method which at any stage uses an embryo is excluded, is narrower in scope whereas the latter expression, which literally indicates a direct use of the embryo in question is broader. See in this regard Bostyn 2011, 17.
1120 ‘If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?’
provision was applicable to applications filed before the entry into force of the Rule in question.\textsuperscript{1121} From this point of view, the EBA took the position that Rule 28 contributed to the interpretation of Article 53(a) EPC by offering more detailed guidance than previously, but not changing the substantial requirements for patentability:

The introduction of this new chapter without any transitional provisions, can only be taken as meaning that this detailed guidance on what was patentable and unpatentable was to be applied as a whole to all then pending applications. […] Already by 1984 […] instrumentalization of the human body (as opposed to parts of it), thus degrading it to an object of technology, had been considered as a barrier to patentability. There is no indication that the commercial exploitation of human embryos was ever regarded as patentable.\textsuperscript{1122}

By such statement the EBA confirmed that Rule 28 is in fact founded on the pillar of case law with regard to Article 53(a) EPC, and is to be used as more detailed guidance to the interpretation of that particular rule. In addition, the EBA also confirms that it is the commercial exploitation of human embryos that is, in fact, excluded from patentability. In relation to the general morality exclusion in Article 53(a) EPC, the EBA further held that:

In this context [i.e. the performing of the invention is considered as commercial exploitation], it is important to point out that it is not the fact of the patenting itself that is considered to be against \textit{ordre public} or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts.\textsuperscript{1123}

The differences between the wording of ‘industrial or commercial exploitation’ in Rule 28(c) and ‘commercial exploitation’ in Article 53(a) was unfortunately not elucidated by the EBA. The use of the two concepts as interchangeable indicates that the outcome of interpretation would have been the same under Article 53(a) EPC.

\textit{13.12.2.3 Effects of WARF}

The effects of the \textit{WARF} decision were confirmed in the later decision \textit{Stem cells}.\textsuperscript{1124} A patent application entitled ‘Mammalian multipotent neural stem cells’ was rejected by the Examining Division for lack of novelty (in parts) and for contravening the provisions of Rule 28(c) EPC. Claim 1 of the main request

\textsuperscript{1121} G 2/06, Reasons for the Decision, para 13.
\textsuperscript{1122} Id.
\textsuperscript{1123} Id., para 29.
\textsuperscript{1124} T 522/04 (Stem cells/CALIFORNIA).
was directed towards a method of proliferating *in vitro* a clonal population of neural crest stem cells of mammalian origin, which also covered the mammalian neural crest stem cells as such. Claim 1 of the first auxiliary request differed from the main request in that the phrase ‘wherein the cells are not derived from an embryo’ had been added to the preamble just after the words ‘mammalian neural crest stem cells’. Claim 1 according to the second auxiliary request went even further regarding the source of the material, in that the phrase ‘capable of being derived from adult tissue’ had been added, just after the words ‘mammalian neural crest stem cells’.1125

The Board of Appeal found that Claim 1 of the main request clearly included (stem) cells of human origin and thus fell under the embryo exclusion in Rule 28(c) EPC. The patent application even contained in its description and examples an isolation process in which an early embryo is dissected for the purpose of obtaining the base material for the invention.1126 The fact that Claim 1 did not include this process did not change the status of the invention as being unpatentable, for the reason that the Board of Appeal regarded the only teaching of how to prepare human neural crest stem cell cultures as the use (involving their destruction) of human embryos.1127

Unfortunately, the two auxiliary requests were dismissed on formal grounds. The auxiliary requests were introduced into the patent application after the dismissal by the Examining Division. No changes were made regarding the rest of the application, which still contained the methods described in relation to the main request. Thus, the Board of Appeal held that the features introduced by the auxiliary requests intended to provide a technical teaching. However, they had no support in the application as filed, since no technical disclosure other than isolation from embryos was found. This resulted in the conclusion that the introduction of those features in the claims amended the application in such a way that it contained subject matter extending beyond the content of the original application as filed.

The Board could not test the auxiliary requests from a material perspective, which would have been very interesting. Such an assessment would have been an indicator of how far the destruction of embryo-reasoning stretches, when a

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1125 Claim 1 of the main request read: ‘1. A method of proliferating *in vitro* a clonal population of mammalian neural crest stem cells, wherein the cells are cultured *in vitro* in a feeder cell-independent culture medium on a substrate, wherein the culture medium does not contain foetal calf serum to produce a population of neural crest- stem cells and differentiated progeny thereof, wherein the neural crest- stem cells are characterised by being capable of self-renewal in the culture medium and capable of differentiation to progeny cells that are peripheral nervous system neuronal or glial cells, wherein said neural crest- stem cells express low-affinity nerve growth factor receptor (LNGFR) and nestin, but do not express glial fibrillary acidic protein (GFAP), and wherein progeny cells that are peripheral nervous system neuronal cells do not express LNGFR or nestin but do express neurofilament and progeny cells that are peripheral nervous system glial cells express LNGFR, nestin and GFAP’. T 522/04, Summary of Facts and Submissions, para V.

1126 T 522/04, Reasons for the Decision, para 5.

1127 Id., para 7.
claim is expressly formulated as containing material not derived from an embryo. Of course, based on the reasoning by the EBA, such a claim would not matter if the material used was based on material derived from an embryo. Since at this point in time, there exists no other way of procuring hESCs (and resulting material) other than the use of human embryos, thereby involving their destruction, the outcome would have been in line with the case law established in WARF.

13.12.2.4 Expansion of Rule 28 under Article 53(a) EPC?

The objections recognized by the EBA in the WARF decision are to a large extent dependent upon the formulation of the questions by the referring Board of Appeal. The focal Question 2 asks whether ‘Rule 23d(c) [now 28(c)] EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?’

This construction of the question sets the framework for the assessment. By such a formulation the preparation of the invention, and hence the development of the same, becomes crucial for the decision regarding patentability. The possibility for the EBA to disregard the developmental aspects of the invention is still present, because the developmental aspects are not part of the claims. The EBA, however, chose to include an extremely broad range of developmental aspects in the assessment of patentability, in contrast to the established standard where the invention, i.e. the claims including the description, was the only matter under scrutiny.

From the reasoning of the EBA in WARF three important points may be deduced:

(1) The EBA considers developmental aspects of the invention as an integral part of the term commercial exploitation (making of the invention);
(2) The EBA considers the scope of invention as being equal to the acts included in the monopoly granted; and
(3) The reference to ‘uses […] for industrial or commercial purposes’ in Rule 28(c) denotes a part of the concept of commercial exploitation, and is not to be considered as a stand-alone prerequisite.

It is quite clear from the text of the decision that the EBA considers the invention to consist of actual procurement of hESCs from human embryos. The reasoning is directed upon establishing the matter of embryo destruction in relation to the invention, rather than testing the actual prerequisites of the em-

1128 G 2/06, Summary of Facts and Submissions, para 1, 2.
bryo exclusion. The EBA would presumably have reached the same conclusion, i.e. the denial of patentability, without recourse to the introduction of the concept of embryo destruction, by simply concluding that the invention requires the use of embryos (notwithstanding their eventual destruction). But the reasoning of the EBA opens up an area of legal uncertainty, since the actual guidelines as to the interpretation of the embryo exclusion, consists of the introduction of the concept of embryo destruction, a concept which does not even exist in the legal text – it is therefore not an actual legal criterion. The EBA could have arrived at its conclusion of non-patentability simply by applying the terms of the embryo exclusion without adding unnecessary provisos. The result would have been that the WARF application would still have been considered unpatentable, but the exclusion would have had more firmer and predictable boundaries.

It is a fact that the embryo exclusion, as well as the other three examples in Rule 28, has been placed under Article 53(a) EPC and are but examples of inventions fulfilling the terms of the latter. Although the origin of the list is Article 6(2) of the Biotech Directive, the placement of the list under the morality clause (both in the Directive as well as the EPC) means that due account must be paid to the already established principles of interpretation for Article 53(a) EPC. The inventions excluded by Rule 28 consequently need to fulfil the prerequisites of Article 53(a) EPC – they are by definition examples of inventions considered by the Member states of the European patent organisation to fulfil the criteria of Article 53(a). This relation was confirmed also in WARF.1129 But it becomes problematic when considering the established case law with regards to the inclusion of developmental aspects under the commercial exploitation concept, where a narrow view is endorsed by the Boards of Appeal.

Two alternative effects are possible following the WARF decision for the understanding of the commercial exploitation concept. The first is that the interpretation of Rule 28(c), if considered correct, necessitates the taking into account of developmental aspects in the assessment of the applicability of the exclusion, and thereby including such under the concept of commercial exploitation. From this point of view, and against the background of the principles of established case law of the Boards of Appeal, the scope of Rule 28(c) would actually be broader than the scope of Article 53(a) EPC. The second alternative is that the EBA considers the concept of invention to include also its making (i.e. development), indicating a broad interpretation exceeding the standard claims scope. A change of interpretation is thereby indicated compared to the findings in, for instance, G 1/98 (Transgenic plant/NOVARTIS II) Oncomouse II, Euthanasia compositions and Breast and ovarian cancer. Certainty on these issues can only be reached through an actual Article 53(a) EPC assessment with re-

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gard to a similar type of invention, and this was never formally tried in WARF. The statements by the EBA nevertheless indicate such a reading.

13.12.3 The Importance of Human Dignity

Rule 28 EPC rests on the basis of Article 6(2) of the Biotech Directive, where it is evident that the protection of human dignity was a major concern in the enactment process, resulting in the exemplifying list.\textsuperscript{1130} Although at least two different moral approaches exists within the four examples of Rule 28 (utilitarian test in 28(d) and human dignity in 28(a)-(c)), the EBA identified the purpose of the embryo exclusion in Rule 28(c) as to prevent a misuse in the sense of a commodification of human embryos, to protect human dignity and to prevent a commercialisation of human embryos.\textsuperscript{1131}

As mentioned in Section 13.4.2, Rule 28 EPC belongs to a norm category which is lower than Article 53(a) EPC due to the norm hierarchy between of the EPC and its Implementing Regulations, and Rule 28 must necessarily be interpreted in relation to Article 53(a) EPC. If Article 53(a) EPC sets the outer limits of the general morality clause, the presumption is that the interpretation of Rule 28 must not exceed the framework of Article 53(a). From this point of view the WARF decision either implies a shift in legal practice or points to the fact that Rule 28 can (and perhaps requires) an interpretation which stands free from the requirements of Article 53(a).

The analysis of the outcome of the WARF decision has shown that in relation to Article 53(a) EPC, the concepts of ‘commercial exploitation’ and ‘invention’ are interpreted in a very broad fashion which is contrary to earlier statements in legal practice.\textsuperscript{1132} This could imply a change in legal practice that will have effects also on the general assessment according to Article 53(a) EPC. On the other hand, Rule 28(c) EPC contains an explicit exclusion for ‘uses of human embryos for industrial or commercial purposes’ and the resulting interpretation indicates an operation of the embryo exclusion that is freestanding from the general exclusion in Article 53(a) EPC. The fact that the rules on Rule 28 all have their own formulations and should – perhaps – be interpreted literally, lends support to this conclusion.

Nevertheless, in an overall balance of relevant issues, e.g. the norm hierarchy, the statements in legal practice and the origins of Rule 28, the logical conclusion must be that Article 53(a) must still be relevant for the operation of Rule 28(c) EPC. In addition, the alleged consensus to exclude the subject matter contained in Rule 28 EPC from patentability does not extend to the regula-

\textsuperscript{1130} See Section 14.3.2.
\textsuperscript{1131} G 2/06, Reasons for the Decision, para 18, 20.
\textsuperscript{1132} Cf. T 866/01, T 315/03 and T 1213/05.
tory legislation, since there is no consensus in Europe on the question of whether uses of human embryos is morally permissible or not according to national laws.\textsuperscript{1133} It must be stated, however, that different opinions exist on whether the commercialisation of products derived from the destruction of human embryos is actually allowed (not least with regard to Article 18.2 of the Convention of Human Rights and Biomedicine).\textsuperscript{1134} Nevertheless, the effects of the broad interpretation in \textit{WARF} require legal guidance that could only be reached through an Article 53(a) EPC assessment in relation to an invention regarding human biological material.

Despite the alleged broad interpretation of Rule 28(c) in relation to the concepts of commercial exploitation and invention in Article 53(a) EPC, it is a fact that the wording 'uses of human embryos for industrial or commercial purposes' was also broadly defined in itself.\textsuperscript{1135} The reason for these broad interpretations, both in relation to Article 53(a) and Rule 28(c) EPC is presumably that the issues involved concerned human dignity and certain principles such as non-commodification and non-commercialisation, which cannot be compromised. Thus, the outcome mirrors the rebuttable presumption test, but does not adhere to a standard of abhorrence.

Furthermore, the concepts of 'commercial purposes' and 'commercial exploitation' are not only broadly defined but considered as implied in the exclusive right.\textsuperscript{1136} Such a view makes an assessment of the commercial exploitation on the market unnecessary, since it is implied in the exclusive right. The position of regulatory legislation is consequently not of interest in such an interpretation, since the exclusion under such an interpretation is directed towards the immorality of the act of granting; to put the applicant in a monopoly position in relation to the subject matter of the invention. Even though the legal criteria, as defined and delimited in earlier decisions, do not correspond to the outcome in \textit{WARF}, the interpretation is nevertheless in line with the arguments by some commentators.\textsuperscript{1137} When the invention concerns human dignity, the focus of the exclusion is on the monopoly position awarded to the patentee. Consequently, the legal criteria are tailored to reach the purpose of not compromising human dignity, of which \textit{WARF} is an indication of.

\textsuperscript{1133} See e.g. Plomer 2009:1, 191.

\textsuperscript{1134} See Plomer 2009:1, 190 ff. and Sterckx 2008, 492 ff.

\textsuperscript{1135} See Plomer 2009:1, 190 ff. (advocating a narrow construction of the morality exclusion in Article 6(2)(c) of the Biotech Directive, with equal effect on Rule 28(c) EPC), and Hellstadius 2009, 132 ff. (on the more narrow approach to Rule 28(c) EPC of some national patent offices pre-\textit{WARF}). Cf. Sterckx 2008, 485 ff. (explaining why \textit{WARF}'s patent must be excluded even under Article 53(a) EPC).

\textsuperscript{1136} See Sterckx 2008, 492.

\textsuperscript{1137} See Moufang 1994, 507, Beyleveld, Brownsword and Llewelyn, 179 and Sterckx 2008, 492.
13.13 A Necessary Direction for Article 53(a) EPC

The interpretation of Article 53(a) EPC rests on three general principles. The first principle is the perceived nature of Article 53(a) EPC as an exclusion to the general entitlement of patent, and in terms of interpretation as well as the background of the EPC system, such exclusions should be interpreted narrowly. This principle seems to be accepted but not without exception. Even though there is repeated confirmation from the EPO Divisions and Boards of Appeal of the narrow construction, case law likewise opens up for an analysis on a case-by-case basis. Following WARF, deviation from the principle of narrow construction is not only acceptable but appears recommended.

The second principle is the affirmation by the last sentence in Article 53(a) EPC, that a prohibition by national law or regulation in some or all of the Contracting states does not merely equal exploitation contrary to \textit{ordre public} or morality. From such an indication follows that the establishment of \textit{ordre public} or morality concerns must be based on factors not merely related to national laws or regulations. National laws or regulations can be taken into account but a national prohibition may not serve as an automatic criterion for the application of Article 53(a) EPC. At least this is not advocated by the EPO. The effects of such national (or European) prohibitions in relation to the interpretation of Article 53(a) EPC is still subject to discussion, where on the one hand it is held that if the exploitation of an invention is permitted then patent protection cannot be refused on the basis of Article 53(a) EPC.

Conversely, the existence of a legal or factual prohibition of the exploitation of the invention does not render an invention automatically unpatentable, but a further assessment is necessary for the denial of patent protection under the morality clause. This interpretation is apparently in line with the principle of the narrow interpretation as well as the principle that Article 53(a) EPC should only be applied in rare and extreme cases. On the other hand, the EPO has repeatedly (with few exceptions) insisted on making the assessment of breach of the morality clause independent from the existence of national or European legal prohibitions, despite convincing arguments for taking such prohibitions (or permissions) into account, not least with regard to the requirements of Article 27.2 TRIPS.\textsuperscript{1138} When the assessment of immorality is detached from the regulation on exploitation, there is a risk that an invention may be found unpatentable without a corresponding prohibition on its commercial exploitation.

The third principle is that the intended exploitation of the invention must be exclusionary contrary to \textit{ordre public} or morality. If an invention has several uses of which at least one is non-contrary, then Article 53(a) EPC is not applicable.

\textsuperscript{1138} See Sections 12.7 and 12.8.
On the basis of these general principles the primary conclusion with regard to Article 53(a) EPC is that its application is restricted in several regards. There are solid arguments for its narrow application, at least as a point of departure in its interpretation. The existence of a national prohibition does not suffice to render an invention non-patentable, but a further analysis is required from the EPO Divisions and Boards of Appeal. The avowed use in the patent application must be exclusionary contrary to *ordre public* or morality, otherwise it is not applicable.

The distinction and assessment of the individual elements in Article 53(a) EPC is of profound importance. The scope of application of the provision is dependent on the interpretation of its individual elements, and in Article 53(a) the assessment of the prohibition is dependent upon the following terms and their internal relations: inventions, commercial exploitation, and contrary to *ordre public* or morality.

*Ordre public* and morality are usually treated as two separate concepts. The content of the *ordre public* concept seems to possibly contain public policy considerations, including environmental concerns, but its scope is debated and it is not clear from the EPO case law how far the protection in relation to *ordre public* reaches. The EPO approach seems to be narrower than the broader public policy-concept, which includes fundamental principles of the legal system, usually ethically-established norms of vital significance. The focus of the Boards has been on enumerating interests to be protected under *ordre public* such as public security, physical integrity of individuals and the environment as well as defining positive law to be taken into account, such as e.g. ethically based constitutional or other rules, usually backed up by penal provisions. The latter definition stems from *Euthanasia compositions* and seems to include also aspects usually connected to the concept of morality. This is closer to the stance argued by commentators than the more narrow position taken by the TBA in *PGS*. The Boards have also been reluctant to discuss the notion that if *ordre public* is defined as a body of certain laws (constitutional or lesser status could be discussed), the commercial exploitation of an invention is only contrary to *ordre public* if it is prohibited by law.

There seems to be a consensus in defining morality as a body of norms which are ethically based, and their legitimacy as such norms stems from their status as being generally accepted standards of behaviour; standards which are deeply rooted in a particular culture. The application of Article 53(a) EPC in relation to morality thus requires the assessment of whether the commercial exploitation of the invention in question is to be regarded as reprehensible by society in general or at least by the trade concerned, i.e. in breach of the by society generally accepted norms.1139 This methodology may seem attractive in

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1139 T 866/01, Reasons for the Decision, para 6.12.
theory. It is more difficult to implement them in a practical assessment, a fact that has already been recognized by the Boards themselves. The standard rather gives rise to adjacent questions of evidence while leaving the interpreters of the EPC with a method for establishing morality that, according to the statements of the Board, is quite impossible to use already from the start. In addition, the methodology of different tests and standards is not consistent.

The approach taken by the Boards to objections confirms an inconsistency in their view of the concept of commercial exploitation, namely whether developmental and other issues are included in the assessment.

The effects of withholding patent protection for an invention whose commercial exploitation is found to be contrary to morality or _ordre public_ is that it would be free for anyone to exploit the invention. If there exist no prohibitions on its exploitation, the effect would be that no monopoly would exist for its exploitation. If the patent office has reached its decision with the use of the balancing test-methodology, in the case of e.g. genetically modified animals where the benefits to mankind does not balance against the suffering of the animal, the result will perhaps lead to a situation where more test animals can and will be used, and thus suffer. Or in the case of risks to the environment – would the patent office find substantiated risks and thus deny patent protection without corresponding regulatory prohibition, the result would be an invention free for all to use which implies raised environmental risks.

What is then the purpose of having the patent office investigate all these possibilities and make their own assessments of the risks or suffering involved in the invention? Well, the focal point is then the monopoly position that the patentee will gain by the granting of a patent for an immoral invention. The prevention of such a monopoly position is thus the aim of the patent system morality clause, because the effect of its application will not be the prevention of use of the invention – at least not upfront. The denial of patent protection will undoubtedly lead to a shortage in funding and thereby prevent the development or application of inventions within the field in question. But it will not prevent the use of the invention as such, due to the nature of the patent as an exclusionary right.

The prevention of the monopoly position, the ultimate sanction possible in the patent system, is the effect of the application of the morality clause. If the aim of the legislation were to act as a filtering mechanism, to sort out and prevent the stamp of approval from society for inventions which are truly abhorrent, should not that denial of a monopoly position require some interaction with the rules regulating the use (in society) of such inventions? If such correspondence is neglected in the patent law assessment of the application of the morality clause, the result is that inventions considered immoral by the state in terms of the patent system are free for anyone to use and commercialise. Surely, an invention so truly abhorrent that the granting of a monopoly position must be deprived, must also be prohibited from use in society? The removal of ex-
clusivity should therefore correspond with a prohibition on its use, or the patent law morality assessment will lose its credibility.

If no correspondence should exist, then the reasoning must turn to the next probability, namely that the function of the morality clause is to prevent a situation in which the commercial exploitation of an invention is abhorrent, and therefore should not enjoy a state monopoly. But it must also be possible to imagine that uses other than the commercial exploitation of the invention could be regarded by society at large? Is there a difference between the commercial exploitation and the invention as such, or perhaps the act of granting a patent for the invention, in this regard?

By such reasoning it becomes important to define exactly what is meant by commercial exploitation. Is it the marketing and sale of a specific invention? It also matters how broadly the concept of commercial exploitation is defined. For instance, if it is truly the future use of the invention, i.e. the marketing and sale of the invention, then this is a rather narrow interpretation of the concept.
14.1 Structure

An analysis of the effects of the introduction of the morality clause in the EU legal system requires a focus on Article 6 of the Biotech Directive. An understanding of this version of the morality clause, however, requires a point of departure that embraces the broader legal context and background, especially regarding the concepts of *ordre public* and morality. Before entering into the CJEU’s application of the clause, Section 14.2 depicts the position of the Court in relation to the operation of *ordre public* and morality in the context of free movement under the Treaty. Against this background, Section 14.3 describes the challenging process of the enactment of the Directive and the considerations reflected in the process behind the introduction of the morality clause. The legal analysis of the EU morality clause is conducted in Chapter 15.

14.2 Morality and Ordre Public in EU Law

When treating the morality clause within the EU setting, it is necessary to ponder the broader context for the operation of the terms of morality and *ordre public*. Not only have the concepts of *ordre public* and morality a long history as criteria for the lawfulness or the grant or exercise of IP rights, nowadays also in significant EU legislative acts, but they (especially *ordre public*) have also a wider significance in EU law. For instance, Arts. 36, 45, 52 and 65 TFEU all refer to *ordre public* (in French) or public policy (in English) as grounds for permitted prohibitions or restrictions of the principle of free movement. Public morality (bonnes moeurs/moralité publique), on the other hand, only occurs in Article 36 TFEU, in the context of derogation from the principle of free movement of goods. It has been discussed in the context of other fundamental freedoms as well, for instance regarding the freedom to provide services.

Under the Treaty, Member states are allowed an area of discretion with regard to the particular circumstances justifying recourse to the concept of public policy. The concept of *ordre public* is likewise used in the harmonising measures applied by the EU legislature, and no apparent contradiction is expected by conferring a degree of discretion on national authorities even in harmonized areas. The scope of discretion given to the Member states is firmly set

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1140 Of goods, workers, establishment and capital respectively. Article 36 (goods) likewise refers to 'moralité publique'/'public morality'.

1141 Bakardjieva Engelbrekt 2009, 238.

by the CJEU in a restrictive manner. The following Sections are devoted to a
description and analysis of the division of competences between the Member
states and the EU as regards the recourse to derogations based on ordre public
and morality concerns in the context of free movement, including exploration
of their content. This broader EU context serves as a background for the un-
derstanding of the operation of the concepts in the patent law setting.

14.2.1 Ordre public

It is suggested that the concept of ordre public/public policy in the EU setting
covers mandatory rules from which there is no possibility for deviation. For
instance, the protection of fundamental (human) rights serves as a founda-
tion for the concept in many cases, both as regards the treaties and secondary
legislation. Where compatibility of national legislation with EU law is at issue,
the CJEU leaves a room for manoeuvre for national discretion, but the Court
still asserts jurisdiction and aims at providing guidance for national courts on
their interpretation. The CJEU asserts a broad scope of jurisdiction in cases
regarding free movement, even though the possibility for legislative review does
not exist, in principle, where national legislation is outside the scope of EU law.
But the Court has been reluctant to actually exclude phenomena by definition
(as e.g. product or services) from its jurisdiction, and situations where the Trea-
ty is deemed inapplicable are consequently rare. Despite this assertion of jur-
sdiction, the Court has been cautious to actually rule issues with (specifically)
moral or public policy implications, which has been left to the discretion of
Member states.1144

The expansion of fundamental rights protection in the EU culminated with
the entering into force of the Lisbon Treaty, where the EU Charter of Funda-
mental rights was proclaimed legally binding. The CJEU have been consistent
in recognizing fundamental rights (in particular as laid down in the ECHR) as
part of the EU legal order and ensuring observation of these rights under EU
law. Fundamental rights formed part of EU law early on, as general principles
common to all Member states, subject to the overall objectives of the EU.1145
The cases where fundamental rights are seen as part of the broader concept of
public policy are many, and the Court has repeatedly stated that public policy
considerations as grounds for justifications for restrictive measures need to be
interpreted strictly and ‘its scope cannot be determined unilaterally by each

1143 Or fundamental values of social, cultural or economic origin.
1144 See e.g. Bakardjieva Engelbrekt 2009, 241 and Shuibhne, 72.
1145 See Case 29/69 Erich Stauder v City of Ulm, Judgment of the Court of 12 November 1969 and Case 11/70
Internationale Handelsgesellschaft mbH v Einfuhrgemeinde für Getreide und Futtermittel, Judgment of the Court
of 17 December 1970. See also de Vries, 169 ff. and Bakardjieva Engelbrekt 2009, 241, with further reference
to Hartley.
Member State without being subject to control by the institutions of the Community. Thus, the CJEU has declared itself authorized to give national courts the necessary guidance to assess the compatibility of national law to fundamental rights. National authorities are nevertheless granted a certain degree of discretion to decide on the content of the *ordre public* concept, even though it is emphasized that not every infringement of national law can be regarded as a violation of public policy. It necessitates ‘the existence […] of a genuine and sufficiently serious threat to the requirements of public policy affecting one of the fundamental interests of society’. Such fundamental interests are for instance found in the ‘constitutional traditions common to the Member states’, and safeguarding of these fundamental interests requires that measures incompatible with fundamental rights recognized by national constitutions should not be upheld.

But even constitutional principles protecting fundamental rights which are not common to the Member states should, in principle, be respected. The discretion of Member states to protect fundamental rights as subject to national views is quite broad, and there is no need for commonality in the system of protection between the Member states.

For instance, in the *Omega* decision, the entertainment *Laserdrome* (a game of shooting opponents with laser guns) was prohibited by the German state North Rhine-Westphalia with the argument that they constituted a violation of public order, whereas *Omega* (the company operating the entertainment service) claimed that the order was contrary to EU law and the principle of free movement of services. The CJEU decision centred on whether the principle of human dignity as enshrined in the German constitution could justify the derogation from the principle of free movement, and the Court respected the national concern regarding respect for human dignity. Of importance is the interpretation by the Court that the respect for the notion of human dignity is part of the EU system of fundamental rights and not as part of national (in this case, German) law, but room for national views on the protection of human dignity still exists under the EU system. Consequently, there was no attempt to impose the same standard of protection on the UK, where similar games were

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1146 Case 36/75 Roland Rutili v Ministre de l'intérieur [ECR] 1219, paras 27, 32.
1151 Case C-36/02 Omega [2004] ECR I-9609, paras 33-35.
allowed. It is of interest to note that the CJEU has admittedly refused to place the level of protection in the EU to the greatest offered among the Member states.\textsuperscript{1152}

In the area of secondary EU law, where a measure of positive integration is at issue, the (albeit limited) case law shows a similar leeway for national authorities to interpret \textit{ordre public} as in non-harmonised areas. There is thus no apparent contradiction in leaving such discretion and still achieving a desired level of harmonisation.\textsuperscript{1153} Many of the secondary EU instruments contain \textit{ordre public} and/or morality exceptions, notably in the field of IP where such exceptions are habitually included.\textsuperscript{1154} As a general rule, the more detailed the secondary law is, such specific provisions need to be taken into account. On the other hand, where reference is made to concepts without further guidance, the Court has retorted to the logic of the case law on free movement.\textsuperscript{1155}

14.2.2 Morality

The CJEU has allowed Member States a wide margin of discretion in the justification of measures on public morality grounds under the Treaty, and in the rare decisions where this has been a separate ground of justification the issues have been in the sense of sexual and private morality.\textsuperscript{1156} With regard to secondary EU law, the same principle as for \textit{ordre public} concerns apply, namely that specified provisions require Member states to take such into account, but where more open concepts are used, principles drawn from the case law on free movement may support the assessment.

National views on morality have been recognized as justified derogations from the principle of free movement, under the requirement that such derogations do not cause arbitrary discrimination between the states. In \textit{Henn and Darby}\textsuperscript{1157}, the UK prohibition on the import of goods (films and magazines) with violent and sexually explicit nature (originating in Denmark) was allowed due to public morality concerns, in essence because there was a national prohibition in

\begin{itemize}
\item \textsuperscript{1152} See Case C-244/06 Dynamic Medien Vertriebs GmbH v Arides Media AG, [2008] ECR I-505, paras 44-45. See also e.g. Bakardjieva Engelbrekt 2009, 242, with further references to Smith and Fetzer, and Weiler.
\item \textsuperscript{1153} See e.g. the Opinion of Advocate General Jacobs delivered on 14 June 2001 in Case C-377/98, Netherlands v Parliament and Council, para 102.
\item \textsuperscript{1154} See the Opinion of Advocate General Jacobs delivered on 14 June 2001 in Case C-377/98, Netherlands v Parliament and Council, para 96. An analysis directed towards finding a common, all-valid approach of the \textit{ordre public} exceptions in trade mark, design and patent law respectively will naturally result in null as there are differences regarding the policy area (notably patent law), precision of legislative act and justification techniques. See further Bakardjieva Engelbrekt 2009, 243. Cf. Wennersten’s analysis of the practice regarding Community trade marks and designs, 314 f., 342 f., 450.
\item \textsuperscript{1155} See e.g. Case C-100/01 Ministre de l'Intérieur v Aitor Otteza Olazabal, [2002] ECR I-10981, para 48.
\item \textsuperscript{1156} Case 34/79, Regina v Maurice Donald Henn and John Frederick Ernest Darby (Henn and Darby), [1979] ECR 3795 and Case 121/85 Conegate Limited v HM Customs & Excise (Conegate) [1986] ECR 1007.
\item \textsuperscript{1157} Case 34/79, Regina v Maurice Donald Henn and John Frederick Ernest Darby, [1979] ECR 3795.
\end{itemize}
force for products manufactured within the UK. In *Conegate*\(^{1158}\), on the other hand, an UK import restriction targeting inflatable dolls of a sexual nature and other erotic products (from Germany) was not justified on the grounds of public morality because the UK legislation did not contain a similar prohibition on the manufacture or marketing of the same goods on its territory.\(^{1159}\) In both cases, the Court held that ‘in principle, it is for each Member State to determine in accordance with its own scale of values and in the form selected by it the requirements of public morality in its territory’.\(^{1160}\) The margin of appreciation for national authorities to apply the concepts of *ordre public* and morality is, however, not without boundaries, as their decisions will always be subject to review by the CJEU under the Treaty. But as mentioned, the Court is reluctant to impose common standards in this respect.

Morality in relation to divergent religious and ethical traditions has been subject to a number of cases. In *Torfaen Borough Council*\(^ {1161}\) restriction on Sunday trading was justifiable on grounds of public morality due to religious-based objections. Whilst Advocate General van Gerven held that the prevention of offence to religious convictions did not fall within the concept of public morality, the Court did not take a stand on this particular point in the judgment.\(^ {1162}\) In later cases the issue of religious aspects of morality has been transferred to arguments related more to public policy than morality.\(^ {1163}\)

The issue of public morality within the area of harmonized law was discussed in a decision related to quantitative restrictions on exports of calves for rearing in veal crates from the UK.\(^ {1164}\) A refusal by the UK minister to prohibit the export was subject to judicial proceedings brought by a private party (an animal welfare body). The CJEU found that claims related to public policy or morality could not be relied upon to justify prohibiting intra-Community export under Article 36 TFEU. Although the protection of public policy or morality was not subject to harmonisation as such, the claims as to these topics were in the view of the Court related to an aspect of the justification relating to the protection of animal health. As such, they were included in the scope of a Directive regulating these matters, and derogation from the rules was simply not

1158 Case 121/85 *Conegate Limited v HM Customs & Excise* [1986] ECR 1007.
1160 Case 34/79 *Henn and Darby*, para 15 and Case 121/85 *Conegate*, para 14.
1164 Case C-1/96 *R. v. Minister of Agriculture, Fisheries and Food, Ex parte Compassion In World Farming Limited* [1998] ECR I-1251.
possible due to the full harmonisation of the specific field at hand. The Court did, however, expand on the question of whether a Member State can rely on Article 36 to restrict export for reasons related to public policy or morality not subject of the Directive. Of interest is the statement related to how Member States are to determine the content of public policy or morality:

In any event, a Member State cannot rely on the views or the behavior of a section of national public opinion […] in order unilaterally to challenge a harmonizing measure adopted by the Community institutions.

Thus, the Court ruled out a standard of morality based on a section of national public opinion. This rejection of public opinion as a basis for morality is not foreign to patent law as it has been repeatedly held in EPO practice that opinion polls cannot function as a standard for establishing morality. The statement of the CJEU has, on the other hand, been subject to criticism as the weight attached to specific groups of public opinion should be a matter for the national constitutional order to decide, and not the CJEU.

In essence, the CJEU tends to leave a broad margin of discretion to the Member states in relation to morality, especially regarding questions of a private nature. But the separation of issues of public policy and public morality is not always clear on behalf of the Court, and there is undoubtedly a blurring of concepts from the point of view of morality. On the other hand, public policy (ordre public) is more easily separated as its relation to legislation is often discussed when searching for a definition of content. But public policy tends to be used as a justification only after every other means is exhausted.

National legislation outside of the scope of EU law can never be subject to jurisdiction of the Court, but as mentioned, activities per se are rarely excluded from the scope of the Treaties. Instead, the Court navigates sensitive issues from the point of view of justification and proportionality. In Grogan, for issues related to morality in terms of the termination of pregnancies the Court found that the provision of abortion constituted a service within the meaning of Article 57 TFEU, but declined to take a stand on the moral aspects of the Irish national law:

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1165 Case C-1/96 R. v. Minister of Agriculture, Fisheries and Food, Ex parte Compassion In World Farming Limited [1998] ECR-I-1251, paras 64-66. The reduction by the Court of questions of public policy and morality to questions of health protection has been critisised in literature, see Bakardjieva Engelbrekt 2009, 239, with further references to Woods and Oliver and Jarvis.


1167 See e.g. T 356/93, Reasons for the Decision, para 15 and V 8/94, Reasons for the Decision, para 6.5.

1168 Bakardjieva Engelbrekt 2009, 239, with further reference to Woods.

1169 See e.g. Shuibhne, 72.
Whatever the merits of those arguments on the moral plane, they cannot influence the answer to the national court’s first question. It is not for the Court to substitute its assessment for that of the legislature in those Member States where the activities in question are practised legally.\textsuperscript{1170}

The result in \textit{Grogan} confirms that the Court avoided the question of termination of pregnancies – an issue with moral, constitutional and religious implications and different national approaches. The CJEU has shown similar leeway with regards to national prohibitions based on morality concerns regarding lotteries (\textit{Schindler}\textsuperscript{1171}) and prostitution (\textit{Jany and others}\textsuperscript{1172}), which after all were held to fall under the free movement clauses of the Treaty. In \textit{Jany and others} the Court stated, with reference to \textit{Grogan} and \textit{Schindler}, that as regards the alleged immorality of an activity which is practised legally under national law (prostitution), the CJEU should not substitute its own assessment of that with the legislatures of a Member state.\textsuperscript{1173} Apart from this particular statement the alleged immorality of the acts in question was treated as an issue of public policy where the Court precluded the application of a uniform set of values imposed on the Member states on behalf of the EU. Instead reference was given to the principle that conduct contrary to public policy must be of a sufficiently serious nature to justify – in this case – restrictions on entry to, or residence within, the territory of an EU Member state of a national of another Member State ‘where the former Member State does not adopt, with respect to the same conduct on the part of its own nationals, repressive measures or other genuine and effective measures intended to combat such conduct’.\textsuperscript{1174}

14.2.3 The Margin of Manoeuvre for Member States

The concepts of \textit{ordre public} and morality, especially regarding their operation in the field of fundamental rights, are part of general EU law as legal prerequisites of provisions regarding derogation from free movement in the Treaty. Whilst

\begin{footnotesize}
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\item\textsuperscript{1170} Case C-159/90, \textit{The Society for the Protection of Unborn Children Ireland Ltd v Stephen Grogan and others}, [1991] ECR I-04685, para 20
\item\textsuperscript{1171} Case C-275/92 \textit{Her Majesty’s Customs and Excise v Gerhart Schindler and Jörg Schindler}, [1994] ECR I-1039,
\item\textsuperscript{1172} Case C-268/99 \textit{Aldona Malgorzata Jany and Others v Staatssecretaris van Justitie}, [2001] ECR I-8615.
\item\textsuperscript{1173} Id., paras 56-57: ‘So far as concerns the question of the immorality of that activity, raised by the referring court, it must also be borne in mind that, as the Court has already held, it is not for the Court to substitute its own assessment for that of the legislatures of the Member States where an allegedly immoral activity is practised legally (see, with regard to abortion, Case C-159/90 \textit{Society for the Protection of Unborn Children Ireland} [1991] ECR I-4685, paragraph 20, and, with regard to lotteries, Case C-275/92 \textit{Schindler} [1994] ECR I-1039, paragraph 32).57. [\ldots] Far from being prohibited in all Member States, prostitution is tolerated, even regulated, by most of those States, notably the Member State concerned in the present case.’ Also notice the blurring of concepts as in the continuing reasoning the CJEU specifically refers to ‘public policy’ and not morality.
\item\textsuperscript{1174} Case C-268/99, \textit{Jany and others}, para 60, where reference was made to \textit{Joined Cases 115/81 and 116/81 Adoui and Cornuaille} [1982] ECR 1665, para 8.
\end{itemize}
\end{footnotesize}
the approach by the CJEU is quite generous as to the inclusion of these topics under its jurisdiction, the Court has nevertheless left much room for the Member States to decide on these particular matters in accordance with national views. The function of morality and ordre public justifications for derogations as treated by the CJEU (in particular in relation to the principles of free movement, but also in secondary EU law), thus, leaves discretion to the Member States to decide on their content and influence. A simple breach of national law is not sufficient as such to be contrary to ordre public, where focus is placed on rights of a fundamental nature. Even regarding such general principles, the CJEU tends to leave room for manoeuvre for the Member States but retains a role as overarching guide. Likewise the Court has refrained from taking a stand on morality issues of a sexual or religious nature.

The unobtrusive position by the EU in relation to its Member States in matters of morality and ordre public in the context of general EU law is subjected to a complete reversal in the subsequent development of EU patent law in terms of the Biotech Directive. Today, in 2015, the position of the Union as regards the creation of common EU concepts which replace national preferences of morality and ordre public is more advanced. The focus on ethical issues was gradually strengthened throughout the process of enactment of the Biotech Directive, and culminated in the CJEU decision in Brüstle in 2011.

The function of the morality clause in the EU legal system is subject to a number of different parameters which differ fundamentally from its operation in the EPO setting. The necessary starting point for investigating these parameters is the political and legal landscape in which the morality clause in the Directive was formed. The following Sections 14.3-14.4 depict the process of enactment of the Directive and the political context in which it took place.

14.3 The Drafting of the Biotech Directive

14.3.1 General Observations

The main reason for the enacting of the Biotech Directive was to ensure that the Member States were operating from the same starting point as when they considered the validity of a biotechnological invention. An effective and harmonized protection throughout the Member States was deemed essential in order to maintain and encourage investment in the field of biotechnology, and it was held that the differences existing in the legal protection of biotechnolog-

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1175 See e.g. the Opinion of Advocate General Jacobs delivered on 14 June 2001 in Case C-377/98, Netherlands v Parliament and Council, para 95 ff.
1177 Chahil, 25.
cal inventions offered by the laws and practice of the different Member States could create barriers to trade and hence impede the proper functioning of the internal market. The aims of the EU are clearly visible in the preamble of the Directive, where the increasingly important role of biotechnology and genetic engineering for a broad range of industries is emphasized, and likewise, the fact that the protection of biotechnological inventions was of fundamental importance for the Community’s industrial development.

The turbulent overall mix of concerns was observed politically in the negotiation of the Directive, and when studying the amendments made throughout the negotiation process it is clear that especially ethical concerns had a major influence over the final result. With regard to the approaches taken towards biotech inventions in e.g. US and Japan, the EU Directive differs in a profound way, namely in terms of the impact placed on morality as an evaluative criterion in European patent law. The traditional exclusion from patentability on the grounds of morality and ordre public was already present in European patent law, both nationally and in Article 53(a) of the EPC, dating back to the time of the Strasbourg Convention (1963). The morality clause in the Directive’s Article 6 is nearly identical to the EPC version, however, the exclusion was reinforced in the Directive’s Article 6(2) with an exemplifying list of non-patentable inventions, including processes for human cloning and uses of human embryos for industrial or commercial purposes. In Article 5(1), the preservation of human dignity and non-commodification was articulated by the rule that the human body as such cannot constitute a patentable invention. On the other hand, the perceived ban on patents relating to the human body is modified by the Directive’s Article 5(2) in which elements of the human body are considered patentable, as long as they are ‘isolated’ or ‘produced by means of a technical process’.

In the political process the morality concerns were an important factor and the resulting text mirrors the yielding to these particular concerns. But it is necessary to study the process of enactment and especially the insertion of the exemplifying list in Article 6(2) and follow the observations that influenced the result, especially the concerns voiced in the so-called Rothley Report. The relation of national law and patentability possibilities is a particularly important factor, in the sense that according to the Rothley Report it was never foreseen that the morality exclusion should exclude from patentability inventions which were permitted to be exploited by national legislation.

1178 Recitals 3 and 5 of Directive 98/44/EC.
1179 Recital 1 of Directive 98/44/EC.
1180 See Porter 2009:1, 3-26.
1181 Article 5(3) contains an express specification regarding the function of the industrial application criterion regarding gene sequences, which has given rise not only to legal controversy but also national discrepancies.
14.3.2 The Horse Trading

14.3.2.1 The Pro-patent Initiative

The Biotech Directive was enacted on July 30, 1998, but the drafting took nearly ten years of debate among EU institutions, and several drafts. The rationales for the first draft were clearly economic in nature and focused on giving the biotechnology industry the possibility to treat the Community as a single market, foster the innovatory potential and improve the possibilities of protecting biotechnological inventions in Europe, compared to the US and Japan:

Whereas the two leading nations in biotechnology, the United States of America and Japan, have been able continuously to adapt their patent protection according to the latest needs of the industry, science and consumers, the Member States, representing comparable potential of intellectual manpower and capital, are immobilized by a not yet completed and […] in part outdated legal framework.

The harmonisation of patent law was regarded by the Commission as a key factor in this process. Although it was recognized that biotechnology poses problems in relation to ethics, the majority of the predicted problems in the first draft concerned the patenting of animals and plants, especially the exclusion for animal and plant varieties.

In the initial stages the draft was supported by industry stakeholders, promoting various arguments for patents such as e.g. the incentive to invest and create for firms/individuals, protecting the value of knowledge, encouraging economic growth and competitiveness (creating job opportunities) and supporting the commercial potential of inventions. The relationship between medical cures and patents was also emphasized. The approach of these arguments was clearly economic utilitarian.

When circulated, the first draft ran into difficulties. Anti-legislation stakeholders condemned the draft, arguing against the granting of private monopoly rights over living material. The argumentation was based on a plurality of moral

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1182 Above all, the primary difficulty in the creation of the Directive was the reconciliation of opposing interests, where the debates were characterized by fiercely locked positions with regard to moral and economic beliefs. The stakeholders attempted to secure inclusion of provisions reflecting their primary concerns. An important feature of the negotiations was the practical compromises on behalf of both camps, thereby making the legislative process a matter of give and take i.e. horse trading (as labelled by Harmon 2006:1, 647).

1183 This protracted process resulted in part from the highly controversial nature of the subject matter, as well as the fact that the legislature used for the first time a new co-decision procedure, which gave more power to the Parliament. See Gitter, 2.


1185 Id., 22.

1186 Id., 1 ff.

1187 Harmon 2006:1, 646-647, especially fn. 22.
approaches: contrary to human dignity, blocking of access to fundamental resources, stifling of research and increasing research costs, and dilution of the patentability criteria leading to patenting of mere discoveries and expansion of piracy. The unholy alliance of diverse interest groups participated heavily in public engagement throughout the remaining process, with the aim of securing the inclusion of certain provisions in the draft.\textsuperscript{1188}

As for the position of the EU institutions, the intense lobbying gave result. The Economic and Social Committee expressed regrets that ‘human beings per se are not expressly mentioned in the Directive as not being patentable’.\textsuperscript{1189} The European Parliament suggested a number of amendments to the draft, including incorporating the non-patentability of inventions contrary to morality or \textit{ordre public}.\textsuperscript{1190}

The Commission included some, but not all of the suggested amendments into an amended draft, with a stronger focus on ethical issues. More specifically, the amended proposal took account of the provisions on public policy and morality, to give more precise guidance to national patent offices and courts in determining what was or was not patentable: certain practices were deemed to be not patentable (the human body or parts of the human body as such, processes for modifying the genetic identity of the human body which had a non-therapeutic purpose and which were contrary to the dignity of man, processes for modifying the genetic identity of animals which were likely to cause them suffering or physical handicaps without any substantial benefit to man or animal). An amendment establishing the farmer's privilege was also incorporated. At this stage, there was yet no mention of an exclusion regarding human embryos.\textsuperscript{1191}

\subsection*{14.3.2.2 The Rise of Ethical Concerns}

The Commission held that even though it had not raised the ethical issues in the first draft, these issues were part of the classical exceptions to patentability, e.g. in Article 53(a) EPC and exist also under national laws and are therefore always applicable. Also, ethical issues are fundamentally linked to the rules that intend to safeguard human rights at the level of applications for research funding and marketing, e.g. the marketing of pharmaceuticals, stated the Commission. Even though the aim of the Directive, in the Commissions view, was related to the harmonisation of patent laws and not to establish a European

\begin{flushleft}
\textsuperscript{1188} Harmon 2006:1, 647-648, especially fn. 24.
\textsuperscript{1190} European Parliament, 1992/93 session, Minutes, Notice No 92/C 125/01-05, OJ C 125 of 18.05.1992, 112-183.
\end{flushleft}
standard of ethics, the Commission still deemed it essential that patent law
should include certain barriers in order to provide guidance to courts and pa-
tent offices with regard to the interpretation of the notions of ordre public and
morality. This was a sort of U-turn from the position in the first draft and an
indication of the political storm and public engagement in the process, which
gave echo in the following draft.

Based on this reasoning the Commission proposed the inclusion of an ex-
emplifying list containing non-patentable subject matter, i.e. the human body or
parts of the human body as such, processes for modifying the genetic identity
of the human body which had a non-therapeutic purpose and which were con-
trary to the dignity of man and processes for modifying the genetic identity of
animals which were likely to cause them suffering or physical handicaps without
any substantial benefit to man or animal.\footnote{1192} The Council confirmed the ap-
proach taken by the Commission in its amended proposal by integrating Par-
liament's amendments that it had accepted, but also added several other
amendments.\footnote{1193}

Despite the fact that several amended versions had already passed between
Council, Parliament and Commission, the troubles were not yet over. In a con-
tinued process, the Parliament suggested further amendments to the Council’s
proposed draft, based on the ground that several members of the Parliament
advocated the further focus on ethical issues. The Council rejected those pro-
posals in September 1994, which led to conciliation proceedings between the
Council and the Parliament.\footnote{1194} The resulting joint text was later rejected by the
Parliament in March 1995.\footnote{1195} The rejection was primarily grounded on concerns
for the ethical issues in the text.\footnote{1196} The protracted process was an indication of
the turbulent mix of political lobbying and intense discussion of competing
interests.

\footnote{1192} COM(1992)589 final – SYN 159, Amended proposal for a Council Directive on the legal protection of
\footnote{1193} The Council e.g. clarified the scope of the non-patentability of the human body or its elements, particular-
ly nucleic acids; it removed the concept of human dignity as a criteria for determining the exclusion from
patentability of certain processes for modifying the genetic identity of human beings - under which chapter it
raised the issue of so-called germ line gene therapy - and thus rejected the association with it for therapy
purposes. The Council furthermore strengthened the criteria of benefits in permitting an assessment of the
acceptability of a procedure for determining the genetic identity of animals, and improved the consistency of
certain elements in the proposal with the EPC. Common Position (EC) No 4/94 adopted by the Council on
\footnote{1194} Porter 2009:1, 13.
\footnote{1195} This was the first time that the Parliament had used its veto powers since the coming into force of the
Maastricht Treaty on 1 November 1993, which prescribed a co-decision procedure under the then Article
\footnote{1196} Gitter, 10. Another issue was the wording of the then tenth recital of the Council’s common position
regarding whether the expression ‘as such’ in Article 2(3) of the proposal differentiated sufficiently between a
discovery and an invention as regards body elements of human origin. Eventually the words ‘as such’ was
retained in the twelfth recital, which was reworded.
14.3.2.3 The Separation of Ethical and Technical Issues

At this time, developments on the national level seemed to give substance to one of the fears that had prompted the introduction of the Biotech Directive, namely the continuing enactment of national legislation which contributed further to a fragmenting of patent rules in Europe. In July 1994, the French Parliament approved a bioethics law.1197 The law prohibited the patenting of the human body and its products and elements, resulting in a ban on the patenting of human genes, even if isolated from the human body. It was feared that other Member States would follow suit and enact national legislation contributing to a growing legal crevice between the EU and its Member States in the field of biotechnological patents. To make matters even more pressing, substantial economic arguments were raised in that it was estimated that the world market for biotechnological products had doubled to approximately ECU1198 83.3 billion in the seven years following the first draft proposal in 1988.1199

Taking these developments into account, the Commission presented a new proposal for a Directive in December 1995.1200 With regard to the lack of an ethical dimension in the first proposal, the Commission stated that:

\[ \text{[t]he initial proposal was […] largely technical in character. Not that the ethical dimension was ignored but, at that time, it appeared that the exclusion from patentability of inventions the publication or exploitation of which would be contrary to public policy or morality, which was common to all the Member States' legislation on patents for invention and to the EPC [Article 53(a)], met the need to take into account the ethical dimension of biotechnological inventions. Further harmonization of national laws did not appear justified, given that they were already based on a common principle and that each case had to be assessed on its merits.} 1201 \]

The Commission referred to the classic example of a letter-bomb as an invention that must be excluded on grounds on public policy or morality. Furthermore, it is interesting to note that the Commission stated that at the time, the patent law was even more incomplete and uncertain than in 1988, and singled out the ethical dimension as the most important issue in this stage:

1198 European Currency Unit, replaced by the EURO since 1 January 1999.
The most important thing is to assess the ethical dimension of certain biotechnological inventions which, unless otherwise clarified by the legislature, could turn out to be a Pandora’s box from which emotive issues are constantly likely to emerge.\textsuperscript{1202}

The proposal was to a large extent focused on the clarification of the distinction between discoveries and inventions as regards elements of human origin. The Commission stated that this difference was not to be interpreted in relation to an exclusion from patentability on grounds of being contrary to morality or public order, but rather as a technical question. The fundamental principle that excludes all rights of ownership in respect of the human being cannot be affected by patent law, held the Commission, and concluded that ‘a gene or a cell, in their natural state, must be excluded from patentability because they cannot be regarded as patentable inventions.’\textsuperscript{1203} By this statement, the Commission made clear that there was no need for patent law to adopt an ethical stance for reasons of public policy or morality in relation to excluding from patentability elements of the human body, but rather to follow and observe its own principles by using the conventional system of patent law established by the national laws in the Member States as well as the EPC.\textsuperscript{1204} The result was that the questions on patentability of the human body were withdrawn from assessments made on grounds of morality or \textit{ordre public} and reduced to a question of technical patent law interpretation.\textsuperscript{1205}

At this time, the patentability of transgenic animals was heavily debated in Europe. EPO had already refused a patent application for a transgenic hairless mouse on the grounds of \textit{ordre public} and morality, and the first decision regarding the Harvard Oncomouse application was issued, introducing the utilitarian balancing test with regard to the application of Article 53(a) EPC to animal inventions.\textsuperscript{1206} Against this background the Commission sought to add to the existing jurisprudence regarding the morality clause in the Biotech Directive. The general exclusion on grounds of morality or public order was placed in Article 9(1), followed in Article 9(2) by an illustrative list containing the two remaining exclusions that were considered to be based on grounds of morality and \textit{ordre public} and consequently removed from Article 2(3): an exclusion for


\textsuperscript{1204} Id.

\textsuperscript{1205} Id. The human body patentability requirements were accordingly moved from Article 2(3) to Article 3.

\textsuperscript{1206} See T 19/90 and Gold and Gallochat, 359. The hairless mouse patent application was filed by the Upjohn Company, PCT WO 90/06367.
‘methods of herm line gene therapy on humans’ and another for transgenic animals. Further guidance was provided by the proposed Recital 21:

Whereas it must be determined whether applications offend against public policy and morality in each specific case, by means of an appraisal of the values involved, whereby the benefit to be derived from the invention, on the one hand, is weighed and evaluated against any risks associated therewith, and any objections based on fundamental principles of law, on the other hand […]

14.3.2.4 The Concerns for the Human Embryo

In July 1996, the Economic and Social Committee issued an Opinion on the Commission’s 1995 proposal. The Committee urged the Council and the European Parliament to rapidly adopt the Directive mainly for reasons of an economic nature, given the competition from the US. However, the Committee proposed further clarifications with regard to ethical issues, and proposed an express exclusion for the human embryo. This exclusion was placed under the then Article 3, which contained the exclusion from patentability for the human body. The Committee stated that the wording of the Article could be interpreted as not including the embryo in the concept of human body, and considered that the inclusion of an exclusion for the human embryo would give a higher political profile to the argument. This was the first time an explicit mention was made of the term human embryo within the context of the Directive. The European Parliament had issued two Resolutions on human embryo research in 1989 and 1993, which were both morally restrictive.

The formulation of the Committee’s proposal is important, as it supported the clarification in Article 3 that in accordance with Article 27.1 of the TRIPS Agreement, an invention obtained after isolation or through a technical process may be patentable, in any biotechnological area, provided that it is new, implies

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1210 Id., para 3.
1211 The Committee proposed that the beginning of Article 3 be reworded as follows: ‘The human body, including germ cells and notably the human embryo, and all elements of the human body, shall not be considered patentable inventions’. Opinion of the Economic and Social Committee CES 878/1996, para 4.3.2.
1212 European Parliament, Comm. Legal Affairs and Citizens’ Rights (84), Resolution on the Ethical and Legal Problems of Genetic Engineering and Resolution on Artificial Insemination ‘In Vivo’ and ‘In Vitro’ (16.03.1989) (followed later by the European Parliament resolution on human cloning, OJ C 135, 7.5.2001, 263). Another important event that took place at this particular time was the birth of the sheep Dolly on 7 March 1996 – the world’s first cloned mammal. This evidently heightened ethical concerns about biotechnology around the world. Porter 2009:1, 18.
an inventive activity and is capable of being applied in industry. This would mean that even if a human embryo would be non-patentable, isolated parts of the embryo would be, according to Article 3(2), provided that they meet the patentability criteria of novelty, inventive step and industrial application. The distinction was in line with the discussions on the Directive which had focused upon the distinction between an invention and a discovery in the field of biotechnology patents. If this formulation would have prevailed, that would have made it clear from the formulations in the Directive that at least pluripotent hESC would be *prima facie* patentable, no matter their way of production, since they are products isolated from the human body (or human embryo).

The Economic and Social Committee’s major contribution to the subsequent developments of the Biotech Directive was the proposal of an introduction of a ban on the patenting of a human embryo, which was always present in subsequent proposals. The Opinion was followed by a Report from the Committee on Legal Affairs and Citizens’ Rights (the so-called Rothley Report) containing numerous amendments to the Commission’s proposal, which were also to a large extent included in the upcoming amended proposal.

For instance, an important amendment in the upcoming proposal concerned Recital 13, which in previous proposals had only mentioned the unpateintability of ’the human body and its elements in its natural state’. This recital was suggested to have the following wording:

’Whereas patent law must respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, its elements, including germ cells, its products and the sequence or partial sequence of a human gene cannot, in their natural state, be patented: whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented’.

The wording ‘at any stage in its formation or development’ suggests that the unpatentable area was wider than previously proposed, and was also repeated in the proposal for a new Article 3(1).

As regards the exclusion based on morality or *ordre public* the Rothley Report contained the new Recital 19b, which mirrored Article 27.2 of the TRIPS

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1213 Opinion of the Economic and Social Committee CES 878/1996, para 4.3.2.3.
1215 Recital 19b (of the Rothley report): ‘Whereas the TRIPS Agreement provides the possibility of excluding inventions from patentability when prevention of their commercial exploitation is needed in order to protect public policy or morality, including to protect human, animal or plant life or to prevent serious harm to the
Agreement\textsuperscript{1216} and the grounds therein for excluding inventions to protect \textit{ordre public} or morality, including protecting human, animal or plant life or health or to avoid serious prejudice to the environment, ‘provided that such exclusion is not made merely because the exploitation is prohibited by their law’. Recital 19b did not, however, mention ‘health’ as one of the objectives. The new Recital 19c repeated much of the text in 19b, but contained the additional text that: ‘Whereas other prohibitions on exploitation under national law are not sufficient to exclude patentability; whereas such an exclusion presupposes that the commercial exploitation of the invention is prohibited in the Member State in question; whereas an invention, the commercial exploitation of which is permitted, may not be excluded from patentability.’ Recital 19c did not survive the enactment process. The concept of ‘health’ was instead inserted into Recital 19b (which became Recital 36 in the Directive).

The aim of Recitals 19b and 19c was to clarify the framework set by the TRIPS Agreement with regard to the exclusion of patentability on grounds of morality or \textit{ordre public}, and to express two points. First, it is not sufficient for the application of the morality clause that the national law of the Member States contains prohibition(s) on exploitation for the invention under scrutiny – additional requirements are necessary. Second, exclusion from patentability is only possible if the industrial application of the invention is actually prohibited in the Member State in question. Logically, it follows that if the industrial application for an invention is permitted, such invention can never be excluded from patentability. In conclusion, the application of the morality clause necessitates as a starting point a prohibition in national law, but such prohibition cannot function alone as a foundation for the operation of the clause. These were the conclusions of the Rothley Report, held to be in line with the interpretation of Article 27.2 TRIPS.

\textbf{14.3.2.5 The Purpose of the Morality Clause}

The Rothley Report is very vocal on the fact that patent protection is a morally neutral means of promoting technology, and it was held that the risks associated with technological development cannot be controlled by the patent system, with genetic engineering no exception. The control aspect is a matter for general legislation.\textsuperscript{1217} But other amendments in the Rothley Report specified the

\textsuperscript{1216} Article 27.2 TRIPS: ‘Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect \textit{ordre public} or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.’

\textsuperscript{1217} Report on the proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions (COM (95)0661 - C4-0063/96 - 95/0350(COD)), Committee on Legal Affairs
role given to morality and *ordre public*, and it was pointed out that the moral considerations should only supply the standard legal checks of patent law.1218 Methods for intervention in the germ line of human beings as well as cloning of human beings were seen as unequivocally excluded.1219 Regarding Article 9(1) (the morality exclusion) the Report added ‘publication’ to exploitation as a criterion for when an invention is contrary to morality or public policy.1220 The exemplifying list in Article 9(2) was expanded to include five examples, of which Article 9(2)(d) specifically mentioned ‘[m]ethods in which human embryos are used’.1221 There was no mentioning of this new addition in the Explanatory Statement attached to the report, and the intended breadth of the example is therefore not known. The European Parliament adopted the Rothley Report on 16 July 1997, by 370 votes to 113 with 19 abstentions.

The Commission submitted an amended proposal on 29 August 1997, which took account of principally all of the European Parliament’s suggested amendments.1222 Article 9 was renumbered as Article 6, and the word ‘publication’ was removed to ensure consistency with Article 27.2 of the TRIPS Agreement. The attempts by the Parliament to introduce a broader exclusion with regard to wider-range ethical concerns in respect of biotechnology were successfully resisted by the Commission, and the result was shown by the fact that the exemplifying list in Article 6(2) was restricted to four examples, including ‘methods in which human embryos are used.’1223 The example of human (non-reproductive) cloning was removed, however, signalling a cautious approach to

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1218 Recitals 20 and 23.
1219 Recital 24.
1220 The text did not yet contain the wording *ordre public*.
1221 Amendment 55, Article 9(2) of the Rothley report reads as follows: ‘(a) procedures for human reproductive cloning; (b) processes for modifying the germ line identity of human beings; (c) processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial medical benefit to man or animal and also animals resulting from such processes; (d) Methods in which human embryos are used; (e) methods for the artificial production of human embryos containing the same genetic information as another human being or a dead person (human cloning).’ Report on the proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions (COM(95)0661 - C4-0063/96 - 95/0350(COD)), Committee on Legal Affairs and Citizens’ Rights, Rapporteur: Mr Willi Rothley, DOC_EN\RR\330\330382, PE 218.021/fin., OJ C 286 of 22.09.1997, 31.
1222 COM(97) 446 final, 95/ 0350 (COD), 1997, OJ C 311 of 11.10.1997, 12. The only unacceptable amendment was No. 76, which required patent applications for inventions consisting of biological material of animal, plant or human origin to disclose certain information. The requirements went too far in relation to the commitments of the Community regarding the Convention on Biological Diversity and Directives on disclosure of personal data.
1223 Article 6(2): On the basis of paragraph 1, the following shall be considered unpatentable: (a) procedures for human reproductive cloning; (b) processes for modifying the germ line genetic identity of human beings; (c) methods in which human embryos are used; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes.’ See also Gold and Gallochat, 359.
the issue of patents in the field of therapeutic cloning (somatic cell nuclear transfer, SCNT).\textsuperscript{1224}

The following Common Position approved by the Council retained in Article 5 the statement of non-patentability of the ‘human body, at its various stages of its formation and development’ with the understanding that this included human embryos, thus safeguarding the ethical guarantee that the human body in a raw state is unpatentable.\textsuperscript{1225} The human embryo exclusion in Article 6(2)(c) was subject to a narrowing formulation, in that the expression was changed to cover only ‘uses of human embryos for industrial or commercial purposes’. This interesting specification of the exclusion was introduced to separate between industrial or commercial uses of human embryos as opposed to inventions for therapeutic or diagnostic purposes which are applied to the human embryo and useful to it, which were not excluded from patentability.\textsuperscript{1226} This latter formulation was introduced in Recital 42.

Although Recital 42 may at first glance appear to clarify exactly which types of inventions relating to human embryos fall under the exclusion in Article 6(2)(c), the question remains as what exactly the term ‘industrial or commercial purposes’ intends to cover, also in relation to ‘therapeutic or diagnostic purposes’. The explanatory memorandum following the Common Position does not elucidate the matters. In general, industrial/commercial and therapeutic/diagnostic are not mutually exclusive concepts, but from a patent law perspective there are possibilities that the expressions overlap. For instance, an invention must always disclose the industrial application in the patent application. It is presumed that such an application may take place within the health care sector as an example. Still, such an invention may very well be of a commercial nature, for instance a commercial diagnostic test. The inclusion of the word industrial also seems to be a redundant concept, as inventions are per nature of industrial application.

The debates in the Parliament indicate that the inclusion of the narrowing element of ‘industrial or commercial purposes’ in Article 6(2)(c) was made with the UK in mind. The rapporteur, Mr. Rothley, made a statement:

\textsuperscript{1224} At this time, the European Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine CETS No.: 164 and its Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings CETS No.: 168 were negotiated. The wording of the Protocol is ambiguous, as it is unclear whether it only covers reproductive human cloning or also therapeutic cloning. The Convention has been signed by 32 out of 47 Member States, of which eight signatures have not been followed by ratification (including Sweden). The Protocol has been signed by 20 States, of which 12 have not been followed by ratification (including Sweden). Germany and the UK have not signed the Convention.


\textsuperscript{1226} Recital 42 relates directly to Article 6(2)(c). OJ C 110 of 08.04.1998, 30.
In relation to the use of embryos, the Council has set some limitations: they are not to be used for industrial or commercial purposes. But I would only ask you to remember that this was done with the United Kingdom in mind. We cannot as European legislators decree that something which does not contravene the underlying legal principles of all Member States is a contravention of public order, and we cannot brand something that we do not jointly regard as abhorrent as a contravention of common decency. That is not acceptable! It is only exemplary in any case, that is to say, other ways of using embryos may be investigated with the proviso that they do not contravene public order and common decency for other reasons.\textsuperscript{1227}

Thus, it was out of concern for a Member State’s situation with regard to national legislation that prompted a change of the Directive’s rules. At this time, the technology of SCNT used to create Dolly the sheep had only just emerged, and the UK was in the middle of initiating a process to amend the Human Fertilisation and Embryology Act to include further purposes for embryo handling in research.\textsuperscript{1228} From Mr. Rothley’s speech it can be inferred that the Parliament regarded the exclusion as being applicable only when there is a consensus of the underlying legal principles of all Member States. However, it is quite clear that during the drafting of the Directive the extent and formulation of the morality clause was not considered in detail, nor was the question of patentability of hESC-related technology. The final wording of the human embryo exclusion in Article 6(2)(c) seems to have been shaped \textit{ad hoc}, in the last stages of the drafting and with a sudden amendment of the wording, apparently due to developments in the forefront of technology. Stem cell technology, and especially hESC was not fully developed and it is not surprising that the controversies of this particular technology would arise later on, following technical progress, and be a matter for the patent offices and courts rather that the legislator.

\subsection{14.3.2.6 The Introduction of the ‘Embryo Destruction’ Criterion}

In 2005, during the time of consideration of the EPO concerning the \textit{Edinburgh} and \textit{WARF} patents, the Parliament adopted a resolution on patents for biotechnological inventions, constituting an update of its position following the

\textsuperscript{1227} Debates of the European Parliament, Sitting of Monday, 11 May 1998, at www.europarl.europa.eu/debats/debats?FILE=98-05-11&LANGUE=EN&LEVEL=DOC&GCS ELEMENT&GCSELECTPERS=27 (26 April 2015). The statement was also repeated in the Amicus Curiae Submission of the United Kingdom to the \textit{WARF}-decision, G 2/06, where it was used to promote the line or argumentation that the exclusion did not extend to preventing the patenting of the products of the use of human embryos, nor did it extend to preventing the patenting of uses of human embryos for purposes which were neither industrial nor commercial. www.ipo.gov.uk/warf.pdf (13 December 2010).

events taking place in the patent offices, especially the EPO.\textsuperscript{1229} The major part of this resolution concerned the application of the exemplifying list in Article 6(2), which was indicative of its problematic interpretation. Some statements are very interesting, especially the introduction of the formulation of ‘destruction of embryo’ which was later repeated in EPO case law. For example the Parliament held that:

\begin{quote}
\[T\]he definition of ethically motivated limits is of particular importance in biotechnology.\textsuperscript{1230}
\end{quote}

\begin{quote}
\[F\]or the creation of embryonic stem cells embryos have to be destroyed and the patenting of technologies where human embryos are destroyed or used for commercial or industrial purposes is excluded according to Article 6(2)(c) of the Directive.\textsuperscript{1231}
\end{quote}

Supports further stem-cell research and other alternatives to promote human health but underlines its fundamental position regarding the application of biotechnology to human beings, especially the rejection of interventions in the human germ line, the rejection of cloning of the human being in all phases of its development and the rejection of research on human embryos, which destroys the embryo.\textsuperscript{1232}

\begin{quote}
Insists that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6(2)(c) of the Directive.\textsuperscript{1233}
\end{quote}

The Parliament also recognized the possibility for any person to file a notice of opposition to a patent according to the EPC, and even urged the Commission to file a notice of opposition in relation to a specific patent concerning human germ cells.\textsuperscript{1234} Due to the sensitivity of the issue, it also requested the EPO to set up a further body which, as an independent ethics committee examining the patents from an ethical point of view, would check patents that are sensitive from an ethical point of view before they are granted.\textsuperscript{1235}

It is apparent from the study of the enactment process that the provisions with regard to morality or \textit{ordre public} gained in importance from the first draft

\textsuperscript{1230} Id., para E.
\textsuperscript{1231} Id., para N.
\textsuperscript{1232} Id., para O 3.
\textsuperscript{1233} Id., para O 14.
\textsuperscript{1234} Id., para O 11-12.
\textsuperscript{1235} Id., para 18.
to the resulting Directive. The Rothley report gives interesting clues to the reasoning of the Parliament, specifically the background to its perceived application and the relation between the requirements for the exclusion from patentability and the situation in national law with regard to permissibility of research and exploitation.

In summary, the conciliation of different points of view in the process of the enactment of the Directive, the intense public engagement and the tense atmosphere that characterized the public debates resulted in an enhanced focus on ethical issues, notably the protection of human dignity. But the Directive is still a result of negotiation between stakeholders and the final version contains a mixture of moral approaches which is the result of the political bargain.

14.3.3 The Moral Approaches

The moral approaches contained in the Biotech Directive are evidence of a plurality of interests present during the negotiations, and the provisions reflect the prevailing different concerns. For example, the utilitarian approach is found notably in the balancing test of Article 6(2)(d), but also permeates a number of core requirements in a pro-patent fashion (see e.g. Recital 10-11, Arts. 3(2) and 5(2)), since the primary value of corporate/researcher autonomy (self-governance and freedom of will) underlies the benefits of individual financial reward, economic development and scientific advancement in the risk/harm weighing of factors. The human rights (or deontological) approach (human dignity as empowering) is represented throughout the Directive, but Recital 26 is the foremost expression of the principle of autonomy and justice, resting on the notion of valuing the worth of human beings. Also Recital 43 (protecting fundamental rights as contained in ECHR and Member State constitutional traditions) and Article 11 (farmer’s rights) represent a human rights concept following the notion of human dignity as empowering. Finally, Harmon argues that the so-called dignitarian approach (human dignity as constraint) is found in Article 5(1), Recital 16 and Article 6(2) of the Biotech Directive, because these articles set limits on the possibility to patent biological material based on personal integrity and human dignity. In his approach, human dignity as constraint is represented by the principle of instrumentalisation of human life. The primacy of human autonomy is also present, but individual choices are limited in this view if they compromise human dignity.

As explained, the content of the principles of non-instrumentalisation/non-commodification/non-commercialisation are not universally agreed upon and their meaning may vary according to context and differ between legal acts and

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1236 Harmon 2006:1, 651 ff.
1237 Id., 654 ff.
interpreters. Therefore, Harmon’s conclusions that Article 6(2) is based on a dignitarian approach cannot be entirely supported. Admittedly, the findings in case law display an influence of the dignitarian approach. However, this is not automatic from the text of the Directive, which permits a number of conclusions.\footnote{In this respect, it is interesting to relate these approaches to the methodology of tests and standards as implemented in the EPO. See Section 13.6, especially Section 13.6.7.}

\subsection*{14.4 National Implementation\footnote{The facts and conclusions presented are from Hellstadius 2009.}}

As mentioned, the Directive was finally adopted on July 6, 1998. During the aftermath of its adoption, the intense political debates were moved on to the national level of the Member States. The provisions in Article 5 (the human body and human genes) and Article 6 (morality) have been the most problematic ones in terms of implementation and interpretation in national law.\footnote{The rest of the Directive’s rules have not (yet) caused any major concerns. Article 2 contains some definitions and Article 3 establishes the patentability of biological material even if naturally occurring. Article 4 contains the exclusion from patentability for plant, varieties, animal varieties and essentially biological processes for the production of plants or animals. The plant and animal exclusion is in line with the EPO interpretation of the correspondent EPC exclusion (See G 1/98 (Transgenic plant/NOVARTIS II) and T 315/03 (Transgenic animals/HARVARD). Cf. Article 4(2) of the Biotech Directive), and the exclusion for ‘essentially biological processes’ has, in addition, been subject to further interpretation by the EBA (See G 1/08 (Tomatoes/STATE OF ISRAEL) of 9.12.2010, G 2/12 (Tomatoes II) of 25.3.2015, G 2/07 (Broccoli/PLANT BIOSCIENCE) of 9.12.2010 and G 2/13 (Broccoli II) of 25.3.2015). Article 8 and 9 concerning the extent of the protection for biological material or genetic information, and how the exclusive right is extended to subsequent generations have also been subject to a decision of the CJEU (See Case C-428/08 Monsanto Technology LLC v Cefetra BV and Others [2010] ECR I-6765).} Some of the recitals have also caused difficulties, especially Recitals 23 and 24 – referring to the ‘function’ of DNA sequences as a decisive criterion for patentability – which has been subject to differing interpretations in the legal doctrine and also in national implementation processes.\footnote{See Hellstadius 2009, 117 ff.} The rest of the Directive’s rules have not (yet) caused any major concerns comparable to those raised in connection to Articles 5 and 6 and the nationally disparate rules, of which the harmonisation goal could be seriously questioned.\footnote{See Hellstadius 2009, 117 ff. and Bostyn 2011, 13 ff.}

Before the enactment of Article 6 of the Biotech Directive, the morality exclusion in EPC as well as its counterparts in national legislation provided for a case-by-case approach, both with regard to the EPO and the national legal regimes. States have been able to apply the exclusion taking into consideration their domestic views on morality and \textit{ordre public}. Neither the fundamental treaties of the European Union nor the draft Constitution provide that the Member States have placed this fundamental competence at the disposal of the Europe-
The determination of such concepts is done outside patent law, in a human rights context. Both international and national laws are founded on the values found in human rights principles. Such rights are fundamental and must guide the international as well as the national legislator. In this context, it is agreed that morality is a concept which relies heavily on the norms accepted in a particular culture, regional or national, or in exceptional cases, international. This conclusion is recognised by the EU Member States by concluding the Biotech Directive.

With regard to the implementation of Article 6 of the Directive, the majority of the EU Member States have made a literal, word-for-word translation of the provision when incorporating it into the relevant national legislation. In contrast, some states have amended the exclusion by either inserting direct references to (medical) legislation or modified the wording of the provision. The embryo exclusion has been modified in Austria, Estonia, the Netherlands and Switzerland, but the effects of the deviations remains to be assessed. References to medical legislation are introduced in the national patent laws of Austria, Germany and Estonia. Such references have a direct impact on the interpretation of the embryo exclusion, since the medical legislation of reference concern research on and the handling of human embryos and stem cells, usually in the context of reproductive medicine and processes such as IVF. Correspondence is thus established between regulatory regimes and the granting of patent rights, at least on a national level.

As will be evidenced in the following Sections, the development in the practice of the CJEU has moved towards a situation where national attitudes towards research are not taken into account in the interpretation of the morality clause on the EU level, at least not regarding the exclusion in Article 6(2)(c). Such a stance is contrary to the national statutory laws where such a tie is rather emphasized.

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1244 Hellstadius 2009, 121 f.

1245 Alterations of the term ‘for industrial or commercial purposes’. Section 2(1)(3) of the Austrian Patents Act excludes the use of human embryos per se and not only if they are used for industrial of commercial purposes. The Netherlands has also taken an approach similar to that of Austria by exempting the use of human embryos per se, and not just for industrial and commercial purposes (Article 5 of the Dutch Patents Act 1995 of 15 December 1994). The Estonian Patents Act excludes uses of human embryos for only commercial and not industrial, purposes. From a literal point of view such amendments may serve the purpose of broadening the scope of the exclusion, but as mentioned, the legal implications are quite difficult to predict. Perhaps the formulations are simply taking into account the difficulties encountered in the national transposition of the Biotech Directive’s rules. Hellstadius 2009, 122 ff.

1246 Art 2 (1)(e) of the Swiss Patents Act (232.14 Loi fédérale sur les brevets d'invention, 25.06.1954) excludes from patentability unmodified hESCs and stem cell lines.
15 The Morality Clause in the EU Legal System

15.1 Structure

This Chapter on the EU legal system starts with an overview of the general issues related to the origins of the EU morality clause as well as provisions of relevance within the Biotech Directive (Sections 15.2 and 3). The construction of the morality clause is treated hereunder, in Section 15.4, with a specific view of the relationship between the general exclusion in Article 6(1) and the list in Article 6(2) of the Directive. Of importance to the analysis regarding this fundamental issue is the reasoning of the Court in the so-called Brüstle decision, which is described in Section 15.5. The concepts of invention and commercial exploitation are treated in Sections 15.6 and 15.7, respectively. The Chapter ends with conclusions in Section 15.8.

15.2 Points of Departure

The turbulent process of negotiating and completing the Biotech Directive reflects a reconciliation of the competing interests at stake. On the one hand the purpose of safeguarding (permissive) patentability criteria is often held to simply accommodate the interests of the (biotechnology) industry. However, automatically dismissing these concerns as industry lobbying misses an important point, namely concerns aimed at protecting a stable, predictable and stringent application of patent law standards in line with the foundational aims of the system. On the other hand, concerns about protection of human dignity and the commercialisation/commodification of life, animal welfare and environmental harm is today regarded as an absolute necessity that must be taken into account also with regard to the granting of exclusive protection in systems such as patents, and the Directive reflects these moral concerns.

Although these concerns do play a significant role in the EPO as evidenced by the emergence of the body of case law relating to Article 53(a) EPC, the point of departure regarding the EU setting is remarkably different due to several factors. First, the role of the morality clause in the enactment process of the Directive was by contrast more pronounced than was ever the case with Article 53(a) in the negotiations preceding the EPC. Such focus highlighted the tensions associated with the reconciliation of the differing interests involved and the necessary but fragile consensus of which the Articles, especially 5 and 6, is a product. Second, the general concepts of morality and ordre public/public

1247 See Chapter 13 for the interpretation of Article 53(a) EPC.
policy had already been subject to treatment under the rules of free movement in EU law.\textsuperscript{1248} In this particular domain, their content, including the jurisdiction between EU and its Member States in finding a suitable base for the value-attached content of especially morality, was established by the CJEU in a fashion which has not necessarily been followed in the Biotech Directive setting.

Article 6 of the Directive has been the subject of decisions from the CJEU in four cases; one action for annulment (the Netherlands case\textsuperscript{1249}), one action for failure to fulfil obligations (the Italy case\textsuperscript{1250}), and two decisions regarding the scope of application of Article 6.2(c) in connection with national processes regarding the patentability of inventions consisting of hESCs (Brüstle\textsuperscript{1251} and Case C-364/13\textsuperscript{1252}). The first two decisions contain guidance principally for the interpretation of Article 6(1), while the two latter decisions concern Article 6(2)(c) of the Directive exclusively. It is nevertheless possible to draw interesting conclusions concerning Article 6(1) based on the reasoning of the Court in the cases regarding Article 6(2)(c) (notably Brüstle).

In contrast to the case law within the EPO, the guidance to be drawn from the CJEU is of a rather different nature, partly due to the specific focus on the protection of fundamental rights and especially the concept of human dignity. The role of the CJEU in the EU legal order as the interpreter of EU law, providing guidance to national courts, bringing actions for failure to fulfil obligations and actions for annulment, is fundamentally separate from the operation of the EPO and the decisions of the Boards of Appeal. When analysing the function of the morality clause in the EU setting it is therefore necessary to understand the differences. The character of the CJEU decisions makes it difficult to apply a similar construction of the requirements of the morality clause as is done in the analysis of the EPO case law, notably due to the lack of a full body of decisions to draw conclusions from. The CJEU has not addressed the requirements of the provision in detail, except in the Brüstle decision where the interpretation of Article 6(2)(c) of the Directive left plenty of room for discussion.

In essence, the combination of a list with specific examples in Article 6(2) of the Directive and the focus on human dignity in the Directive’s provisions has led to an application of the morality clause which is notably distanced from the principles developed by the EPO in earlier decisions under Article 53(a) EPC, including also earlier views in EU law on the scope of manoeuvre on behalf of the Member States \textit{vis-à-vis} the Union. In this Chapter it is demonstrated that

\begin{flushleft}
\textsuperscript{1248} See Section 14.2.
\textsuperscript{1250} Case C-456/03 Commission of the European Communities v Italian Republic [2005] ECR I-53.
\textsuperscript{1251} Case C-34/10 Oliver Brüstle v Greenpeace eV [2011] ECR I-9821.
\textsuperscript{1252} Case C-364/13, International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, Judgment of the Court (Grand Chamber) of 18 December 2014.
\end{flushleft}
the CJEU’s interpretation of the exemplifying list in Article 6(2) (specifically Article 6(2)(c)) and the focus on human dignity in the Directive causes disruption of the legal boundaries set by Article 6 (at least as developed in connection to Article 53(a) EPC by the EPO, but also with regard to decisions of the CJEU with regard to Article 6(1)).

Before proceeding to the different requirements of Article 6, a presentation of the legislative framework established by the relevant provisions of the Directive is necessary.

15.3 Relevant Provisions

Article 6 of the Directive reads as follows:

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

   (a) processes for cloning human beings;

   (b) processes for modifying the germ line genetic identity of human beings;

   (c) uses of human embryos for industrial or commercial purposes;

   (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The morality clause in Article 6 is supported by a number of recitals. Recital 37 partly repeats the wording of Article 6(1) and it is uncertain exactly what else it aims to add:

(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against *ordre public* or morality must also be stressed in this Directive;

Article 6 and Recital 37 must furthermore be read in conjunction with Recital 39, which stresses the scope of manoeuvre for national moral principles:

(39) Whereas *ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly im-
important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;

Article 6(2) draws from Recital 38, which in addition to the exemplifying list contained in the article also recognizes the unpatentability of processes for the production of chimeras or totipotent human or animal cells:

(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;

It is stated in the first part of Recital 38 that the exemplifying list in Article 6(2) is not exhaustive. The clarification in the last part (‘whereas processes, the use of which offend against human dignity [...] are obviously also excluded from patentability’) could be read so as to imply that in addition to the examples in the list of Article 6(2), processes offending human dignity are also to be excluded. Such a reading gives the impression that the first part of the Recital as well as Article 6(2) excludes something other than processes offending human dignity. The natural conclusion is that ordre public and morality are not concepts equalling human dignity, but rather something else, perhaps overlapping with the principle of protection of human dignity or notions building on other foundations.1253

Four more recitals are relevant in connection to Article 6(2): Recitals 40, 41, 42 and 45. Recitals 40 and 41 establish the necessary foundation for the exclusions in Article 6(2)(a) and (b) respectively, namely the consensus within the Community, as well as the definition of human cloning:

(40) Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against ordre public and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;

1253 See also the Opinion of Advocate General Jacobs, delivered on 14 June 2001, Case C-377/98, Netherlands v Parliament and Council, paras 110-112. See further reasoning with regards to Recital 38 in Section 15.4.2.3.
(41) Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;

If the focus of Recital 40 is the recognition of the consensus within the Union with regard to the immorality of germ line modifications in Article 6(2)(b), Recital 41 contains more of a technical definition of what constitutes a process of human cloning in Article 6(2)(a). Recital 42 stresses an important limitation for the non-patentability of uses of human embryos in Article 6(2)(c):

(42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;

According to this Recital, the use of human embryos for therapeutic or diagnostic purposes are thereby potentially patentable, or at least do not fall within the exclusion in Article 6(2)(c) of the Directive. Finally, Recital 45 copies the text of Article 6(2)(d):

(45) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit in terms of research, prevention, diagnosis or therapy to man or animal, and also animals resulting from such processes, must be excluded from patentability;

Recital 45 also adds a definition of phenomena of which a medical benefit may consist of, namely ‘research, prevention, diagnosis or therapy’.

In addition to these recitals which are particularly central to the interpretation of Article 6, other recitals are clearly relevant. For instance, Recital 14 addresses both the negative nature of a patent right and the recognition of its limitations to regulate research and commercialization:

(14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;

Recital 16 (which relates to Article 5) lays down the respect for fundamental principles of dignity and integrity of the person:
(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

Recital 43 continues in the same vein by recognizing the respect for fundamental rights contained not only in international and national legislation, but also in the constitutional traditions common to the Member States, taking the form of general principles of EU law:

(43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law;

Recital 26 stresses the importance attached to respecting the principle of free and informed consent for inventions based on material of human origin:

(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law;

In addition to Article 6, Article 7 contains the provision that ‘The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.’ Article 7 is supplemented by Recital 44, which simply adds that: ‘Whereas the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law.’

15.4 The Construction of the Morality Exclusion

15.4.1 Scope of Manoeuvre for Member States

In the context of EU law, the question concerning the narrow construction of the morality clause (as an exclusion) is connected to the division of competences and margin of manoeuvre for the Member States in relation to the EU. For
this reason, the question of narrow construction of the morality clause has not been as prominent with regard to Article 6 of the Biotech Directive compared to its counterpart in Article 53(a) EPC, since the crucial point of the CJEU’s interpretation has been the Member States’ margin of appreciation and not the breadth of the exclusion as such. From a patent law viewpoint this is perhaps surprising; given the function of the CJEU it is not.

As evidenced in the process of enactment of the Biotech Directive and the resulting chosen concepts, the character of which are open and vague, sensitivity towards national divergences was a major concern and consideration, as recognized first and foremost in the text of Recital 39.1254 The concepts of ordre public and morality should correspond ‘in particular’ to ethical and moral principles recognized in a Member State, and that ‘such ethical and moral principles supplement the standard legal examinations under patent law regardless of the technical field of invention’. On this issue, the CJEU held in the Netherlands case that:

As regards, first, Article 6 of the Directive, which rules out the patentability of inventions whose commercial exploitation would be contrary to ordre public or morality, it is common ground that this provision allows the administrative authorities and courts of the Member States a wide scope for manoeuvre in applying this exclusion.1255

However, that scope for manoeuvre is necessary to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State, a context which the national legislative, administrative and court authorities are better placed to understand than are the Community authorities. That sort of provision, which allows patents to be refused where there is a threat to ordre public or morality is, moreover, a well known one in patent law and appears inter alia in the relevant international legal instruments, such as the EPC.1256

Furthermore, the scope for manoeuvre left to Member States is not discretionary, since the Directive limits the concepts in question, both by stating that commercial exploitation is not to be deemed to be contrary to ordre public or morality merely because it is prohibited by law or regulation, and by giving four examples of processes or uses which are not patentable. Thus, the Community legislature gives guidelines for applying the concepts at issue which do not otherwise exist in the general law on patents.1257

1255 Case C-377/98, para 37.
1256 Id., para 38.
1257 Id., para 39.
The overarching theme of the reasoning of the Court is found in the third plea of the applicant, i.e. the breach of legal certainty due to the alleged exacerbation of legal ambiguities on behalf of the Directive. The scope of manoeuvre referred to by the CJEU is specifically directed to the application of the concepts of ordre public and morality. The necessary leeway identified by the Court is the ‘taking into account of the particular difficulties to which the use of certain patents may give rise to in the social and cultural context of each Member State’. It is apparent that the CJEU recognised the provision to be of an open-ended character and that its operation permits national differences with regard to its content, thereby indicating intent to accommodate divergent concerns.

This approach was confirmed in the Italy case, where the CJEU held that Article 6(1) of the Directive ‘allows the administrative authorities and courts of the Member States a wide discretion in applying [the morality exclusion]’. The scope is not, however, discretionary, as the Court identified the proviso in the last sentence of Article 6 as a limiting statement, and the exemplifying list is equally viewed as guidelines for the application of the clause, functioning as guiding principles for the Member States. Of interest is also the reference to the EPC as a relevant legal instrument for the application of the provision, perhaps indicating an alignment to the handling of (first and foremost) national principles in other fora, such as the European Patent Organisation.

The principle to leave room for manoeuvre for decisions on morality or ordre public to the Member States is in line with the current principle of EU law in relation to morality questions, established already in Henn and Darby. According to this principle, the discretion is accorded a Member State to determine the scope of the concept of public order or public morality in accordance with its own scale of values, albeit under the jurisdiction and guidance of the CJEU. As concluded with regard to the case law on free movement in Section 14.2, the Court has consistently refrained from interfering in national opinions (of especially morality) in sensitive areas.

Advocate General Jacobs, on the other hand, hinted at the creation of EU-wide concepts in his Opinion to the Netherlands case. He stated that the traditional position of the CJEU on issues related to morality and ordre public, i.e. the discretion of Member States stemming from the case law on free movement, should perhaps be read with some caution. The Advocate General stated that common standards evolve, and held that the ethical dimension of some of the basic issues within the Directive should be appropriately regarded as governed by such (e.g. human dignity). The Advocate General found support in the case

1258 Case C-456/03, para 78.
1259 Case 34/79, Regina v Maurice Donald Henn and John Frederick Ernest Darby (Henn and Darby), [1979] ECR 3795.
law of the EPO, more specifically in the PGS decision where the concept of morality was defined with reference to the ‘belief [...] founded on the totality of the accepted norms which are deeply rooted in a particular culture’. The fact that common standards of morality may be more appropriately used in some cases than in others did not, in the view of the Advocate General, preclude a degree of harmonisation under Article 6(1) of the Directive.

As witnessed, the statements of Advocate General Jacobs were neither followed by the Court in the Netherlands case, nor in the Italy case, where the wide scope of manoeuvre on behalf of the administrative authorities and courts of the Member States was stressed in relation to Article 6(1). Nevertheless, the opinions expressed by the Advocate General are significant of the future development of EU patent law, especially in relation to the exemplifying list in Article 6(2) of the Directive. If the position with regard to Article 6(1) of the Directive rests on recognition of national divergences, Article 6(2) displays a different function: a set of guiding principles common to all Member States.

15.4.2 The Relation Between Article 6(1) and 6(2)

15.4.2.1 The Framework in Article 6(1)

In contrast to the Court’s position in relation to the application of Article 6(1), which appears to recognize heterogeneity and diversity, at least regarding the interpretation of the concepts of ordre public and morality, the exemplifying list in Article 6(2) contains examples of inventions that are manifestly unpatentable. The foundation of the exemplifying list is therefore of interest, as it rests on a consensus of the unpatentability of the subject matter contained therein. It furthermore follows from the preamble to Article 6(1), and by the use of the words ‘in particular’, that the list in Article 6(2) is not intended to be exhaustive, which is also confirmed by the CJEU.

The CJEU has established that the purpose of the exemplifying list in Article 6(2) of the Directive is ‘to give definition to the exclusion laid down in Art[.] 6(1)’. The estimation of the immorality or breach of ordre public that the commercial exploitation of these examples may cause thus appears unnecessary, i.e.

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1261 T 356/93, Reasons for the Decision, para 6.
1263 Case C-377/98, para 76. Most commentators agree that the list contains categorically unpatentable examples, but there are arguments for treating the list as illustrative only. See Case C-456/03, paras 77-78 and Case C-341/10 para 33. See also Opinion of Advocate General Cruz Villalón delivered on 17 July 2014 in Case 364/13, International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, paras 33-34. Cf. the arguments given by Beyleveld, Brownsword and Llewelyn that Recital 38 gives the impression that the list in Article 6(2) is illustrative only, thereby promoting an interpretation with the effect that the categories in the list are not categorically unpatentable, i.e. they are a grey-list instead of a black-list. Beyleveld, Brownsword and Llewelyn, 168.
the application of Article 6(1) is precluded by the terms of Article 6(2). The examples are agreed upon in the legislative process as being unpatentable. The consensus with regard to their unpatentability must logically mean that at the time of drafting, these examples fulfilled the criteria in Article 6(1) of the Directive, namely that their commercial exploitation would be contrary to morality or *ordre public*.

The wording of Article 6(1), repeated in Recital 37, confirms the fact that the morality exclusion targets inventions ‘where their commercial exploitation [would be contrary to] *ordre public* or morality.’ The first formulation (would be contrary to) is the wording found in Article 6(1) and the second (offends against) is taken from Recital 37. The difference between something ‘being contrary to’ or ‘offending against’ from a literal viewpoint is minimal, and the choice of wording in not one, but two places in the Directive, does not appear to be random. Therefore, the requirements of Article 6(1) of the Directive logically necessitate an assessment of the immorality or breach of *ordre public* caused by the commercial exploitation of the invention in question.

In addition, the examples in Article 6(2) should be subject to the framework established by Article 6(1). Interpretation of the general clause should not be necessary with regard to the examples, because they are viewed as already being subject to a consensus regarding their unpatentability under Article 6(1) of the Directive. Still, such consensus must reflect the overarching theme in Article 6(1), namely that the examples in Article 6(2) are all inventions whose commercial exploitation would be contrary to *ordre public* or morality. For example, the exclusion regarding ‘uses of human embryos for industrial or commercial purposes’ in Article 6(2) must be read as follows, if combined with the overarching requirements of Article 6(1): the commercial exploitation of uses of human embryos for industrial or commercial purposes is always contrary to *ordre public* or morality. Already here the inclusion of the supplementary wording ‘for industrial or commercial purposes’ in Article 6(2)(c) may appear redundant. 1264

Before treating this apparent duplication of concepts, it is necessary to investigate this foundation of consensus allegedly underlying the list in Article 6(2).

15.4.2.2 The Consensus of Article 6(2)

There is little evidence and documentation regarding the choices of or justifications for the four examples in Article 6(2) of the Directive, but a qualified conclusion is that these areas represent the major ethically controversial aspects of science at the time of adoption of the Directive. It is apparent from the study of the enactment process in Section 14.3 that the provisions are the result of negotiating different interests, and the lack of an (inherent) logic of the list (as

1264 But we will come back to an analysis of its implications in Section 15.5.2.

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well as corresponding recitals) is an effect of the legal bargaining that took place at the time. The appropriateness of these specific examples has consequently been called into question for being both premature and inflexible, firstly because they were put into the Directive before a moral decision could be formed but also due to the fact that they did not allow change over time.1265

Another issue that adds uncertainty to the perceived consensus in relation to the list is that the examples of Article 6(2) rest on different ethical approaches. Whilst example (d) rests on an utilitarian approach, examples (a) and (b) concern a broad undefined aspect of human dignity. Example (c) also concerns human dignity, but adds instrumentalisation and commercialisation to that concern.1266 If the wording of Article 6(1), especially the requirement of ‘commercial exploitation’ is seen as narrowing the scope of its application, then the examples in Article 6(2) give the impression that they are stand-alone exceptions, which naturally is in conflict with the introductory wording of Article 6(2) as mere examples under the framework set by Article 6(1).1267 This observation leads to the question of which types of moral approaches Article 6(1) targets? Is there room for a diverse range of moral foundations in the application of the requirements of Article 6(1)?

The answer touches upon the margin of appreciation for the Member States to decide on the scope of excluded subject matter (i.e. inventions whose commercial exploitation is contrary to morality or *ordre public*). To the extent that general principles of EU law exist, these could be used to establish common European principles of what constitutes morality or *ordre public*. But it is necessary to separate between the situations where research as such or non-commercial activities are contrary to morality or *ordre public*, or where the commercial exploitation of an invention is. A regular criticism towards the examples, especially as regards the embryo exclusion in Article 6(2)(c), is that there is no consensus as to the regulatory legislation between Member States concerning the use of human embryos for the procurement of hESC lines.1268 This prompts the question of whether is it a requirement that the examples on the list are subject to consensus between the Member States only as to their unpatentability, detached from the question of permission or prohibition to use the cells under regulatory legislation and authorisation? If the answer is yes, then the following question must be, just exactly what should the consensus relate to? Is it agreement between the Member States that the examples on such a list need to be excluded from patentability because the activities as such are contrary to morality or *ordre public*? Or is it consensus that the commercial exploitation of the processes and uses is contrary to morality or *ordre public*?

1265 Beyleveld, Brownsword and Llewelyn, 167.
1266 See Case C-377/98, paras 76-77 and Laurie 2008, 99-100.
1267 See Laurie 2008, 100.
The alleged consensus on the unpatentability of the examples in Article 6(2) is apparent from the negotiations because it resulted in the inclusion of the examples on the list. However, the foundation for this consensus is not clearly expressed in the provisions of the Directive. As regards the exclusions for germ line and cloning modifications in Article 6(2)(a) and (b) it is explicitly referred to in Recital 40 that ‘there is a consensus in the Community that interventions in the human germ line and the cloning of human beings offends against ordre public and morality’ (emphasis added). The consensus regarding these subject matters, thus, is expressed as offending against ordre public and morality. But the remaining examples on the list, namely the uses of human embryos in 6(2)(c) and transgenic animals in 6(2)(d), lack explicit corresponding references (in the recitals, at least) to the alleged consensus in relation to these particular examples. Guidance regarding the character of the foundation for consensus for these must be found elsewhere.

Consensus regarding the exclusions in Article 6(2)(a) and 6(2)(b) reflects the regulatory position on the subject matter contained therein with regard to the EU and its Member States at the time of the enactment of the Directive, namely that (especially) human reproductive cloning is expressly prohibited in European states. The regulatory situation with regard to the uses of human embryos (including their destruction) in Article 6(2)(c) was, and is, by contrast diversified. It is of interest to note that a proposal for exclusion also of processes for therapeutic cloning (SCNT) was withdrawn from the Directive, probably due to the different legal situation in the Member States, signalling a cautious approach. The consensus being a reflection of the regulatory situation is, thus, not a possible foundation for Article 6(2)(c) of the Directive. In order to trace this foundation, an investigation into the human dignity concerns underlying the enactment of the list is necessary.

15.4.2.3 Protection of Human Dignity

Recital 38 and Recital 16 mention the respect for fundamental principles of safeguarding human dignity and integrity of the person. Recital 16 is connected to the principle of inviolability of the human body, expressed most prominently in Article 5(1). The CJEU has nevertheless emphasized the supplementary role of Article 6 in the safeguarding of human dignity. The origins of this supplementary role can be traced back to the events during the enactment of the Direct-
rective, and more specifically the separation of the question of patentability of parts of the human body from the scope of the morality clause.

The first proposals for an illustrative list of unpatentable subject matter under the morality clause contained exclusions in relation to the human body, with references to the safeguarding of human rights. In later proposals, the question of unpatentability of the human body became a matter of a purely technical distinction (although resting on ethical considerations) between discoveries and inventions and was consequently moved from the morality clause to form a provision of its own (Article 5). The separation of the human body issue from the scope of the morality clause was a result of the discussions regarding the patentability of human genes. The wish to allow product patents on human gene sequences prompted a clarification that for patentability, such (human) subject matter must either be isolated or produced by means of a technical process (Article 5(2)), whilst the human body as such can never form a patentable subject matter (Article 5(1)).

In a sense, the aim of this clarification was to placate the opposition by creating proper boundaries guarding the human body in its natural state, and at the same time specifying criteria for the patentability of human body parts. But the result actually changed the framework for patentability questions regarding the human body and parts thereof. The difference between Article 5(1) (unpatentability of the human body in its natural state) and 5(2) (patentability of parts of the human body under certain circumstances) of the Directive now rests on the technical distinction between a discovery and an invention, and this particular distinction is, thus, removed from the scope of Article 6.

The question whether this legal construction still permits an assessment of the morality of patenting subject matter regulated in Article 5(2) and 5(3) of the Directive under Article 6 is interesting. Since Article 6 must be regarded as having an overriding function, such an assessment should be possible in theory. Since the patentability of such subject matter is legally-technically correct, the morality concerns must necessarily be directed towards other aspects that the unpatentability of the material as such.

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1272 The insertion of Article 5(3) regarding the industrial application criterion further adds to the explanation problem that the whole gene patent discussion caused, and is indicative of the sensitive balancing act characterizing the whole enactment process, but also of the success for those wishing these types of patents.


1274 The effects of moving the human body from the domain of the morality clause to an article of its own, where the assessment rests on purely technical grounds, are interesting to discuss. If the requirements in Article 5(2) are fulfilled (in addition to the rest of the patentability criteria) for an invention regarding human body parts, does this preclude an assessment of the patentability of the invention under Article 6? If Article 6 is seen as containing overriding standards for patentability, of which ordre public and morality must form part, then there is no principal objection towards bringing a challenge under Article 6. But in practice, against the background of the exhaustive legal-technical framework provided for human gene sequences in the Directive,
During the negotiations prior to the coming into effect of the Directive, it was feared that the human embryo would not be included in the ‘human body’ concept, and additional exclusions from patentability for the human embryo as such were therefore proposed. These were placed under the morality clause, perhaps with the intent to reinforce the connection to human dignity. It was subsequently clarified that the human embryo is, indeed, included in the definition of a human body in the Directive and is protected against patentability in its natural state. Following such clarification the human embryo exclusion under the morality clause was subject to a narrowing in scope in the form of a supplementary formulation, i.e. ‘industrial or commercial purposes’.

Following this development where the safeguarding of human dignity resulted in two sets of provisions, with differing purposes (technical vs. moral), a logical conclusion would be that the remaining examples in the exemplifying list rest on a foundation of concern for human dignity. Recital 38 recognises the function of the illustrative list as a general interpretative guide to ‘the reference to ordre public and morality’ for national courts and authorities but also stresses the safeguarding of human dignity on behalf of Article 6(2). In this vein, respect for human dignity is the natural foundation for the examples on the list, at least with regard to examples (a) to (c). Such an interpretation is also advanced by the CJEU, which held in connection to the supplementary role of Article 6 and Recital 38 in Brüstle that ‘[t]he context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected.’

But Recital 38 contains built-in possibilities for different interpretations in connection to Article 6(2) and also in relation to Article 5. First, the inclusion in Recital 38 of examples of additional unpatentable subject matter such as ‘processes to produce chimeras from germ cells or totipotent cells of humans and animals’ is confusing. If further examples of unpatentable inventions were
agreed upon, why were these phenomena not included in the list in Article 6(2) instead of in a recital? The status of this example of further excluded subject matter being placed in a recital rather than in an Article could consequently be called into question.1279

Second, the outline of Recital 38 starts with a description of the aim of the illustrative list, followed by the statement that the list cannot be exhaustive, and concludes with the following: ‘whereas processes, the use of which offend against human dignity […] are obviously also excluded from patentability’. The question could be raised as to whether the use of the word ‘also’ in this context entails that the phenomena referred to in the first part of the Recital (i.e. the inventions included in the exemplifying list) rest on a different foundation than being offensive against human dignity. As far as the statement relates to Article 6(2)(d) this is true, since that specific exclusion targets transgenic animals and has an explicit test resting on an utilitarian approach. Still, this is not the most logical reading of the Recital.

If the intention of Recital 38 is to lay down offenses against human dignity as an all-embracing foundation for the operation of the list in Article 6(2) of the Directive, it is not reflected in the wording of the Recital. The reference to human dignity is, as mentioned in Sections 5.3.3. and 5.3.4, subject to different interpretations and views, and in addition the human embryo exclusion was subject to additional concerns regarding the commodification or commercialization question.1280 These views are not reflected in the text. The actual outcome of the text of Recital 38 is that the list in Article 6(2) is illustrative and non-exhaustive, and that in addition to the examples contained therein, the use of processes which offend against human dignity should also be excluded. It is not possible to deduce a relation between such human dignity-offensive uses of processes (such as the chimera example) and the already existing examples from a literal reading of the Recital. In sum, the wording of the Recital is unclear and leaves room for questions as to the foundation for excluding the types of phenomena found in the list. The only conclusion so far is that the consensus of the examples in the exclusion was simply a result of a political bargaining process, thus, creating an uncertain legal situation which was exacerbated by the wording of the Directive’s provisions.

from germ cells or [from] totipotent cells of humans and animals’. (Opinion of Advocate General Jacobs, para 110) This insertion clarifies the content of the provision. But apparently, room for reading the provision as specifying two sets of examples of unpatentable inventions also exist; either ‘processes to produce chimeras from germ cells’ or ‘totipotent cells of humans and animals’. By the insertion of the word ‘from’ by Advocate General Jacobs the meaning of the statement as pointing towards an understanding of it as one phenomenon was made much clearer. Support for the Advocate General’s reading could also be found in the fact that non-human totipotent cells are actually patentable. Despite the question whether Recital 38 contains one or more additional excluded items, the fact that Article 6(2) is not exhaustive in its exemplifying subject matter is confirmed by Recital 38.

1279 See Section 9.4 on the status of recitals.
1280 See Section 14.3.2.4.
Before proceeding to an analysis of the relationship between Article 6(1) and Article 6(2), a presentation of the *Brüstle* decision is necessary. The reasoning of the CJEU with regard to Article 6(2)(c) will contribute to an understanding of the Court’s construction of the exemplifying list, which is necessary for the discussion of its relation to Article 6(1), and the general function of the morality clause.

15.5 The *Brüstle* Decision

The importance of the *Brüstle* decision lies in the interpretation provided by the Court in relation to Article 6(2) of the Directive. The deficiency of the decision is that it is tied to the specific facts related to Article 6(2)(c) of the Directive, and it is therefore difficult to draw general conclusions from that specific decision. Despite this, the decision provides some interesting statements from the Court as to the function of Article 6(2) of the Directive, which prove important for the application of Article 6(1).

The origin of the decision was a German patent filed in 1997, held by Oliver Brüstle. The claims of the patent covered isolated and purified neural precursor cells, processes for their production from ESCs and the use of neural precursor cells for the treatment of neural defects. On application by Greenpeace, the German Bundespatentgericht (Federal Patent Court) ruled the patent to be invalid in so far as it covered precursor cells obtained from hESCs and processes for the production of those precursor cells. The Bundesgerichtshof (Federal Court of Justice) upon appeal referred the case to the CJEU for an interpretation of Article 6(2)(c) of the Biotech Directive, which corresponded to the German embryo exclusion.

The dispute under this ruling was determined by the questions referred to the Court for a preliminary ruling. Evidently the focus of the questions was directed towards the definition of a human embryo:

1. What is meant by the term “human embryos” in Article 6(2)(c) of [the Directive]?

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1281 Oliver Brüstle, a German scientist, worked with transplantation of brain cells into the nervous system for methods of treatment of various neurological diseases. The aim of the invention was to produce ESCs for transplantation. The Bundespatentgericht (Federal Patent Court) ruled, on the basis of Paragraph 22(1) of the PatG, that the patent at issue was invalid in so far as it covers precursor cells obtained from hESCs and processes for the production of those precursor cells. The defendant appealed against that judgment to the Bundesgerichtshof (Federal Court of Justice), who referred the case to the CJEU. (Case C-34/10, para 15 ff.)

1282 The German version of the exclusion is found in para 2(2), first sentence, point 3, of the PatG (Patentgesetz 05.05.1936).
(a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?

(b) Are the following organisms also included:

– unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;

– unfertilised human ova whose division and further development have been stimulated by parthenogenesis?

(c) Are stem cells obtained from human embryos at the blastocyst stage also included?

2. What is meant by the expression “uses of human embryos for industrial or commercial purposes”? Does it include any commercial exploitation within the meaning of Article 6(1) of [the Directive], especially use for the purposes of scientific research?

3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching:

– because the patent concerns a product whose production necessitates the prior destruction of human embryos,

– or because the patent concerns a process for which such a product is needed as base material?

The reasoning of the referring Court was that since Article 6(2) of the Directive did not allow the Member States any discretion as to the patentability of the subject matter listed therein, the only possible interpretation of the contents of Article 6(2)(c) and specifically the term ‘embryo’ is European and unified. The first question related to the concept of human embryo and, specifically, whether the hESCs which serve as base material for the patented process constitute ‘embryos’ within the meaning of Article 6(2)(c) of the Directive. The referring Court also asked ‘whether the organisms from which those human embryonic stem cells can be obtained constitute ‘human embryos’ within the meaning of [Article 6(2)(c)]’.

To this effect, the stem cells serving as base material for the patented process were not all totipotent, but some pluripotent.1283

1283 Case C-34/10, paras 21-22. See Section 3.2 on the scientific background.
The questions will be dealt with according to the order in which they were posed by the referring Court, starting with the concept of human embryo.

15.5.1 Human Embryo Definition

An important part of the decision related to the question of the interpretation of the concept ‘human embryo’. By reference to settled case law, the CJEU stated that ‘the need for a uniform application of European Union Law and the principle of equality require that the terms of a provision of European Union law which makes no express reference to the law of the Member States for the purpose of determining its meaning and scope must normally be given an independent and uniform interpretation throughout the European Union’. With the aim of a smooth functioning of the internal market, the CJEU held that for the purposes of the application of the Directive, the human embryo concept designated for such application must be an autonomous concept of European Union law, and must be interpreted in a uniform manner throughout the territory of the union.

The reasoning of the Court in the search for a European definition of the embryo concept contained many arguments for the position that the definition should be independent from the positions of the Member States. Since the embryo concept is a very sensitive social issue in the European states the position of the Court would have been rather difficult – or impossible - if they had searched for a definition by reconciling the different traditions and value systems in the states. The Court furthermore identified the creation of a definition not as a matter of medical or ethical nature, but restricted the task to a legal interpretation of the relevant provisions of the Directive.

By such statement the Court seems to imply that this embryo definition is solely provided for the needs of the biotechnological patent field. In principle, the Court cannot go further, outside the harmonised area, and create a definition for the whole field of connected (medical, ethical and general legal) issues. Still, the creation of an embryo definition will have a compelling effect also on areas outside the specific field of patents for biotechnological inventions relating to human material.

The regard for fundamental rights, and specifically the dignity of the person, was the foundation for the resulting human embryo definition by the Court. The CJEU referred to a number of provisions, specifically Recital 16 and the ‘dignity and integrity of the person’ and held that the combined aims of Article 5(1), Article 6 and Recital 38 in the context of the Directive show that ‘the Eu-
European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. From this platform of human dignity the Court concluded that the concept of ‘human embryo’ must be understood in a wide sense. A human embryo is consequently defined by the capability of the human material to commencing the process of development of a human being:

Accordingly, any human ovum must, as soon as fertilised, be regarded as a ‘human embryo’ within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive, since that fertilisation is such as to commence the process of development of a human being. [...] That classification must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis. Although those organisms have not, strictly speaking, been the object of fertilisation, due to the effect of the technique used to obtain them they are, as is apparent from the written observations presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so.

By creating a European definition of human embryo, the Court created new European law. Since the Court so strongly emphasised the creation of a novel definition, without recourse to the definitions already existing in the Member States, the resulting definition stands alone as an autonomous EU law concept. But the actual definition created by the Court seems – at first glance – to lend quite a large scope of manoeuvre for the Member States to determine its content. The question of whether stem cells obtained from a human embryo (at the blastocyst stage) have the capability of commencing the process of development of a human being and is thereby contained within the embryo definition, is left to the Member States to decide (in the light of scientific developments).

The definition in Brüstle is quite broad, covering not only fertilised human ova but also a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and additionally, a non-fertilised human ovum whose division and further development have been stimulated by
parthenogenesis. This wide definition was subsequently limited by the CJEU in Case C-364/13, where the Court expanded on the statement ‘commence the process of development of a human being’, thereby specifically excluding non-fertilised human ova whose division and further development have been stimulated by parthenogenesis. Thus, according to current scientific knowledge, the human embryo definition created by the CJEU covers any subject matter that has the inherent capacity of developing into a human being, typically fertilised human ova, but excludes materials not capable of developing into a human being. The CJEU did not, however, in any of the cases, establish whether a stem cell obtained from a human embryo at the blastocyst stage constituted a human embryo within the meaning of Article 6(2)(c) of the Directive. This particular question is left open to the Member States to decide.

The room of manoeuvre for the Member States to decide on the inclusion of the actual stem cells under the human embryo definition may seem quite large. However, the extent of the embryo definition is not decisive for the outcome of the interpretation of the embryo exclusion, as the further reasoning of the Court will show.

15.5.2 The Relevance of Industrial or Commercial Purposes

The second question addressed by the referring Court was whether the concept of ‘uses of human embryos for industrial or commercial purposes’ within the meaning of Article 6(2)(c) of the Directive also covers the use of human embryos for purposes of scientific research. The Court stated that the grant of a patent clearly implies its ‘industrial or commercial application’. Recital 14 lends support to such an interpretation, reasoned the Court, because stating that a patent for invention ‘entitles [its holder] to prohibit third parties from exploiting it for industrial and commercial purposes’ indicates that the rights attached to a patent are, in principle, ‘connected with acts of an industrial or commercial nature’. The CJEU followed up by stating that:

1290 Mammalian parthenotes, created by the activation of an oocyte, in the absence of sperm, by a variation of chemical and electrical techniques, are capable of dividing and further developing. According to current scientific knowledge, mammalian parthenotes can never develop to term, because they do not contain any paternal DNA, needed for the development of extra-embryonic tissue. Such parthenotes have been shown to develop only to the blastocyst stage, over about five days. Case C-364/13, International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, Judgment of the Court (Grand Chamber), 18 December 2014. para 17. The decision is dependent on the specific facts of the case, and also leaves the final decision to the national court, but serves to limit the definition of Brüstle. This clarification focuses on the potential of the cells to develop into a human being, thus including every totipotent cell and also unfertilized human ova which are the results of cloning processes, provided that they also have that potential. In essence, the area of unpatentable subject matter is consequently broadened.

1291 Case C-34/10, paras 41-42.
Although the aim of scientific research must be distinguished from industrial or commercial purposes, the use of human embryos for the purposes of research which constitutes the subject-matter of a patent application cannot be separated from the patent itself and the rights attaching to it.1292

Thus, even though the CJEU views research as potentially having an aim which is not industrial or commercial, the fact that subject matter used in research (in this case, human embryos) constitutes the content of a patent application makes that same subject matter inseparable from first, the patent itself, and second, the rights attached to it. There are consequently two types of phenomenon that are inseparable from the subject matter of a patent application – the patent and the rights attached to it. The Court, regrettably, neither elaborated on the content of the two different phenomena nor did it elaborate on whether they were to be regarded as separate or not.

Instead, the ‘clarification’ in Recital 42 was investigated and the CJEU concluded that the fact that there are actually some types of inventions that fall outside the exclusion in Article 6(2)(c) and as a result are consequently patentable (i.e. inventions for therapeutic or diagnostic purposes which are applied to the human embryo and useful to it) also confirms that ‘the use of human embryos for purposes of scientific research which is the subject matter of a patent application cannot be distinguished from industrial or commercial use and, thus, avoid exclusion from patentability’.1293 Finally, to lend support to its findings, the CJEU concluded that ‘[t]hat interpretation is, in any event, identical to that adopted by the [EBA]’ (i.e. WARF).1294

The reasoning of the Court gives the impression that the inclusion of the qualification ‘industrial or commercial purposes’ is redundant, because patent rights are always connected to acts of an industrial or commercial nature. It is natural to question the purpose of including such a statement at all, if it does not contribute with any content to the interpretation of the provision in which it is set to function. A possible aim of the qualification is the separation of unpatentable uses of human embryos (for industrial or commercial purposes) from patentable uses of human embryos (inventions for therapeutic or diagnostic purposes which are applied to the human embryo and useful to it). But the identification of patentable uses of subject matter need not be contrasted to unpatentable uses by a specific qualification that the unpatentable uses are for industrial or commercial purposes. It would suffice to simply mention the patentable uses, especially since the qualification with regard to unpatentable uses

1292 Case C-34/10, para 43.
1293 Id., para 44.
1294 Id. It is quite amusing that the final statement contains an ‘in any event’-formulation, giving the impression that even if the reasoning of the Court would be deficient, it still holds up, not by strength of argument but because it is identical to the EBA’s findings.
does not add any further information in addition to what can be inferred from the characteristics of a patent (or a patent right), namely industrial or commercial purposes. Furthermore, the inclusion of patentable uses of a human embryo in a patent application would make such subject matter subject to ‘acts of an industrial or commercial nature’, but the invention would still be potentially patentable because it is for ‘therapeutic or diagnostic purposes which are applied to the human embryo and useful to it’. In this sense, the purposes listed in Recital 42 (therapeutic or diagnostic) functions as a characteristic of the invention, and not as characteristic of the patent right. Why would the qualification ‘for industrial or commercial purposes’ be regarded as being connected to the patent or the rights attaching to the patent, and not to the invention as such, when that is clearly the situation with regard to the specification for patentable subject matter?

The conclusion is that the function of the qualification ‘industrial or commercial purposes’ must necessarily be read as narrowing the scope of the provision, and the reasoning of the Court is consequently erroneous in this regard. If the legislator had intended a broader scope of the exclusion it would simply have sufficed to state that ‘uses of human embryos’ would be excluded (with the possible exception for uses for therapeutic or diagnostic purposes). The existence of the qualification in Article 6(2)(c) of the Directive cannot be negated, especially considering the wording with regard to patentable inventions in Recital 42. This reasoning is the first indication of a broadening of concepts on behalf of the CJEU. The next indication concerns the concept of embryo destruction and the effects of this reasoning for the scope of the concepts of invention and commercial exploitation, respectively.

15.5.3 The Relevance of Embryo Destruction

The third question from the referring court read:

Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching:
- because the patent concerns a product whose production necessitates the prior destruction of human embryos,
- or because the patent concerns a process for which such a product is needed as base material?

The CJEU reformulated the question by stating that ‘by the third question the referring court asks the Court, in essence, whether an invention is unpatentable even though its purpose is not the use of human embryos, where it concerns a product whose production necessitates the prior destruction of human embryos
or a process for which requires a base material obtained by destruction of human embryos.’ The CJEU thus equates ‘technical teaching’ with ‘invention’. The changes appear to be only textual, but already here a broad understanding of the scope awarded to the concept of invention is indicated.

The reasoning of the CJEU centres on the fact that the invention, even though not claimed as such, presupposes the use of stem cells obtained from a human embryo at the blastocyst stage, and that the removal of a stem cell from a human embryo at that stage entails the destruction of that embryo. Referring to the human dignity argumentation in connection with the first question (embryo definition), the Court stated that ‘an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos’.1295 There is no difference, in the Court’s view, between this latter situation and the actual destruction of an embryo, even though the actual destruction necessitated by the invention may precede the invention not only in time but also in material aspects. For instance, the material covered by the invention is not necessarily identical to a human embryo, but derived from a human embryo.

There is also the fact that the use of the invention may not even be the reason that the destruction took place in the first place. But, this does not affect the unpatentability of the invention at hand. This is because, continues the Court, ‘[t]he fact that destruction may occur at a stage long before the implementation of the invention […] is, in that regard, irrelevant.1296 The Court adds that to exclude the present invention from the scope of Article 6(2)(c) of the Directive could make the exclusion redundant by allowing a patent applicant to avoid its application by skilful drafting of the claim, and finishes by referring to the EBA’s argumentation in WARF as a further argument of the fact that the right decision is reached.1297

What the Court actually states is that the exclusion cannot be avoided, even when the claimed invention covers subject matter not excluded as such, but derived from excluded subject matter. Hence, an invention, as claimed, is included under the scope of the exclusion even though the invention as such, the object of the patent right, does not cover subject matter which is defined as excluded subject matter in the provision. But because the invention uses subject matter that is derived from other subject matter which would be excluded if someone tried to claim it as part of the patent application, the invention as such cannot avoid the exclusion. The linking of the invention to the subject matter

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1295 Case C-34/10, para 49.
1296 Id., paras 48-49.
1297 Id., para 50.
targeted by the exclusion is, furthermore, only possible by expanding present concepts of patent law.

15.5.4 Lessons Learned

15.5.4.1 The Moral Complicity

The purpose of the invention under scrutiny is apparently not the use of embryos, but in the words of the Court ‘a product whose production necessitates the prior destruction of human embryos or a process for which requires a base material obtained by destruction of human embryos’. The destruction argument is decisive and forms the basis of the reasoning of the Court with regard to the application of the exclusion. Even though the claimed subject matter, i.e. the neural stem cells and the method of their production, does not directly presuppose the repeated destruction of embryos for the working of the invention, the fact that the invention presupposes the use of stem cells, and those stem cells are obtained by destruction of embryos, makes the invention unpatentable. In this situation, the use is equal to destruction, and the requirement of use is thereby fulfilled, even though the destruction may occur at a stage long before the implementation of the invention.

The conclusion is that the embryo exclusion is applicable to an invention ‘where the technical teaching which is the subject matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.’ (emphasis added) By reference to the use of human embryos as base material the decision creates a situation where material based on hESCs are disqualified from patent protection. By means of its decision the Court succeeded in aligning its reasoning with that of the EPO in the WARF case. But the main issue that these decisions uncover is the implications of the material in question. The moral complicity of the (apparently) immoral act of destroying a human embryo taints the resulting invention because there is a material connection between the embryo and the resulting cells. In essence, the invention cannot be separated from its development.

By the reasoning of the Court, using a human embryo for the procurement of human stem cell lines disqualifies the use of such stem cells in inventions, even though the actual implementation of the invention does not, in fact, use or destroy an embryo. It is sufficient for the application of the embryo exclusion that the material used in an invention at some point in time required the

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1298 Case C-34/10, para 47.
1299 Id., para 52.
destruction, i.e. use of a human embryo. The decisive reason for such an interpretation seems to be that patent applicants should not avoid the application of the embryo exclusion by skilful drafting of the claim(s).\textsuperscript{1300} It does not matter whether or not the hESCs would be included under the embryo definition. By such an interpretation of the use criterion in the embryo exclusion such material is excluded not because they are regarded as human embryos, but because their production requires the use/destruction of human embryos. Thus, the use of stem cells as base material for an invention is disqualified because their production is dependent on the use of human embryos.

15.5.4.2 The Qualification of ‘Industrial or Commercial Use’

The Court found that the embryo exclusion is applicable also to the uses of human embryos in scientific research. In the view of the Court, the rights attaching to a patent are, in principle, connected with acts of an industrial or commercial nature. The Court stated that although the aims of scientific research must be distinguished from industrial or commercial purposes, the use of human embryos for the purposes of research which constitutes the subject matter of a patent application cannot be distinguished from industrial or commercial use.\textsuperscript{1301} The mere fact that an application for patent protection is created, results in the subject matter contained therein being considered as industrial and commercial use. According to the Court this is also supported by Recital 42 of the Directive, where it is stated that the embryo exclusion ‘does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it’. Such inventions are regarded as being for industrial or commercial use, but unlike non-therapeutic or non-diagnostic inventions they do not fall under the embryo exclusion and are therefore patentable.

15.5.4.3 The Dignitarian Approach

The reliance on a broad embryo interpretation and the reasons for such stance implies a safeguarding of ‘life’ in all forms commensurate to a dignitarian approach. Dignitarian considerations are clearly present in the Opinion of Advocate General Bot. He considered totipotent cells as being legally categorized as human embryos, and also that human dignity is a principle which must be applied ‘not only to an existing human person […] but also to the human body from the first stage in its development, i.e. from fertilisation’.\textsuperscript{1302} A pluripotent cell, on the other hand, can never constitute an embryo, and accordingly would

\textsuperscript{1300} Case C-34/10, para 50.
\textsuperscript{1301} Id., para 43.
\textsuperscript{1302} Opinion of Advocate General Bot delivered on 10 March 2011 in Case C-34/10, \textit{Oliver Brüstle v Greenpeace eV}, paras 85, 96.
fall under Article 5(2) of the Directive as an element isolated from the human body.

The Advocate General vehemently rejected an interpretation of Article 6(2)(c) of the Directive which would only take into account the claims, or technical teaching of the patent, where an invention would necessitate an exploitation of the human body in its initial stages of development. He also referred to the fact that allowing the industrial or commercial exploitation of human embryos would be inconsistent with the concept of *ordre public* and would also not be consistent with an ethical conception shared by all the Member States of the Union.\footnote{Opinion of Advocate General Bot delivered on 10 March 2011 in Case C-34/10, *Oliver Brüstle v Greenpeace eV*, para 114.} The statements by the Court as well as the Advocate General confirm that the prevailing notion is a dignitarian one, and the Court definitely, despite their cautionary statements, took a moral stance, because an alternative interpretation would have led to a result which would have been unacceptable from a dignitarian standpoint. A natural conclusion of the CJEU’s reasoning in *Brüstle* is that the scope of moral concerns exceed the act of patenting as such and extends to general instrumentalisation. The use of human embryos in the R&D of an invention is a sufficient obstacle for patentability of that invention.\footnote{Laurie 2008, 101.} It has also been claimed that the result is even more traditionalist and conservative than customary international law, which only prohibits research activities on any embryo over fourteen days old, and not from fertilization.\footnote{Bonadio, 6.}

15.5.4.4 The Breadth of the Exclusion

The interpretation of the embryo exclusion in Article 6(2)(c) of the Directive as demonstrated in *Brüstle* results in quite a broad exclusion. Even though the breadth of the exclusions in Article 6(2) of the Directive has not been discussed by the Court, support for a narrower interpretation is found in legal doctrine. The starting point for a narrower view is the character of the exemplifying list as giving definition to the exclusion in Article 6(1), from an approach which could be characterized as definitional and excluding any room for harbouring divergent moral approaches, or simply excluding an assessment of morality or *ordre public* at all (i.e. excluding an examination of all requirements in Article 6(1)).\footnote{See e.g. Plomer 2009:1, 189.} The specific exclusions in Article 6(2) are in this sense illustrative of the general principle in Article 6(1).\footnote{See Case C-456/03, para 78 and Case C-377/98, paras 37-39.}

From the point of view of the definitional approach, the alleged immorality or breach of *ordre public* by the commercial exploitation of the invention is from
this perspective not to be subject to interpretation. A definitional approach requires only an interpretation of the wording of the exclusion; an interpretation where the words have to be given their natural meaning. There is an imminent danger if the definitional approach is deviated from, namely, that in interpreting the terms of the exemplifying list necessary parameters of the fundamental framework set by Article 6(1) are overlooked. Such parameters must still be followed since Article 6(2) contains examples and embodiments, of the general morality clause in Article 6(1).

The application of a definitional interpretation of Article 6(2)(c) of the Directive entails two effects. First, the scope of application of the exclusion would only reach specifically and only to the uses of human embryos and not to the derived hESC (because they simply would not be regarded as embryos in the natural meaning of the wording, being pluripotent cells and lacking the capacity to develop into a human being). Second, the concept of ‘uses’ extends only to ‘industrial’ or ‘commercial’ uses of human embryos. Here, the act of granting a patent is seen as distinct from its industrial or commercial use. The foundation for this view is consequently different from the notion held by the CJEU; that a patent grant is inseparable from a commercialisation.

Despite the diverse opinions the outstanding issue remains the correspondence of the Brüstle reasoning to the general framework of Article 6(1) of the Directive. In order to expand on this analysis, an investigation of the terms ‘invention’ and ‘commercial exploitation’ is necessary.

15.6 The Scope of Invention

The CJEU has not provided any interpretation of the concept of ‘invention’ except in Brüstle, where the Court equalled ‘use’ to ‘the implementation of the invention’, and whether such implementation required the destruction of human embryos. The third question by the referring court related to the issue of whether an invention is unpatentable even though its purpose is not the use of human embryos, where ‘it concerns a product whose production necessitates the prior destruction of human embryos or a process for which requires a base material obtained by destruction of human embryos’.

The CJEU took a broad view of the concept of ‘invention’:

The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of

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1308 Plomer 2009:1, 189.
1309 Case C-34/10, para 49.
1310 Id., para 47.
human embryos is, in that regard [even if the claims do not concern the use of human embryos], irrelevant.  

The focus may have been on the concept of ‘uses’ in Article 6(2)(c) of the Directive, but the reasoning is specifically related to the commercial exploitation of the invention, including how the term invention should be understood. The meaning of ‘invention’ is also held to be ‘the claimed technical teaching’. If a narrower interpretation would have been applied, in which such procedures would have been outside the scope of the concept of invention as set out by the Court, there would have been a risk for redundancy of the provision in the avoidance of its application by ‘skilful drafting of the claim’.  

15.7 Commercial Exploitation

15.7.1 General Approach

Due to the limited number of decisions, and the lack of guidance by the CJEU regarding the contents of Article 6(1), there are simply not enough precedent for a fully-fledged analysis of the function of the concept of commercial exploitation. Nevertheless, the reasoning of the Court provides interesting material.

The CJEU has identified the operation of the morality provision as to ‘allow[s] a patent to be refused where there is a threat to ordre public or morality’. The immediate understanding of this formulation is that the main aim of the provision is to prevent inventions that threaten (national) ordre public or morality. It is a fairly broad and sweeping description of the exclusion, which does not identify, nor take into account the other prerequisites of the provision, especially the notional qualification of ‘commercial exploitation’. Instead, the CJEU treats ‘commercial exploitation’ first (and foremost) as a limitation of the concepts of ordre public and morality by reference to the qualification in the last sentence of Article 6(1), namely that ‘commercial exploitation is not to be deemed to be contrary to ordre public or morality merely because it is prohibited by law or regulation’. The function of the exemplifying list in Article 6(2) is likewise identified as merely the qualification, providing guidelines ‘for applying the concepts at issue [ordre public or morality] which do not otherwise exist in the general law on patents’.

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1311 Case C-34/10, para 49.
1312 Id., para 50. The CJEU also referred to the findings of the EBA in the WARF case, see para 51 of the judgement.
1313 Case C-377/98, para 38.
1314 Id., para 39.
The Court does not recognise nor take into account the specification provided by the actual wording of Article 6(1), namely that ‘[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to \textit{ordre public} or morality’. For instance, in the \textit{Netherlands} case the applicant submitted that Article 6(1) of the Directive was incompatible with Article 53(a) of the EPC. At the time, Article 53(a) EPC excluded from patentability inventions the ‘publication or exploitation’ of which would be contrary to \textit{ordre public} or morality, whereas Article 6(1) of the Directive excluded inventions on the basis of their ‘commercial exploitation’ being contrary to the former.\footnote{The wording of Article 53(a) EPC was subsequently amended to ‘commercial exploitation’.} The CJEU stated that ‘\textit{in the absence of specific examples to the contrary, it seems reasonable to suppose that a breach of \textit{ordre public} and morality as regards a specific invention could be equally well established by reference to its publication, exploitation or commercial exploitation.’} By this statement the Court either meant that establishing that the ‘commercial exploitation’ of an invention is contrary to morality or \textit{ordre public} is not necessary for applying the Article (thereby indicating an assessment based on other criteria that those specifically mentioned in the wording of the Article), or that the concept of ‘commercial exploitation’ is sufficiently broad so as to include also the concepts of ‘exploitation’ and ‘publication’ alone. In light of \textit{Brüstle}, such a broad interpretation seems to have been intended by the Court.

15.7.2 Guidance From \textit{Brüstle}

The main problem with the CJEU’s decision in \textit{Brüstle} is the breadth awarded to Article 6(2)(c) of the Directive, especially in relation to the narrowing feature of commercial exploitation in Article 6(1). This consequently raises questions as to its compatibility with the framework set in place by Article 6(1) of the Directive as well as the principles for the interpretation of Article 53(a) EPC as established by the EPO.

In the \textit{Brüstle} case the second question referred to the Court read as follows: What is meant by the expression ‘uses of human embryos for industrial or commercial purposes’? Does it include any commercial exploitation within the meaning of Article 6(1) of [the Directive], especially use for the purposes of scientific research?\footnote{Case C-377/98, paras 61-62.} The CJEU did not take the opportunity to interpret the expression ‘commercial exploitation’ in Article 6(1) of the Directive and its relation to the provision regarding ‘uses of human embryos for industrial or commercial purposes’ in Article 6(2)(c) of the Directive. Instead, the Court reformulated the question as to ‘whether the concept of “uses of human em-
bryos for industrial or commercial purposes” within the meaning of Article 6(2)(c) of the Directive also covered the use of human embryos for purposes of scientific research.’\textsuperscript{1318}

The meaning of commercial exploitation in relation to Article 6(1) was therefore not treated by the Court, which is regrettable. What is indicated from the interpretation of Article 6(2)(c), however, is a broad understanding of the concept of ‘industrial and commercial use’ as always included in the rights attached to a patent. Use in the context of scientific research, when put as subject matter in a patent application, will therefore always entail acts of an industrial or commercial nature.

In addition, Advocate General Bot made a statement in the Brüstle Opinion worth paying attention to, addressing the competing interests of different philosophies and religions on the one hand and economic and financial issues on the other:

Patentability and research do not appear to be indissociable from one another. The Member States are obviously free to authorise research under conditions which they lay down. \textit{Furthermore, patentability, i.e. placing on the market with the ensuing conditions relating to production, must be consistent with the requirements laid down by Directive 98/44 with a view to harmonization which integrates ethical considerations so as to prevent the economic functioning of the market giving rise to competition at the cost of sacrificing the fundamental values of the Union.} (emphasis added)\textsuperscript{1319}

In other words, it is apparent that Bot equated the grant of a patent for an invention with its exploitation on the market, a statement (partly) followed by the Court in its ensuing judgment. Asked by the national court whether the concept of ‘uses of human embryos for industrial or commercial purposes’ within the meaning of Article 6(2)(c) of the Directive also covers the use of human embryos for purposes of scientific research, the CJEU answered in the affirmative, stating that ‘clearly the grant of a patent implies, in principle, its industrial or commercial application’.\textsuperscript{1320} The Court found support for this interpretation in Recital 14, holding that ‘[b]y stating that a patent for invention ‘entitles [its holder] to prohibit third parties from exploiting it for industrial and commercial purposes’, it indicates that the rights attaching to a patent are, in principle, connected with acts of an industrial or commercial nature.’\textsuperscript{1321}

Of course, a patent right is connected with acts of an industrial or commercial nature. But there is an important difference between two issues having a

\textsuperscript{1318} Case C-34/10, para 39.
\textsuperscript{1319} Opinion of Advocate General Bot delivered on 10 March 2011 in Case C-34/10, \textit{Oliver Brüstle v Greenpeace eV}, para 44.
\textsuperscript{1320} Case C-34/10, para 41.
\textsuperscript{1321} Id., para 42.
connection (i.e. patentability and exploitation) and two issues describing the same phenomenon (i.e. patentability equalling exploitation). In this regard, Advocate General Bot drew a conclusion that is not the current position of patent law as it functions today, at least not in the EPO setting. Furthermore, reading the entire text of Recital 14 changes the perspective, because it essentially lays down the principal difference between the grant of a patent and its ensuing exploitation; namely that patent law can only be drawn as far as giving the patent holder authorization to prohibit third parties from exploiting the invention, but not to authorise an implementation of that same invention on the market. To equate these obviously interconnected but clearly separate phenomena is not possible, at least not from the text of Recital 14. Continuing the reasoning of ‘commercial exploitation’, it is worthwhile to broaden the discussion by investigating the patentability criterion of ‘industrial application’ with regard to the issue of commerciality.

15.7.3  Industrial Application

The only general patent law criterion that is crucial for patentability with regard to its commercial or industrial use is the requirement of ‘industrial application’ of an invention. To satisfy the industrial application criterion the applicant needs only to prove a potential applicability of the invention; no evidence of actual commercial or industrial use is required. From this point of view, the requirement for patentability according to the industrial application criterion does not automatically necessitate commercial or industrial use; no use in trade at all is necessary to fulfil this criterion, only the capability of using the invention in some kind of industry. According to EPO and e.g. UK case law the notion of ‘industry’ in this respect includes making or using an invention in any kind of industry in ‘its widest sense’, but not necessarily for profit (i.e. financial reward). Even products not intended for use in any trade at all (such as e.g. products useful for rare or orphan diseases) are capable of industrial application.

Of course, the view that a patent right is connected with acts of an industrial or commercial nature does not necessarily entail that the industrial application criterion must be interpreted as necessitating the making of a profit. However, the overview of the interpretation of industrial applicability shows that it is conceivable that a patent right is granted for inventions which need not have any actual industrial or commercial exploitation on the market. It is conse-

1322 See Sections 13.8.4 and 13.8.5.
1324 See T 898/05 (Hematopoietic receptor/ZYMOGENETICS), Reasons for the Decision, para 8.
sequently possible to fulfil the industrial application criterion without engaging in exploitation in the sense of using the patent for making a profit. A related issue is the fact that the creation of an invention, an act which clearly falls within the protected exclusive right, does not necessarily involve any industrial or commercial exploitation. Consequently, the requirements of patentability, most importantly the industrial application criterion, can be fulfilled for an invention without any commercial or industrial use in the sense of commercial exploitation on the market (i.e. for financial profit).

15.7.4 The Function of Industrial or Commercial Purposes

As mentioned in Sections 15.5.2 and 15.5.4.2, the insertion of the qualification of ‘for industrial or commercial purposes’ (in Article 6(2)(c)) must necessarily have a meaning which is distinct from the general industrial application criterion as well as the commercial exploitation requirement in Article 6(1) of the Directive. Otherwise, the qualification would be redundant. From this point of view Article 6(2)(c) necessitates evidence of use for (at least) one industrial or commercial purpose which is separate from the general patentability requirements. Normally, such a qualification would serve the purpose of restricting the range of unpatentable subject matter to acts which involve, specifically, industrial and/or commercial uses of human embryos; where ‘industrial’ and/or ‘commercial’ imply actual use and not a potential use/commercial applicability. To regard a patent as implying the industrial or commercial application of the invention is at odds with the interpretation of the industrial application criterion (even if the two notions operate on different levels).

Against the background of the analysis with regards to both the ‘industrial application’ criterion and the qualification of ‘industrial or commercial purposes’ it is clear that there are outstanding issues. The CJEU seems to disregard that the qualification would have effects on its own and equates it with the patent right as such. This is not only at odds with the notion that the patent right is neutral, but it is also at odds with the current discourse in the EPO. The effect is that the exclusion in Article 6(2)(c) of the Directive is broadened without support in current patent law. This conclusion is also interesting with regard to the alleged consensus of Article 6(2)(c).

15.7.5 Consensus to Prohibit Commercial Exploitation

An important critique of the outcome in Brüstle is that the interpretation of Article 6(2)(c) of the Biotech Directive in the given situation did not reflect a

1325 See Plomer 2009:1, 190, with further references in fn. 63.
1326 Id., 191.
consensus on behalf of the Member States with regard to the uses of human embryos under national regulatory legislation. There is simply no consensus in Europe regarding the moral impermissibility of human embryo destruction, at least not in the sense of allowing such activities to take place under national legislation. Neither is there a consensus on the immorality on the use of hESCs and related inventions, even when obtained by destruction of human embryos. Arguments for a narrow interpretation of the embryo exclusion find support in the process of enactment of the Directive, especially the findings with regard to the Rothley report that permissive research was never intended to be subject to the morality exclusion, and the conclusion that national EU Members may wish to support its industry with the possibility of patent protection, where inventions are the result of lawful research.

In the case of the use of human embryos and the exclusion in Article 6(2)(c) of the Directive, Plomer demonstrates by means of an analysis of the Directives on uses of human tissues and the industrial production and commercialization of related products in the EU that there is no consensus in Europe regarding the effect that destructive uses of human embryos are morally impermissible. Neither is there a consensus that the use of hESCs and related inventions or products should be deemed immoral, when obtained by means of the destruction of human embryos. For instance, Directive 2004/23/EC on human tissues and cells includes ESCs within its scope, and similar use is also regulated in Regulation 1394/2007 on advanced therapy medicinal products. Commercial exploitation of hESC, derived by the destruction of human embryos, is evidently allowed, at least to a certain extent, on the EU level. In addition, national legislation in a number of its Member States is permissive towards these types of actions.

The problem is that the application of Article 6(1) of the Biotech Directive necessitates a finding that the commercial exploitation of an invention is contrary to morality or *ordre public*, and the argument that such activities are permitted under national and EU legislation is not sufficient to counter a decision of immorality. The reason for this is that the method for application of the morality clause does not include an assessment of the relation between regulatory and

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1327 Plomer 2009:1, 189.
1332 See e.g. Isasi and Knoppers, 36 ff. and www.eurostemcell.org/stem-cell-regulations (19 February 2015).
patent law. The existence of a prohibition on patentability does not automatically render an invention unpatentable under the morality clause in accordance with the proviso in the last sentence of Article 6(1). The finding of a breach of the morality clause necessitates a further assessment. But on the other hand, a permission to exploit an invention, against the background of the reasoning of the Court, does not indicate that the invention is moral.

Proponents of a coherent system argue that denying patentability of an invention that at the same time is permitted to exploit commercially indicates that the regulatory laws are immoral or in breach of *ordre public*. Also, the result of denying patentability is the dissemination of the technology which becomes free for all to use. It could therefore be argued that the operation of the morality exclusion necessitates a basis in a regulatory prohibition. If the invention is free to use, then it cannot be immoral.\footnote{See e.g. Straus 2013, 35 ff.}

On the other hand, removing the imprint of state approval in a situation where the invention can be freely used can still be important. First, it removes the economic incentives for the activities in question, an argument which, in order to be plausible, must presuppose a certain relation between patent and regulatory law in the sense that the invention is free to use on the market. Or rather, it points to a situation in which the legislator has not found convincing reasons for a legal prohibition, but still considers the research not to be worthy of economic incentives or state approval in the form of an exclusive right. It could be that the patent precedes the regulatory approval. The first time the technology comes to public attention is at the patent office. The regulatory system may not have had time to find a moral judgement of the technology as such. Thus, there are instances in which the application of the morality exclusion does not necessitate a prohibition. But the main purpose of the operation of the clause must be first to find a prohibition. If no prohibition exists, then immorality could still be established, but such situations should only exist with regard to new technology where the regulatory system has not yet had opportunity to express a moral judgment.

15.7.6 Developmental Aspects

15.7.6.1 Effects of Brüstle

Against the background of the findings of the Court, especially in *Brüstle*, it seems as if developmental aspects are included in the concept of commercial exploitation where a moral complicity exists between the invention and other acts, at least when there is a material connection between the invention and earlier subject matter. The effect of the interpretation of Article 6(2)(c) in the
Brüstle decision necessitates the taking into account of events preceding the invention as well as the patent grant, not only in time but also in material aspects (i.e. material other than the subject matter of the patent application is taken into account, if there is a connection, e.g. derivation of material from the first to the latter).

From the broad construction of Article 6(2)(c) demonstrated in Brüstle, it is conceivable that the requirement to take developmental aspects into account would also apply to the concept of commercial exploitation in Article 6(1), denoting a broad interpretation also in relation to that particular framework. In this context, it is crucial to discuss the effects that such an interpretation would have on the role of the principle of prior informed consent, which is incorporated into Recital 26 of the Directive. As already discussed in Section 13.8.3.1.1, the relevance of prior informed consent has been subject to the reasoning of the Court, which has stated that such pre-grant activities cannot form part of the scope of the Directive which regulates only issues of grant. This statement is difficult to understand under a broad construction of the commercial exploitation requirement, and consequently such a broad interpretation will affect the whole breadth of the morality exclusion. The next Section is therefore devoted to analysing such effects of the principle of prior informed consent on the donation of material which subsequently becomes the subject matter of a patent application, i.e. where there is a material connection in relation to the donation and the invention.

15.7.6.2 Prior Informed Consent

The principle of prior informed consent is recognised in Recital 26 of the Biotech Directive:

> Whereas if an invention is based on biological material of human origin or its uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent in accordance with national law.\(^{1334}\)

The relevance of Recital 26 with regard to patent applications for inventions based on human biological material for which prior informed consent has not been sought is important for the analysis of the delimitation of the concept of commercial exploitation in the EU. The requirement to obtain informed consent for the taking of human material is a basic ethical and legal requirement in the EU.\(^{1335}\) From the EPO and the CJEU decisions it is concluded that there is

\(^{1334}\) See Beyleveld, Brownsword and Llewelyn for an interesting discussion regarding the textual ambiguity of Recital 26, 176.

\(^{1335}\) See e.g. Chapter II of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomed-
no (national or European) procedure to verify informed consent in the framework of the grant of biotechnological inventions, and patent law is not regarded as the appropriate setting for the imposing or monitoring of such a requirement. This conclusion is open to criticism because the absence of a procedure for verification does not release the patent authorities from evaluating the effects of proofs of absence of consent in a patent application based on material of human origin.

The CJEU had the opportunity to expand on the questions when the applicant in the Netherlands case held that the absence of a provision requiring verification of the consent of the donor or recipient of products obtained by biotechnological means undermined the right to self-determination and thereby undermined the principle of human dignity. Advocate General Jacobs had in his Opinion declared that although he considered the wording of Recital 26 to be unclear in terms of what the consent should relate to, issues related to informed consent (due to the inherent nature of a patent right) should not be resolved by patent law. In addition he referred to the unreasonable burden on patent examiners with regard to the obtaining of evidence of informed consent for each sample forming part of the research leading up to the invention. The CJEU, following the reasoning along the terms of the nature of the patent right, held that:

Reliance on this fundamental right [right to human integrity in the form of the free and informed consent of the donor and recipient] is, however, clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patent products.

The CJEU considered the scope of the application of the Directive to be restricted to the grant of a patent and the issues related to the invention at that stage, and not to pre-grant activities such as the question of informed consent. They further held that:

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1336 T 1213/05, Reasons for the Decision, paras 49-51, with reference in para 51 also to the Opinion of Advocate General Jacobs, delivered on 14 June 2001 in Case C-377/98, Netherlands v Parliament and Council, para 211. In connection to this discussion Recital 27 is of interest, where information on the geographical origin of biological material of plant or animal origin should, where appropriate, be included in the patent application. This has prompted the discussion of the introduction of procedures verifying the disclosure of origin of material in patent applications in many countries. See also Papadopoulou, 134.


1338 Id., paras 212-213.

The grant of a patent does not preclude legal limitations or prohibitions applying to research into patentable products or the exploitation of patented products, as the 14th recital of the preamble to the Directive points out.\footnote{Case C-377/98, Netherlands v Parliament and Council [2001] ECR 1-7079, para 80.}

The question of informed consent, thus, belongs to the regulatory rules on research conduct, and by the nature of the patent right such rules should not have a bearing on the grant of a patent, at least according to the reasoning of the Court in this specific decision. Restrictions, prohibitions or the monitoring of research or the use or commercialisation of its result should therefore be completely outside the realm of patent law.\footnote{See Laurie 2007, 225 ff. and Holtz, 518 f.} Whereas such a restrictive stance could well be accepted and upheld, not only in relation to the assessment in the morality clause but also to the assessment of patentability in general, it is nevertheless at odds with the findings with regard to case law as well as commentators related to, for instance, the patentability of hESC. In addition, the statement that pre- or post-grant activities are precluded in the assessment of patentability is not coherent with the findings in Brüstle and the inclusion of pre-grant activities under the assessment of patentability, at least with regard to Article 6.

The discussion on inclusion of pre-grant activities under the patent examination procedure (here, within the scope of the morality clause) is opening up to arguments both pro and con the inclusion of such aspects. A different argument for the inclusion of pre- or post-grant activities is found in relation to the patentability criterion of inventive step.\footnote{See Guidelines for the Examination in the European Patent Office (November 2014), G-VII, 5.}

The assessment of inventive step in the EPO is conducted primarily by the so-called problem-and-solution approach.\footnote{See Guidelines for the Examination in the European Patent Office (November 2014), G-VII, 10.3.} Deviation from this approach is made only in exceptional circumstances. But the application of the approach does not always yield satisfactory answers to the question of non-obviousness of the invention, and in such cases the presence of so-called secondary indicators can assist in the determination of inventive step. One particular indicator is the evidence of immediate commercial success.\footnote{Must always be coupled with evidence of a long-felt want. Guidelines for the Examination in the European Patent Office (November 2014), G-VII, 10.3.} Such commercial success must necessarily occur after the relevant date of filing. If such an assessment is accepted, then the notion that the assessment in relation to the morality clause must not include issues pre-grant should not be upheld in its whole rigidity, since it seems as if a certain leeway is accepted.

The statement by the CJEU may be interpreted to mean that activities that have no direct bearing on substantive patent law are not included with the scope of the Directive, whereas pre- or post-grant issues with such a bearing...
may well be included in that scope. Thus, in line with Recital 16 of the Directive, which specifies that ‘patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person […]’, it could well be argued that the principle of informed consent, or lack thereof, on the basis of Recitals 16 and 26, can be raised as evidence for a violation of the morality clause.

Beyleveld, Brownsword and Llewelyn argue, contrary to the findings of the Court, that Recital 26 should be taken into consideration because it is legally binding on any Member State, unless that state can find legitimate derogating considerations that override the considerations that indicate that the Recital 26 requirement should be imposed. From their point of view, no such derogations are available to a Member State.

Furthermore, in the UK, for instance, the use of human material (human tissue) for commercial research without consent or ethical approval for research is prohibited, and any person doing so would be prosecuted. Even if it could be argued that illegality does not equate with immorality, and that the commercial exploitation of such an invention would not be contrary to morality or ordre public, Odell-West nevertheless states that it is not the commercial exploitation of the patented invention that is illegal but instead the use of the tissue without consent under national legislation. Such use would, however, entail the effect that the commercial exploitation of the invention would be contrary to morality or ordre public due to the moral complicity between the (tainted) material and the resulting invention. Not obtaining the necessary consent for subject matter which becomes the subject of a patented invention arguably renders the commercial exploitation of an invention immorral, despite the avowed use of the invention in the patent application. To ignore a fundamental ethical and legal principle in a situation where patent law specifically provides for the exclusion of inventions from patentability where the commercial exploitation of such inventions would be contrary to morality or ordre public would be contrary to the aims of the system. Logically, to prohibit the obtaining and use of human tissue without consent for ethical reasons, without the commercial exploitation of material based on that same material, would be incorrect.

The presented argumentation in relation to informed consent does not address the fundamental issue of the scope of the given consent in relation to the use of the material. Should the given consent relate to the later patenting or to the commercialisation of the invention, or perhaps both? Or does it suffice that consent is given to the taking of the material for research purposes, without

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1344 Odell-West, 382.
1345 Beyleveld, Brownsword and Llewelyn, 175.
1346 Section 5, Human Tissue Act 2004 (c. 30)(15.11.2004).
1347 Cf. Holtz, 518 f.
1348 See Odell-West, 388.
giving the donor any possibility of consenting future purposes. Perhaps a
broader consent would seem overly prudent in a situation where the final in-
vention is sufficiently removed from the donated material, in that no connec-
tion is possible between the original material and the resulting invention. Also,
in this context it is important to separate between the right to use the material
and any legal rights that the invention may produce. Even though there is con-
sequently no procedure envisaged for monitoring such a requirement on the
level of EU law, Odell-West argues that if prior informed consent for the re-
moval of human tissue is central to the preservation of human dignity, then
such consent should also include consent for patenting, but only where this is a
foreseeable possibility.1349

In conclusion, the treatment of prior informed consent seems to preclude
the inclusion of developmental aspects under the morality assessment, at least
with regard to that specific issue. However, since the reasoning of the Court
related to giving the principle status as a legal concept, perhaps drawing such a
conclusion is too farfetched. It remains to see whether arguments surrounding
the failure to respect the principle of prior informed consent would be consid-
ered in a decision with regard to Article 6 of the Biotech Directive.

15.8  A Proper Framework for Article 6 of the Directive

As mentioned, the foundation of Article 6(2) of the Directive is a consensus
within the Union that the processes and uses defined therein should ‘unequivo-
cally’ be excluded from patentability.1350 The context and aim of the Directive
and particularly the text of Recital 38 has been interpreted to the effect that all
processes, the use of which offends against human dignity, are also excluded
from patentability.1351 The position of the CJEU as demonstrated in Brüstle is
essentially that patentability is excluded where respect for human dignity could
thereby be affected.

The fact that the use of human embryos for scientific research was also in-
cluded under the provision in Article 6(2)(c) of the Directive means that re-
search using pluripotent hESCs which are legally produced (in accordance with
applicable national law) from (supernumerary) human embryos currently falls
under the provision of ‘uses of human embryos for commercial or industrial
purposes’.

Straus holds that the inclusion of the practice of destroying embryos in order
to produce pluripotent hESCs – legally according to national law – in the tech-
nical teaching of the patent application, when this destruction is ‘neither […]

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1349 See Odell-West, 381, 389, with further references to Beyleveld and Brownsword.
1350 Case C-456/03, para 78 and Case C-34/10, para 29.
1351 Case C-34/10, paras 34-35 (with further reference to Case C-377/98, paras 71 and 76).
claimed, nor described, nor is it necessary for performing/implementing the invention as claimed’ is actually contrary to established case law of the CJEU itself. In the Netherlands case, the CJEU explicitly emphasized that ‘reliance on this fundamental right [of human integrity] is clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products’. This particular statement was made in relation to the plea according to which the principle of free and informed consent was not observed. The CJEU has been very vocal on the fact that Article 6(2) seeks to grant specific rights by express exclusions to be taken into account in the patent processes, whereas the principle of free and informed consent is regarded by the Court as being outside that same process. The destruction of embryos is therefore to be regarded as an activity which is included in the granting process, whereas activities preceding the process of grant, such as issues related to the existence of prior informed consent, are obviously not included. But if a broad scope of the morality clause is intended, why is the destruction of human embryos excluded from patentability where the failure to collect a prior informed consent is not even a factor to consider in the patenting process?

Article 6 of the Directive would according to such a reasoning necessarily include within its scope of application every activity related to the patent granting process, regardless of the activity being explicitly mentioned in the patent application (background of invention, description, technical, teaching, claims etc.). To include the destruction of embryos in the technical teaching is undoubtedly an undertaking which necessitates the stretching of established principles very far. The concept of invention would have to be extremely broad, and the concept of commercial exploitation in Article 6(1) must necessarily be interpreted as to include developmental aspects of the farthest kind. Such an interpretation would naturally take into account the origin of the inventions.

The fact is that perhaps the operation of the morality clause necessitates such a broad inclusion of different aspects, to be able to fully function as a guardian of morality and ordre public within patent law. At least its character as having somewhat alien features within the otherwise very technically oriented patent system suggests a different perspective. Such a perspective becomes even more natural considering the foundation of the argumentation of the CJEU, namely the recourse to the principle of respect for human dignity and safeguarding the principle of non-commodification of the human body. But the framework for this safeguarding, in relation to established patent law criteria,

1352 Straus 2013, 35.
1353 Case C-377/98, para 79.
1354 See e.g. Case C-34/10, para 29 and Case C-456/03, para 79.
must be elucidated, especially since the effects for technologies in general, outside the realm of human biological material, are not certain.

An important point of departure for the reasoning in Brüstle is the ‘context and aim’ of the Directive, which, according to the Court showed the intention of the EU legislature to ‘exclude any possibility of patentability where respect for human dignity could thereby be affected’. This particular statement also affects the alleged consensus in the Member States reflected in the categories of the exemplifying list. However, consensus as to the immorality of destroying human embryos was not attained as can be seen by the lack of reference to such in the provisions of the Directive and the state of national legislation. As mentioned, the wording of the embryo exclusion was subject to last minute amendments, and at that time, the prevailing understanding seems to have been to include only what was unequivocally agreed upon as being immoral, precluding activities which were considered morally permissible and/or lawful in the Member States at the time. Thus, would the practice of destroying human embryos in order to establish hESC lines have been agreed upon, surely this would have been reflected in the wording of the exclusion, or at least been included in the recitals? Indeed, this does not matter in the current situation, since the CJEU has already established the relevant interpretation of the exclusion. But it is an interesting issue to ponder.

The principle of protection of human dignity, as mentioned explicitly in Recitals 16 and 43 of the Directive, as well as during the legislation process of the Directive, clearly functions as a foundation for Articles 5 and 6 of the Directive, although the latter has, in this respect, more of a supplementary role. The function of Article 6 as being supplementary to Article 5 in the protection of human dignity was underlined by the CJEU in the Netherlands case. The applicant had submitted in the fifth plea that fundamental rights were undermined by first the permission to patent isolated parts of the human body (human dignity), and second by the lack of a provision requiring verification of the consent of the donor or recipient of products obtained by biotechnological means (the right to self-determination). The CJEU stated that in accordance with Article 5 the respect for human dignity was guaranteed, but also referred to Article 6 and Recital 38 as a measure ensuring additional security, repeating the contents of the exemplifying list in Article 6(2) as well as Recital 38 that ‘all processes the use of which offend against human dignity are also excluded from patentability.’

The link for treating offenses against human dignity as a foundation for exclusions under Article 6(1), provided by inter alia Recital 38, was further es-

1355 Case C-34/10, para 34.
1356 See Plomer 2009:1, 191.
1357 Case C-377/98, paras 69-76. The issue of informed consent was, however, treated as a matter concerning activities pre- or post-grant and thereby outside the scope of the Directive. Case C-377/98, paras 78-81.
tablished in *Brüstle*. The CJEU stated that ‘[t]he context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected’. From this position the Court reasoned that the concept of human embryo must be understood in a wide sense. As mentioned, the concept of human dignity is open to many different interpretations which naturally affect its interpretation.

Serckx and Beyleveld, Brownsword and Llewelyn argue that the focus of the EU morality clause is on whether putting the applicant in a monopoly position in relation to the possible commercial exploitation of the invention gives rise to any moral difficulty. The central issue concerns the morality of granting a monopoly right to control the invention. The moral difficulty would be judged from a morality and *ordre public* basis, both in relation to the invention and in relation to its commercial exploitation. The range of relevant considerations would include not only publication and exploitation but also the morality of the R&D. The prevailing standard in the application of the morality test would be the critical cultural European legal-morality, and due consideration should be given to the instruments such as the ECHR, the Convention on Human Rights and Biomedicine, and the EGE Opinions.

However, such an interpretation is not conceivable according to existing provisions, and presupposes, as envisaged by Beyleveld, Brownsword and Llewelyn, explicit inclusion in preferably the Directive’s Articles. Still, the interpretation in *Brüstle* seems to point to such an understanding. But if a change of direction on behalf of patent law is intended by the Court, it must be explicit, clarified and subject to relevant possibilities for review. As the situation is today, *Brüstle* rather creates a legal uncertainty than providing proper guidance, not least in relation to the framework of Article 6(1) of the Directive.

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1358 Case C-34/10, paras 33-34.
1359 Id., para 34.
1361 See Section 13.5.3.2.
1362 Beyleveld, Brownsword and Llewelyn, 180.
In this thesis, a number of different aspects of the morality exclusions in TRIPS, the EPC and the Biotech Directive are described and analysed. The purpose of Part V is to pick up the threads of discussion throughout the other parts of the thesis and tie them together in a pattern by providing answers to the research questions in Section 2.4. In doing so, an important task is to investigate the different contexts of WTO, EU and EPO and relate them to each other. Consequently, Chapter 16 analyses the concept of commercial exploitation. Chapter 17 examines the concepts of *ordre public* and morality, their definitions and tests and standards. In Chapter 18, the question of TRIPS compliance on behalf of the Biotech Directive and the EPC is analysed. Chapter 19 concludes the discussion on the relationship between patent law and the regulatory framework, and Chapter 20 concludes the thesis with a summary of the requirements for an optimal scope and function of the European morality exclusions.
A prominent issue in this thesis is the specification of commercial exploitation of the invention, which is present in all three morality exclusions. As this thesis indicates, the concept of commercial exploitation is proven crucial for the operation of the morality exclusion, and the first research question is consequently focused on its contents.

Firstly, in Section 16.1 the definition of commercial exploitation is discussed based on the question of whether it is a stand-alone criterion that follows automatically from the patent right. Thereafter, Section 16.2 analyses the scope of the concept of commercial exploitation both in regard to the general morality clause and the exemplifying list in EPC and the Biotech Directive. The relationship between the general exclusion and the list is analysed and the issues of human dignity (especially the role of the principle of prior informed consent) in the legal framework is discussed. Section 16.3 contains an analysis of the requirements of Article 27.2 TRIPS, especially treating the term ‘necessity to prevent’. Finally, Section 16.4 lays the foundation for the forthcoming analysis (Chapter 18) of the compliance of the European morality exclusions with their TRIPS counterpart in terms of scope, content and requirements, and suggests amendments aimed at improving the current legal situation.

16.1 Definition of Commercial Exploitation

As far as the concept of ‘commercial exploitation’ is concerned, Article 6 of the Biotech Directive and Article 53(a) EPC are expressed similarly in that the un-patentability or non-grant is subject to the assessment of whether the commercial exploitation of inventions would be contrary to \textit{ordre public} or morality. In Article 27.2 TRIPS, the exclusion of inventions from patentability is instead subject to the assessment of whether ‘the prevention [...] of the commercial exploitation [...] is necessary to protect \textit{ordre public} or morality’. The evident difference is that while the text of the EPC and the Biotech Directive focuses the assessment on whether the commercial exploitation of the invention would be contrary to \textit{ordre public} or morality, the formulation of Article 27.2 TRIPS directs the focus to an assessment of the necessity of preventing the commercial exploitation of the invention for the protection of \textit{ordre public} or morality. The introduction of this necessity test has effects the scope and application of Article 27.2 TRIPS, which is important also in relation to (specifically) the Biotech Directive, since according to EU WTO Membership (as well as national states’ Membership) similar morality exclusions within the EU legal order must be TRIPS-compliant.
As established in Section 12.6.1, the concept of ‘exploitation’ in the TRIPS context seems to imply the act of normal exploitation on the market, as established with reference to the modalities of exploitation in Article 28 TRIPS (the making (manufacturing), using, offering for sale, selling or import). Since Article 27.2 has not been subject to a Panel decision yet, analogies have been drawn from the interpretation of Article 30 TRIPS. The insertion of the prefix ‘commercial’ before exploitation in Article 27.2 TRIPS has been held to imply a distinction between the grant of a patent and the ensuing commercial exploitation of the invention, as reflected by this particular choice of terminology.

A distinction between the act of patent grant and the commercial exploitation of the invention will be important for the delimitation of the scope of the assessment under respective morality exclusion. The issue is relevant from a general patent law perspective as well, because it affects the perception of a patent right as a neutral exclusionary right – a right which undoubtedly enables a commercial exploitation, but the commercial element according to this view is not inherent in the patent grant, but depends on the actions of the patentee and is subject to regulatory law. Opponents of this approach would, however, find support in the notion that simply by the exclusionary position awarded to the patentee, the situation on the market is affected. The patent right is a limited exception to the natural state of free market competition. This market position will have a commercial effect, independent of the character of the acts that the patent holder ultimately chooses to pursue. They could be non-commercial, but that will not change the character of the patent right, and consequently the act of grant, as having a commercial element.

The majority of the patent system theories, as discussed in Section 4.2, rest on the underlying notion that the exclusivity creates possibilities for remuneration by commercial means. The incentive theory, the reward theory, the incentive to commercialise theory and the protection of investments theory all display an element of presumption for a commercial exploitation to take place. The theories related to knowledge (incentive to disseminate or to disclose) evidently have another focus, in which the commercial aspects are secondary. Still, the function of the system as a tool for promoting economic ends stresses the commercial aspects of a patent right. The fact that patents today are to a large extent used as a mechanism for the protection for investments reinforces this notion in practice, even if many patented inventions are, in fact, not commercially exploited.\footnote{See Section 4.1, 13.8.3.3 and 15.7.3-15.7.5.}

Nevertheless, the traditional view of a patent as a negative and consequently, value-neutral right makes it difficult to properly characterise the patent as equaling a commercial exploitation of the invention.\footnote{See Sections 13.9, 15.7.1 and 15.7.3-15.7.5.} The exploitation (commercial exploitation...
cial or non-commercial) of an invention is subject to legislation the application of which is fundamentally unaffected by the presence of a patent right. A patent right can consequently not enable the commercial exploitation of an invention; a patent right can only enable the prevention of the commercial exploitation by others than the patent holder.

The respective understandings of the nature of a patent right in the context of the morality exclusions will lead to different interpretations of the focus of assessment. The conclusion from a literal reading of the morality exclusions is that the target of the provisions are whether the commercial exploitation of the invention is contrary to ordre public or morality (with the addition of a necessity element in Article 27.2 TRIPS). It is neither the invention as such, nor the technology or the patent that should be assessed in relation to ordre public. These concepts are not the objects of the provision, and the understanding of commercial exploitation will necessarily be decisive for the operation of the exclusion. If commercial exploitation is understood as the actual act of exploitation on the market, the focus of assessment will consequently be directed to the more narrow assessment of whether the commercial exploitation of the invention on the market is contrary to ordre public or morality. No automatic relation is presupposed from the act of patenting to the act of commercial exploitation.

On the other hand, if commercial exploitation is understood as implied in the patent right, the exclusion will be interpreted as being focused on whether the grant of the patent right is contrary to ordre public or morality, and permits a wider range of factors in the assessment of unpatentability.

As this thesis shows, evidence of both notions is present in EPO case law, whilst the CJEU seems to favour a broader approach.\(^\text{1365}\) There is also a difference between the scope of commercial exploitation in relation to the general morality exclusion compared to the exemplifying list in both EPO and EU systems, which will be discussed in Section 16.2, which follows hereunder.

16.2 Scope of Commercial Exploitation

16.2.1 A Broad or Narrow Approach

If the discussion regarding the concept of commercial exploitation is expanded to the breadth of the assessment, the question is whether commercial exploitation is solely directed at the actual act of exploitation on the market, or if other types of acts, for instance acts preceding the exploitation, are included under the concept. According to the analysis with regard to Article 53(a) EPC, it

\(^{1365}\) See Sections 13.8.4, 13.8.5 and 13.9 (EPO) and 15.7 (especially 15.7.1) (EU).
seems as if the established EPO case law supports a narrow approach.\textsuperscript{1366} If, by contrast, a broad view of commercial exploitation is applied, a range of acts connected to the lifespan of the invention will be included in the assessment, including not only issues related to the actual development of the invention, but also aspects of the underlying technology and also the invention as such will naturally be of relevance. As established in Section 13.8.1, the acts, or effects, that are usually discussed in this context are: the development of the invention, the act of granting a patent, the invention (as such), the technology (underlying the invention) or the socio-economic effects caused by the granting of the patent right.

Presently, it is not possible to find a unanimous position of the Boards and Divisions in the EPO as to the breadth of the concept of commercial exploitation (as concluded in Section 13.8.4). Three Board of Appeal decisions (\textit{Oncomouse II, Euthanasia compositions and Breast and ovarian cancer})\textsuperscript{1367} support a narrow reading of the commercial exploitation concept, while the evidence of a broader reading is more inconclusive. This situation makes it difficult to capture a common view of the concept of commercial exploitation, and specifically the impact of the term ‘commercial’ in this context. The inclusion of a broader range of issues under the commercial exploitation concept will move the assessment closer to an evaluation of the actual patent grant (than the commercial exploitation of the invention), namely whether it is contrary to \textit{ordre public} or morality to put the applicant in a monopoly position with regard to the particular invention at issue. Such an interpretation is also endorsed by a number of prominent commentators, as outlined in Section 13.8.5. Nevertheless, it is difficult to accommodate this broad understanding of the morality exclusion under the literal text of Article 53(a) EPC in its current state, in addition to the fact that such a reading is contrary to established case law of the Boards of Appeal. Such an understanding would at least require a clarification of a change of practice from the EBA.

The analysis of the commercial exploitation in the EU in Section 15.7 reveals that the CJEU has not specifically treated the concept of commercial exploitation in the interpretation of Article 6(1) of the Biotech Directive, although the statements of the Court signifies a broad understanding of the concept. The CJEU seems to regard the concept of commercial exploitation as inherent in the patent right, indicating a view where these aspects are not separated and, consequently, provide for an approach to commercial exploitation which opens instead of interprets and defines the concept.


\textsuperscript{1367} The fact that these decisions were based on the previous formulation of Article 53(a) (‘publication or exploitation’) does not change the assessment. See Section 13.2.
Thus, a general overview of the interpretation of the morality exclusion in the different legal systems exposes interesting differences. The view of commercial exploitation as a narrow concept and separate from the act of granting a patent is currently strongest within the WTO system as well as the EPO, while the EU supports a broader notion.

The conclusions with regard to the general morality exclusions must now be subject to an additional element, namely the analysis of the interpretation of the concept of commercial exploitation in relation to the exemplifying list in Rule 28 EPC and Article 6(2) of the Biotech Directive, and the impact that these interpretations have on the general exclusions.

16.2.2 The Effects of the Exemplifying List

The situation regarding the interpretation of the concept of commercial exploitation is both clarified and blurred when an additional aspect is taken into consideration, namely the interpretation of the exemplifying list in Rule 28 EPC and Article 6(2) of the Biotech Directive. As explained in Sections 13.12 and 15.4.2, according to a number of factors, especially their placement under the general morality exclusion, the examples in Rule 28 and Article 6(2) must relate to the frameworks of the general clauses in Article 53(a) and Article 6 respectively. The guidance to be drawn from the interpretation of the exemplifying list will therefore be of interest in relation to the general morality exclusion.

The conclusions in Sections 13.4.2 and 13.8.2.1 show that the findings of the EPO Boards imply that the interpretation of Rule 28(d) EPC (Article 6(2)(d) of the Biotech Directive) is confined within the framework of the general exclusion and does not exceed the boundaries as set by earlier interpretation of inventions concerning animals under Article 53(a) EPC.

Matters are, however, different with regard to the embryo exclusion in Rule 28(c) EPC and Article 6(2)(c) of the Biotech Directive respectively. Since both rules contain a specific exclusion, namely for ‘uses of human embryos for industrial or commercial purposes’, the conclusions drawn from the interpretation with regard to the general morality clause must naturally take this factor into consideration. But even so, the findings in this thesis show that the interpretation of the embryo exclusion exceeds the framework of the general exclusion in Article 53(a) EPC and Article 6(1) respectively, both with regard to the concept of commercial exploitation and with regard to the delimitation of the scope of the subject matter to be considered.\footnote{See Sections 13.12 and 15.5-15.7.}

In the WARF decision, concerning Rule 28(c) EPC, the EBA equated the act of making an invention with a commercial exploitation of the invention, and also that commercial exploitation is being inherent in the exclusive right by
the act of granting the patent. The EBA clarified that it is not the act of patenting in itself that is considered to be against ordre public or morality, but the ‘performing of the invention’, including a step (the use involving the destruction of a human embryo) that contravenes those concepts. Despite this statement, the discussion in Section 13.12.2.4 shows that the outcome of the decision nevertheless points to an understanding of the commercial exploitation as including developmental aspects. This is because according to the EBA, moral complicity exists between an (immoral) act performed in the development of the invention and the resulting claimed subject matter, even though the immoral act (or material) is not included in the patent claims.

In the EU context, the CJEU came to a similar conclusion in the Brüstle decision in relation to Article 6(2)(c) of the Biotech Directive.\(^\text{1369}\) First and foremost, the CJEU’s statement with regard to the question of separation of commercial exploitation of an invention and the act of granting a patent for the invention is interesting, because the Court clarified that it considered subject matter included in a patent application as always connected with acts of an industrial or commercial nature. From such a point of view, a broad perception of the commercial exploitation concept is natural. Consequently, if the act of making subject matter the object of a patent application is always considered as commercial, it would hardly be possible to argue for a conception of the morality exclusion as exclusively directed towards assessing the morality of exploitation of the invention on the market. Furthermore, the exclusion in Article 6(2)(c) (‘uses of human embryos for industrial or commercial purposes’) was found applicable to the invention under scrutiny (neural precursor cells obtained from hESC), even though the use (i.e. destruction) of embryos was not claimed nor described in the patent application.

Thus, not only do these decisions bear witness to the inclusion of developmental aspects under the concept of commercial exploitation, which is consequently broadened in relation to earlier EPO practice, but they also represent a very broad scope of the subject matter considered under the concept of invention. This is partly due to the introduction of new terms (performing and implementation of the invention). The scope of relevant subject matter is treated in the following Section.

16.2.3 The Scope of Relevant Subject Matter

According to the analysis in Sections 13.12.2.2-13.12.2.4 and 15.6, the reasoning of the EBA in \textit{WARF} and the CJEU in \textit{Brüstle} leads to another issue of interest for the legal reasoning in connection with the commercial exploitation concept and hence, the breadth of the exclusion, namely the scope of the subject matter.

\(^{1369}\) See Section 15.5, especially Sections 15.5.4.1 and 15.5.4.4.
under scrutiny. The relevant subject matter to be excluded from patentability (according to all three morality exclusions) is ‘inventions’. However, the relevant term in the embryo exclusions is the ‘uses of human embryos for industrial or commercial purposes’.

Usually in patent law, the term invention (i.e. scope of subject matter) consists of the patent claim scope, namely the claims supported by the description. However, with regard to the exclusions in Article 53, the EPO has taken a more material approach to the concept of invention. In connection to e.g. the exclusion for plant and animal varieties in Article 53(b) EPC, the EBA has stated that it is not the wording but the substance of the claim which is decisive in assessing the subject matter to which the claim is directed.\textsuperscript{1370} This is because it should not be possible to avoid exclusion by clever drafting of claims. The relevant issue to consider is rather the ‘underlying invention’, which is deduced from the claimed invention, which is not restricted to the claims. Other alternative terms for ‘underlying invention’ are ‘the patent teaching’, ‘claimed subject matter’ or ‘the subject matter of the patent’. The relevant assessment consists of establishing the scope of the subject matter under scrutiny where the literal wording of the claim should not be decisive but rather the breadth of application of the invention. This breadth has always been considered to consist of the technical teaching, i.e. an interpretation of the claimed subject matter, which is performed on the basis of the patent application, focussing on the claims, description and the whole concept of the invention.

The \textit{WARF} decision represents a different approach. The EBA used the term ‘the present invention’, which was considered to concern the technical teaching of the application as a whole. The claimed subject matter consisted of a cell culture which used hESC as starting material. The EBA held that the use of the starting material (hESC) presupposed the making of said material, although the method of making the hESC was not claimed in the application. Since at the time of application the only known way to produce hESC was by the use of human embryos (involving their destruction), the invention was considered excluded under Rule 28(c) EPC (‘uses of human embryos for industrial or commercial purposes’). This is because, reasoned the EBA, in order to perform the invention, the starting material had to be made, and the only way to make such material was by means of the destruction of embryos. The destruction equalled the use of the human embryos, and was considered to fall under the exclusion in Rule 28(c) EPC.

If this reasoning of the EBA is considered applicable to the concept of invention in general, it must be considered as a new direction in relation to established principles of claim scope interpretation, at least in light of earlier case law.

\textsuperscript{1370} See Section 13.7.
for Article 53(a) and (b) EPC. The breadth of scope awarded to the concept of invention will naturally affect also the concept of commercial exploitation.

The CJEU applied a similar interpretation to the concept of invention in the Brüstle decision. The Court stated that ‘an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos’.1371 The expression ‘implementation of the invention’ is not a common patent law concept, and resembles the similar expression ‘performance of the invention’ as used by the EBA in WARF. Both these concepts signal a broad approach to the definition of the scope of the subject matter under scrutiny, and denotes a change in direction, at least as compared to earlier EPO practice.

The Brüstle and WARF decision, thus, represent at least a very broad interpretation of the concept of invention (i.e. scope of subject matter under scrutiny), and possibly also a broad interpretation of the requirement of commercial exploitation. An important question relative to this conclusion is, however, the value of this statement in light of the fact that the interpretations concern specific exclusions in the exemplifying list in Rule 28(c) EPC and Article 6(2)(c) of the Biotech Directive, with a different wording compared to the general morality exclusions in Article 53(a) EPC and Article 6(1) of the Biotech Directive. The following Section therefore explores the limitations of the provisions of the exemplifying list set in place by the general morality exclusion.

16.2.4 Challenging the Framework of the General Exclusion

The relationship between the exemplifying list and the general morality exclusion is at first glance quite obvious. All evidence points to a construction of the exemplifying list as giving definition to the general exclusion, both with regard to the relation between Article 53(a) and Rule 28 EPC and Article 6(1) and 6(2) of the Biotech Directive. The application of the general morality clause is precluded by terms of the exemplifying list, in the sense that if subject matter is found unpatentable with regard to the exemplifying list, no assessment of the prerequisites of the general clause is necessary. The application of the exemplifying list also precedes the application of the general exclusion. It is only where the exemplifying list is not found applicable to a patent application that the subject matter contained therein could be assessed under the general exclusion.1372

Consequently, the exclusions on the list are only examples of subject matter that is manifestly unpatentable according to the general exclusion. The place-

1371 Case C-34/10, para 49.
1372 See Sections 13.4.2 and 15.4.2.
ment of the list also points to an understanding of the relation between the provisions where the requirements of the general morality exclusion in Article 53(a) EPC and Article 6(1) of the Biotech Directive are inherently applicable to the list in Rule 28 EPC and Article 6(2) of the Directive. In addition, the norm hierarchy of the EPC and its connecting rules means that the general exclusion in Article 53(a) EPC takes precedence over Rule 28 EPC in case of a conflict. The relationship between the general exclusion and the exemplifying list entails that the framework established in terms of the general exclusion must necessarily also apply to the exemplifying list.

The findings in *Oncomouse II* in relation to Rule 28(d) EPC and Article 6(2)(d) of the Biotech Directive is confined within the limits of the general clause, and does not seem to permit an interpretation exceeding established limits. The broad interpretation of the subject matter under scrutiny in both *WARF* and *Brüstle*, on the other hand, goes outside of the framework established with regard to Article 53(a) EPC and Article 6(1) of the Biotech Directive. The broad definition of the term invention as envisaged by both the EBA and the CJEU in the hESC decisions is therefore at odds at least with previous case law from the EPO. The same could be held for the concept of commercial exploitation, even if the statements from the CJEU and the EBA are not as clear in this regard. If the exemplifying list is seen only as examples of the general clause, such a deviation from earlier practice necessitates identification of this fact and clarification of an intention to change current legal practice, preferably from the EBA. Such deviation is relevant even if the actual wording of the embryo exclusion does not mention ‘invention’ or ‘commercial exploitation’, since in terms of the relationship to the general exclusion its framework must apply, despite differences in text.

The *WARF* and *Brüstle* decisions are also indicative of the fact that the wording of Rule 28(c) EPC and Article 6(2)(c) of the Biotech Directive, as interpreted by relevant authority, leads to an expansion of the scope of unpatentable subject matter in relation to the general morality exclusion as it has been interpreted previously (e.g. according to the narrow approach displayed by the EPO Boards of Appeal in e.g. *Oncomouse II*, *Euthanasia compositions* and *Breast and ovarian cancer*). The question is whether this expansion as a result of the list was intended by its enactment.

Considering the advent of the Biotech Directive, it is evident that the process of enactment was turbulent and aimed at the reconciliation of different

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1373 Even though the EPO is not an authority in regards to the CJEU in terms of legal precedence, this conclusion is nevertheless important as a general comparison.

1374 The choice of terminology (performance of the invention (EBA) and implementation of the invention (CJEU) respectively) indicates that the actual wording of Rule 28(c) EPC and Article 6(2)(c) of the Biotech Directive was not vital in the interpretation, but both instances rather created their own terms for the assessment.
interests, and that the importance of ethical concerns increased through the
proposals, as concluded in Section 14.3. With regard to the specific exclusion
for the use of human embryos, the introduction of such a provision was
prompted by concerns that the concept of human embryo would not be in-
cluded under the prohibition for patentability of the human body. There is not
much information about the decision to formulate and insert the final version
of the embryo exclusion, and in the EU context guidance from the preparatory
works is not considered as a recognized source of law.\footnote{1375} It is the interpretation
of the CJEU that provides the full content of EU law, and the \textit{Brüstle}
decision is clear with regard to how Article 6(2)(c) of the Biotech Directive should be in-
terpreted.

No formal objections can be raised against the interpretation of the CJEU
and the form that it gives the embryo exclusion, not least because the Biotech
Directive is the first harmonising measure in the field of patent law and there is,
thus, no precedential law to take into account. The problem is the impact of the
interpretation in national law, where the sovereignty of the EU in relation to its
Member States in the harmonised field must be accommodated. The EU Mem-
ber States are, however, also Members of the European Patent Organisation.
The EPO case law is normative for national patent law. Should conflicting
interpretations exist between the EU and the EPO, the task of reconciliation of
norm conflicts will ultimately fall upon the UPC.\footnote{1376} The possibility to opt out of
the court system will, however, still enable national divergences.

At present, the interpretations of Rule 28(c) EPC and Article 6(2)(c) of the
Biotech Directive conform, and there is no apparent conflict with regard to this
particular exclusion. But as discussed, the compliance between the embryo
exclusion in its present form and the general morality exclusion is called into
question, which will have repercussions within the future system.

The perceived impact of the interpretation of the embryo exclusion in rela-
tion to the general morality exclusion is different in the EPO. The prevalent
approach of the Boards of Appeal (although inconsistencies exist), nevertheless
represented a more narrow approach to the concept of invention as well as the
concept of commercial exploitation in Article 53(a) EPC than is demonstrated
with regard to the embryo exclusion in Rule 28(c) EPC. Despite this apparent
change in interpretation, a conclusive answer as to whether this broader ap-
proach is preferred also in relation to the rest of the examples in Rule 28, as
well as in relation to Article 53(a) EPC necessitates an examination and appeal
process under this general exclusion. It is regrettable that the EBA did not seize
the opportunity to clarify matters in the \textit{WARF} decision (even though the op-
portunity to do so was restricted from a procedural point of view), and further

\footnote{1375}{See Section 9.2.}
\footnote{1376}{See Chapter 11 and Section 10.1.}
developments with regard to the interpretation of Article 53(a) EPC are eagerly awaited.

16.2.5  Human Dignity - Clarity and Transparency

The concerns regarding human dignity as expressed through the first three examples in Article 6(2) of the Biotech Directive and Rule 28 EPC have opened up for interpretations which, according to the analysis in this study, stretches established concepts very far and thereby broaden the area of unpatentability in a manner which is not compatible with the current position of patent law as regards the framework in which the exemplifying list is set to operate, namely the extent of the general morality exclusion. Nevertheless, the specific character of the material under scrutiny, namely human biological material (which is developed through the destruction of human embryos), perhaps necessitates considerations of the kind that are reflected in the Brüstle and W ARF decisions.

The problem is that the introduction of the exemplifying list under the general morality clause results in the examples being subject to a construction resting on certain foundations, namely the current patent legal framework. If the interpretation exceeds the limits of the existing structure without being supported by explanation or clarification by the relevant interpreter (or the legislator), a situation of legal uncertainty is created.

If deviation from established patent principles is intended, even if done on the basis of enacted legislation and concerns for human dignity, such a deviation must necessarily be clarified and explained, and this has not been done by the EBA, which has this particular responsibility. The CJEU is, by comparison, much more independent to interpret the Biotech Directive, both in relation to the function of EU law and against the background of no earlier EU law in the patent domain.

The findings of the EBA in W ARF will have repercussions for the current state of the law, and leaves open important questions for the interpretation of Article 53(a) EPC. The main question is whether the breadth of the interpretation is confined to Rule 28(c) EPC only, or extends further. For instance, should the concept of commercial exploitation from now on always include developmental aspects, in every kind of situation? Or should developmental aspects only be included where human biological material, and consequently the issue of human dignity, is concerned? Is the current claim, the scope is now always directed to the performing or implementation of the invention, inviting an assessment of the subject matter or material that is not included within the technical teaching? Are the findings applicable to inventions of every kind, or only to inventions concerning human biological material, where concerns for human dignity and the principles of non-commodification or non-instrumentalisation are prevalent? Is there a difference between different cate-
categories of inventions in this respect? Finally, what is the situation with regard to the balancing test for animals, which has a utilitarian base?

The conclusion is, thus, that the concern for human dignity is a prominent and absolutely necessary issue, which needs to be accommodated and clarified in the patent law framework. But as the discussion shows, the current treatment of such concerns, both by the introduction of the exemplifying list and the following interpretations, has not only resulted in legal uncertainty, it also threatens to exacerbate the perceived polarisation of patent law and ethical issues.

If the treatment of human biological material necessitates an extended scope of excluded subject matter, accompanied by changes of established criteria for interpretation, which are wider than the current morality exclusions permit, then such concerns should have been highlighted, explained and tailored to achieve the desired result. Today, the outcome of the hESC cases are (rightly) criticised not only due to different opinions on the adequacy of permitting patent rights in ethically sensitive domains (which is a matter for the legislator), but more importantly, the legal construction of the morality exclusion is called into question by the enactment and in particular the interpretation of the exemplifying list.

Even though these prominent questions must be addressed by the EPO, due to the background of previously established principles, they are highly relevant for EU patent law as well. Alas, the current state of legal uncertainty is undoubtedly the responsibility of the EU legislator, which introduced the exemplifying list without any apparent consideration for or even recognition of the legal framework in which it was placed, nor were any clear guidelines on how the exemplifying list was meant to be interpreted provided. Also, the EBA and the CJEU are responsible for accommodating their findings with regard to Rule 28(c) EPC and Article 6(2)(c) of the Biotech Directive within the framework of the general morality exclusions in Article 53(a) EPC and Article 6(1) of the Biotech Directive, and their further guidance is therefore of great importance to clarify and resolve the outstanding legal issues.

16.2.6 Prior Informed Consent – A Trojan Horse?

As evidenced by the analysis in the previous Section, the prominence of human dignity concerns has prompted the enactment of legislation which challenges the current patent legal framework under the morality exclusion. The interpretations of the embryo exclusions have shown that established patent law concepts are stretched very far to accommodate concerns regarding human dignity, non-commodification and non-commercialisation of human biological material. These conclusions invite the consideration of a related topic, namely the recognition of the important ethical principle of prior informed consent for the do-
nation of human biological material. If developmental aspects are included within the commercial exploitation assessment under the morality exclusion, in addition to a broad scope of the concept of invention, this would mean that it would be free to raise arguments related to immorality at any stage in the development process of an invention or during the examination or appeals procedure. The absence of the recognition of the principle of prior informed consent for human biological material which is subsequently used in an invention would, at least according to the reasoning in WARF and Brüstle, give rise to questions regarding immorality in the development of the invention.

As established in Sections 13.8.3.1.1 and 15.7.6.2, the importance of the principle is furthered due to Recital 26 of the Biotech Directive, which states that where ‘an invention is based on biological material of human origin, or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law’. Leaving considerations of the scope and nature of the consent aside, the relevant question in this respect is the treatment of this particular Recital against the background of inclusion of developmental aspects under the assessment of the morality exclusion.

The position of the EPO is mildly contradictory towards including within the morality assessment the question of whether the principle of prior informed consent has been recognised during the development of the invention, not least since developmental aspects have not been considered as forming part of the assessment under the morality exclusion. The Opposition Division has, stated in relation to the patenting of the substance Relaxin, that the possibility to express free and informed consent for the taking of the material was actually an argument in favour of the morality of the invention, which was found patentable. The Board of Appeal in Breast and ovarian cancer, on the other hand, held that in the absence of a procedure of verification of the informed consent in the framework of the grant of biotechnological patents under the EPC, patent law is not the appropriate framework for the imposition and monitoring of such a requirement.

The treatment of informed consent as a procedural rather than substantive issue originally stems from the CJEU, which stated in the Netherlands case that reliance on the fundamental right to human integrity (in the form of free and informed consent of the donor) was misplaced against a directive which concerns only the grant of patents and ‘whose scope does not therefore extend to activities before and after that grant’. At first glance, this statement seems to indicate that developmental aspects in general are not included under the morality clause, which is interesting considering the later findings in Brüstle.

[1377 Case C-377/98, para 79.]
The CJEU’s treatment of the requirement of free and informed consent in Recital 26 is understandable since it cannot by inclusion in a simple recital achieve the status as a formal patentability criterion. This is also the gist of the Court’s findings, i.e. that such an obligation cannot without further procedural and substantive amendments of relevant legislation function as a formal legal requirement. On the other hand, by its inclusion in the Directive, the principle of free and informed consent becomes at least binding on the Member states. Despite the absence of relevant procedures for verification, there is absolutely nothing that prevents a party in an appeal procedure from raising as an objection under the morality exclusion, the issue of failure to respect the principle of free and informed consent in the obtaining of human biological material which later becomes the object of a patent application or has been used in the process of development of an invention. In such a situation, it is difficult to see how the issue could be categorically refused in the assessment as a matter of argument for non-patentability.

Surely, there cannot be any difference between the uses of human embryos for the procurement of hESC which are subsequently used as starting material for an invention claimed (which is unpatentable) and the use of material to which the donators have not been able to express a free and informed consent (which under the current interpretation cannot be taken into account because a procedure for its verification is lacking). The only apparent difference is that the use of human embryos is a positive act, in that someone takes action to actually destroy the embryos. To refrain from ensuring the free and informed consent is, on the other hand, an act of negligence of or outright refusal to adhere to relevant legislation or regulation. But the nature of the acts per se should definitely not lead to differences in the assessment of the immorality of the acts.

Furthermore, if national legislation is taken into account, the situation is even more interesting. In the UK, the use of human material (human tissue) for commercial research must be subject to consent and/or ethical approval, which is a fundamental ethical and legal principle. On the other hand, the use of human embryos for research is allowed, even though this involves their destruction. The use of derivate from hESC can probably also be used commercially in e.g. stem cell therapies. If these regulatory approaches are compared to the possibilities to obtain a patent, it seems as if derived stem cells, which are legally procured, cannot be patented while subject matter which is produced without the necessary consent, and is thereby illegal, is free to patent (since the absence of a procedure for the verification of informed consent prevents the authorities from taking this into account). Against the background of a broadening of the relevant factors under the morality exclusion this study shows that in terms of fairness, it must at least be possible to raise the issue of prior informed consent under the general morality clause as a general objection to the patenting of an invention.
Two findings are prompted by the analysis so far. First, since the interpretation of the exemplifying list could be called into question with regard to its relationship to the general morality exclusion, the impact of the TRIPS framework in this context is necessary to scrutinize. Second, a prominent concern has been the issue of whether, by excluding the patentability of hESC on moral grounds, subject matter which is free to be used and commercialise under national legislation should be prevented from patentability despite being lawfully used. The handling of the principle of prior informed consent seems, however, to indicate that even a breach of legislation is not relevant for the assessment under the morality exclusion. This, in turn, invites a discussion on the relationship between patent and regulatory legislation, and here the primary focus must be on the impact of the TRIPS regulation of the morality exclusion on the corresponding provisions in the EPC and the Biotech Directive, and specifically, the envisaged handling of national law which is confined in the provisos (or qualifications) in all three clauses. In the following Sections the criteria in Article 27.2 TRIPS are scrutinised, with a specific focus on the requirement of ‘necessity to prevent’.

### 16.3 The Necessity to Prevent the Commercial Exploitation

**16.3.1 The Necessity Test(s)**

Article 27.2 TRIPS states that ‘Members may exclude from patentability inventions, the prevention within their territory of the commercial application which is necessary to protect *ordre public* or morality’. The purpose of the Article is to protect *ordre public* or morality. The means for reaching this protection is, however, dependent upon the concept of ‘necessary’ within the Article. But it is not entirely clear what exactly the term ‘necessary’ embodies.

The link between the prevention of commercial exploitation and exclusion from patentability is not apparent from the wording of the provision. The denial of patent protection will naturally remove the incentives for investments in a particular field, but the actual exploitation of the invention will not be prevented by removing the possibilities for an exclusive right. To the contrary, the absence of patent protection will make it possible for anyone to use the invention. As a result of its wording, Article 27.2 TRIPS opens up for an interpretation where the necessity of excluding the subject matter from patentability to achieve the prevention of the commercial exploitation of the invention could be relevant in the assessment, which is an important difference in relation to the other morality exclusions. For Article 53(a) EPC and Article 6 of the Biotech Directive, the exclusion from patentability follows directly from the as-
assessment that the commercial exploitation would be contrary to morality or *ordre public*, without any further requirements to consider.

Against the background of the indicated differences in interpretation highlighted in Section 12.6.2 and 12.6.3 it could be questioned whether it is really the exclusion from patentability that should be subject to the necessity test in Article 27.2 TRIPS, in particular since the prevention of commercial exploitation is not achieved by the removal of patentability. On the other hand, if the denial of patentability is regarded as having a strong impact on the technical field in question, then it becomes more relevant not only to assess the necessity to prevent the commercial exploitation to protect *ordre public*, but also to separately assess the necessity of removing the possibility of patent protection. This point of view fits in to the framework of WTO generally, i.e. that the measure chosen should be the one that reaches the objectives with the least inconsistencies in relation to the treaty, i.e. TRIPS. The main purpose of TRIPS is to facilitate trade by providing minimum standards for the protection of IP.¹³⁷⁸ The objective of Article 27.2 TRIPS is to exclude from patentability inventions, whose commercial exploitation is necessary to prevent (for the protection of morality or *ordre public*). If such prevention can be achieved without excluding subject matter from patentability, then that way is preferred. Such an argumentation indicates an understanding of Article 27.2 TRIPS where the necessity is assessed both in relation to the prevention of commercial exploitation and in relation to the exclusion from patentability. Still, the limited impact upon the commercial exploitation that the exclusion from patentability can actually achieve in practice indicates support for the other approach, namely that the necessity should be assessed in relation to the prevention of commercial exploitation, and if such necessity is established, the invention will be excluded from patentability.

The choice of approach is important for the question of treaty compliance. If Article 27.2 TRIPS requires a two-tier necessity test, Article 53(a) EPC and Article 6 of the Biotech Directive could be called into question. In fact, even if only one necessity test is required, the compliance could be challenged. If the TRIPS morality exclusion is considered to require an assessment of the necessity to prevent the commercial exploitation of the invention, of relevance, consequently, is the meaning of the concept of prevention.

### 16.3.2 The Concept of ‘Prevention’

The impact of the wording ‘prevention of commercial exploitation’ has not been elucidated by a Panel decision yet, and the content of this particular expression is subject to extensive debate. Two particular approaches to the con-

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¹³⁷⁸ Article 1, TRIPS.
cept of ‘prevention’ are represented in legal doctrine, which are presented in Section 12.6.3. The first approach (the prohibition approach) considers the necessity of preventing the commercial exploitation as requiring a foundation of an actual prohibition to commercialisation of the invention in national law. Without such basis in an existing prohibition, the patent office can never find that the exclusion from patentability is necessary for the protection of morality or *ordre public*. The second part of the test consists of an assessment of the necessity of prevention of commercial exploitation of an invention to protect morality or *ordre public* (i.e. is the commercial exploitation of the invention contrary to *ordre public* or morality), and if such necessity is established, the invention can be excluded from patentability.

The second approach (the necessity approach) takes the view that the assessment according to Article 27.2 TRIPS does not require an actual prohibition in regulatory legislation, but rather an assessment of the necessity of such prohibition. The test according to the necessity approach consists of an assessment of the necessity to prevent the commercial exploitation for the protection of *ordre public* or morality. If such necessity is established (i.e. the commercial exploitation of the invention is contrary to *ordre public* or morality), the invention can be excluded from patentability. The second approach may yield the result that the invention is considered unpatentable and thereby excluded but it could still be exploited commercially under regulatory laws, since the required assessment is detached from the regulatory framework such as legislation or authority decisions.

The difference in approaches is naturally reflected in the interpretation of the qualification in Article 27.2 TRIPS, namely that ‘provided that such exclusion is not made merely because the exploitation is prohibited by their law’. From the perspective of the prohibition approach, the qualification means that the existence of a legal (or factual) prohibition is necessary for the operation of the morality exclusion. However, the exclusion from patentability requires an additional assessment, namely whether exclusion from patentability is necessary to prevent the commercial exploitation for the protection of *ordre public* or morality. The necessity approach interprets the qualification as indicating that the assessment of ‘necessary to prevent’ is independent of the regulatory framework of exploitation, and that the patent office makes the interpretation of the morality exclusion independent from existing prohibitions. In order to qualify the EPO and EU approaches as either the prohibition or necessity kind, a concluding discussion on the interpretation of the proviso in the systems is required.
16.3.3 The Impact of the Proviso

Historically, the proviso stems from Article 4\textsuperscript{quar}ter of the Paris Convention, which stated that restrictions or limitations in domestic law should not prevent the grant of a patent. Neither were such restrictions a valid reason for invalidity. National restrictions could be modified or repealed, which allowed for a subsequent use of the invention on the national market. It was seen as unjust to prevent a patent under such circumstances. This Article, thus, created a presumption for patentability which could not be prevented by national rules of either kind, as discussed in Section 12.2.

If Article 4\textsuperscript{quar}ter is taken into account in relation to the present morality exclusions, and against the background of the presumption for patentability, the natural reading of the proviso is that patentability should not be denied on the basis of national prohibitions but require some other type of assessment. Although such a reading is generally supported in the case law of both the EPO and the CJEU, different opinions exist in relation to the question of whether the existence of such a prohibition is a necessary criterion for the finding that the commercial exploitation of the invention is contrary to ordre public or morality, or if an invention could be excluded in the absence of a corresponding regulatory prohibition. In the TRIPS context, these opinions are represented by the prohibition approach (a regulatory prohibition of the commercial exploitation is required) and the necessity approach (the necessity of a regulatory prohibition is the focus of the assessment, but no actual prohibition is necessary for the finding of non-patentability).

The prevailing approach in the EPO seems to be consistent with the necessity approach, since (usually) the Boards of Appeal have stated that approval or disapproval of the exploitation by national laws does not constitute \textit{per se} a sufficient criterion for the application of Article 53(a) EPC.\textsuperscript{1379} One important reason for this interpretation is perhaps that the examination procedure of the EPO could not be burdened with the investigation of every Member States’ national legislation, which is a completely legitimate argument against the background of the functioning of the European Patent Organisation. But the presumption for patentability seems to have been lost in the EPO approach, as discussed in Section 13.9. As far as the EPO also recognises the various national approaches to morality or ordre public, by indicating a generous approach to the presumption for patentability, such a position fits well with the aims of the proviso as expressed in Article 4\textsuperscript{quar}ter of the Paris Convention. The same situation could be found with regard to the CJEU’s position on the matters, at least as expressed in the Netherlands and Italy decisions.\textsuperscript{1380}

\textsuperscript{1379} See Section 13.9.
\textsuperscript{1380} See Section 15.4.1.
On the other hand, if Article 27.2 TRIPS is found to rest on the prohibition approach, the compliance with the international framework of the interpretations of Article 53(a) EPC and Article 6(1) of the Biotech Directive could be called into question, not least because they both indicate a complete detachment from the assessment in relation to national law. In fact, compliance could be discussed already under the necessity approach. It depends on whether the requirement of ‘necessary to prevent the commercial exploitation’ in TRIPS, is considered fulfilled by the wording of ‘commercial exploitation contrary to ordre public or morality’ in EPC and the Biotech Directive. The interpretations (broad or narrow) of these particular terms will naturally affect the conclusion.

An important issue is, however, that Article 27.2 TRIPS is directed towards a national Member. The provisions of Article 53(a) EPC and Article 6 of the Biotech Directive both represent international organisations, which are comprised of national states. The situation that a WTO Member (such as the EU) contains internally different national regulations naturally complicates matters. Nevertheless, against the background of Article 4quater of the Paris Convention, it seems as if the presumption for patentability even in the presence of national prohibitions has been lost in the detachment of the patent office’s assessment of law or regulation in general. This observation touches upon an important question, namely, the extent to which the ordre public or morality assessment should continue to be isolated from the regulatory framework. This will be further discussed in Chapter 19, since it requires both an assessment of the TRIPS obligations (which follows in Section 16.4) as well as a discussion on the handling of ordre public or morality, which is found in Chapter 18.

16.4 Remarks on Commercial Exploitation

When comparing the three morality exclusions, the first difference to consider is the impact of the necessity test(s) in Article 27.2 TRIPS.\textsuperscript{1381} If the Article is interpreted as requiring a two-tier necessity test, it has the effect that both the necessity to prevent the commercial exploitation of the invention and the necessity to exclude the invention from patentability to reach this objective (prevention from commercial exploitation) must be considered in the assessment of non-patentability. On the one hand, the second tier of the test, namely the necessity to exclude the invention from patentability to protect ordre public or morality, is questionable. The prevention of commercial exploitation of the invention can never be achieved in practice through the denial of patentability. On the contrary, if patentability is denied, the invention is free for all to use. On the

\textsuperscript{1381} The European Patent Organisation is not a WTO Member, and the question of compliance of EPC to TRIPS is therefore not actually investigated. But a comparison is still made since it is interesting for general purposes.
other hand, the required necessity could indicate an assessment of whether it is actually advisable to take such a fundamental measure as an exclusion from patentability. In the spirit of WTO law in general, the measure that reaches the objective with least impact should be chosen. If the commercial exploitation of the invention could be prevented by a less intrusive measure (such as a regulatory prohibition, for instance), the exclusion from patentability should consequently not apply.

The picture becomes a little bit clearer when the term ‘prevention’ in Article 27.2 TRIPS is considered. According to the prevalent approaches (prohibition or necessity) the existence of national prohibitions will entail different effects. The necessity to prevent the commercial exploitation of the invention can never be fulfilled, according to the prohibition approach, if the decision of non-patentability is not based in a relevant corresponding regulatory prohibition of the commercial exploitation of the invention, by legislation and/or authority decision. According to the necessity approach, such a corresponding regulatory prohibition is not required for the finding of non-patentability, but the necessity of such prevention must be assessed in the decision to exclude the invention from patent protection.

In the absence of guidance from the WTO panels, it is difficult to assess the compliance to Article 27.2 TRIPS in terms of Article 53(a) EPC and Article 6 of the Biotech Directive since the exact requirements of the TRIPS morality exclusion are not established. But if the term ‘necessity to prevent’ is taken as a point of departure, it is doubtful whether the TRIPS requirements are fulfilled by the corresponding European exclusions regardless of the type of approach considered (prohibition/necessity). As mentioned, the European morality exclusions rest on an assessment of whether the commercial exploitation of the invention is contrary to \textit{ordre public} or morality. The attitude towards corresponding prohibitions – or even permissions – in the regulatory framework (legislation, authority decisions) is detached from this assessment. This detachment could perhaps be accommodated under the necessity approach, which indicates a similar position with regard to legislation. But the necessity approach still requires an assessment of the necessity to prevent the invention from commercial exploitation for the protection of \textit{ordre public} or morality. If this particular requirement is interpreted as included in the assessment of whether the commercial exploitation of the invention is contrary to \textit{ordre public} or morality, then the current position in the EPO and by the CJEU is consistent with the TRIPS requirements. But if the TRIPS necessity approach is interpreted to require a stand-alone assessment of whether it is actually necessary to prevent the commercial exploitation of the invention (which is different from determining that the commercial exploitation contravenes \textit{ordre public} or morality), such a requirement is not reflected in the current case law. To read in an additional assessment of necessity as a requirement does not, however, seem reasonable from this point of view.
Therefore, it must be concluded that the current position of the EPO and the CJEU appears to be consistent with the TRIPS necessity approach, in as far as the assessment under the morality clause neither requires a corresponding prohibition in regulatory law, nor a stand-alone assessment of ‘the necessity to prevent’ which is different from the current assessment.

Corresponding to this conclusion, the requirements of the prohibition approach are consequently not fulfilled by current EPO and CJEU case law. Would Article 27.2 TRIPS be interpreted as necessitating a prohibition in national law as a condition for a finding of non-patentability, which should be based on an assessment which is additional to the prohibition, then the current practice in EPO and the CJEU would be inconsistent with TRIPS. Thus, depending on approach, the current state of European patent law could be either non-compliant (prohibition) or consistent with the TRIPS-requirements (necessity).

The next issue to consider is the scope of factors that are possible to include within the concept of commercial exploitation. If a broad interpretation is intended, including also e.g. developmental aspects, the character of the assessment takes on a different approach, namely, evaluating more patenting in general than the actual commercial exploitation of the invention. In fact, the consideration of factors across the whole scope of development of an invention, from the first research to the commercial exploitation, may actually be relevant for some (or every) kind of inventions, especially in the field of biotechnology. If developmental acts were excluded from the scope of the assessment, it would mean that immorality or illegality in this phase would not impact the ensuing exploitation. It is precisely in such a situation that it would be relevant and desirable to include a broader range of factors, due to the moral complicity between the acts of development and the ensuing invention, as discussed in Sections 13.8.4, 13.8.5 and 15.8.

Furthermore, if a regulatory prohibition is required as a basis for findings of immorality (in accordance with the TRIPS prohibition approach), a broader scope of factors to take into account also makes breaches of regulatory legislation relevant in the process. But if a general broadening of the scope is desired and regarded as necessary to fulfil the functions of the morality clause, such change in relation to established legal practice must be clarified by the relevant authorities (the EPO and the CJEU), or preferably by the legislator.

It seems, however, as if support for a narrower approach is strong within the TRIPS framework, at least as far as a distinction between the act of patenting and the ensuing commercial exploitation of the invention is upheld. This has also been the prevalent approach in the EPO, although decisions (notably from the lower instances) which accommodate developmental aspects also exist.

The outcome of the hESC decisions (WARF and Brüstle) has challenged the current narrow interpretation of the concept of commercial exploitation. Although these decisions are founded upon a specific exclusion for uses of human
embryos for industrial or commercial purposes, the interpretation of the subject matter under scrutiny (i.e. the concept of invention) and the scope of relevant aspects that is taken into account clearly provides a very broad interpretation which is not possible to accommodate under a narrow approach to commercial exploitation. To the extent that Article 27.2 TRIPS requires a narrow approach similar to the earlier framework put in place by the EPO Boards of Appeal, the interpretation of the embryo exclusion by the EBA and CJEU is not TRIPS-compliant.

In sum, this thesis exposes a legal discrepancy between the overarching TRIPS obligations in Article 27.2 and the corresponding European provisions in Article 53(a) EPC and Article 6 of the Biotech Directive, where non-compliance is suspected. The inconsistencies are furthered by the interpretations of the embryo exclusions in Rule 28 EPC and Article 6(2), which are evidently criticised due to their inconsistency with the overarching legal framework put in place by the general morality clauses in Article 53(a) EPC and Article 6(1) of the Biotech Directive, respectively. To remedy this situation, either the exemplifying list in Rule 28 EPC and Article 6(2) of the Biotech Directive should be removed from the general clause and placed in a separate legal provision, or the general morality clause should be subject to clarifications and amendments to accommodate the expansion of the current legal concepts that the concern for human dignity, and perhaps also other types of protection-worthy principles, seems to require. The extent of such a broadening is unclear, not least in determining how such an extension would apply to inventions of different kinds (plants, animals, and non-biotechnological inventions in general).

Also, the situation with regard to the principle of prior informed consent to the donation of human biological material which is used in a subsequent invention, or used as base material for the development of an invention, should be clarified. Recital 26 of the Biotech Directive may not require the creation of a framework for verification of such consent in the patenting process. Even so, not respecting this principle seems inconsistent with the concerns for human dignity in the patenting process, a fact which the interpretation of the embryo exclusion appears to require.

Nevertheless, these suggested amendments would not remedy the apparent inconsistencies in relation to Article 27.2 TRIPS. Even if the conclusions of non-compliance should be confirmed by the WTO, the analysis still points in that direction. This factor is naturally important in the discussions with regard to the relevant scope of the respective European morality exclusions.
The analysis in Chapter 16 elucidates the opinions of the scope of the assessment with regard to the subject matter under scrutiny and the range of factors to take into account under the morality exclusions. The next question is the testing of these factors to assess whether the commercial exploitation of the invention (i.e. scope of relevant subject matter) is contrary to *ordre public* or morality. The implementation of this part of the assessment is primarily conducted (in the EPO, at least) by a methodology involving different types of tests and standards, as investigated in Section 13.6.

The concepts of *ordre public* and morality are well-known legal terms and used in international, regional and national legal instruments. They are not defined in any of the morality exclusions, and the primary guidance to their interpretation is provided by EPO case law. An important difference between the wording of the exclusions is that Article 27.2 TRIPS, in contrast to the corresponding provisions in EPC and the Biotech Directive, contains an enumeration of ‘human animal or plant life or health or to avoid serious prejudice to the environment’ as objectives to be included within the protection of *ordre public* or morality. Such interests, especially the protection of the environment, are recognised in the EPO case law as well. Apart from this difference in wording the three clauses are quite similar also in their recognition of the content of the *ordre public* and morality terms. It is suggested that *ordre public* concerns fundamental principles related to the structure of civil society while the nature of the morality concept is more elusive. Generally, morality is a recognition of values, founded in the belief that some behaviour is right and other behaviour is wrong in a specific societal and cultural context.

A fundamental question concerns the fact that the morality exclusions which are the object of this study are situated in international or regional legal instruments, which to a varying degree contain regulations within the agreed domains on behalf of the national states which adhere to the organisation in question. The extent to which these states have transferred their national sovereignty to the organisation in question also varies. For this part of the analysis, it suffices to note that the EU is the organisation which has the most comprehensive mandate since the Member States have in essence transferred national sovereignty in the harmonised domains, and the CJEU’s interpretation of EU law must be followed by the authorities in the Member States. The position of national Members in relation to the WTO, if a breach of obligations is present, consist of a panel proceeding which has to be initiated. For the European Pa-

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1382 See Sections 12.5, 13.5, 14.2, and 15.4.1.
tent Organisation the recognition of procedures in national law is subject to a division of competences between the EPO and the national authorities, since no formal harmonisation procedure is intended, only validation of a European patent on the same terms as a national patent.\footnote{See \textit{e.g.} Article 135 EPC.}

Against this background the question of whether an invention contravenes morality or \textit{ordre public} and therefore requires an exclusion from patentability has to a large extent been left to the national states to decide.\footnote{As concluded in Sections 12.5, 13.5, 14.2, and 15.4.1} For instance, in the absence of guidance in relation to Article 27.2 TRIPS, WTO case law on GATT and GATS show that where issues of \textit{ordre public} and morality are concerned, the national states are free to decide policy objectives with regard to protection in this specific field, since they naturally vary between states.\footnote{See Section 12.5.4.} Likewise, Member States have a similar margin of manoeuvre on issues of morality or \textit{ordre public} recognised by the CJEU generally in relation to the rules on free movement, and more specifically in relation to Article 6(1) of the Biotech Directive.\footnote{See Sections 14.2 and 15.4.1.} The prevailing attitude of the EPO in relation to Article 53(a) EPC has also been that in the absence of European-wide norms on either \textit{ordre public} or morality, the EPO cannot rule an invention unpatentable under the morality exclusion.\footnote{In relation to Article 6(2) of the Biotech Directive and Rule 28 EPC, this conclusion is not possible since the exemplifying list does not contain a moral judgment, only an interpretation of the exclusions as such. See Sections 13.2 and 13.5.4.4.}

Against this background the guidance from EPO case law consists predominantly of creating methods for assessing \textit{ordre public} and morality. In this thesis, the decisions from the EPO have been analysed as being subject to (at least) two types of test: the balancing test(s) (\textit{Rule 28(d) and T 19/90 tests}) and the \textit{rebuttable presumption test} (where the presence of a moral aspect raises a favourable presumption, which the immoral aspects can only rebut where they are sufficiently significant). As identified in Section 13.5.3.1, the preferred method for \textit{ordre public} is the enumeration of interests to protect, similar to the formulation of conservation objectives in Article 27.2 TRIPS. Relevant sources for \textit{ordre public} are, thus, norms in the form of constitutions or other recognised principles (\textit{e.g.} the ECHR). The findings in Section 13.9 in relation to the proviso also indicate that the EPO (at least) is reluctant to base \textit{ordre public} concerns on national law. The main test employed in relation to \textit{ordre public} is the balancing test(s), which is utilitarian in character.\footnote{See Section 13.6.3.1.}

Conclusions for morality are found in Section 13.5.3.2. The general method for establishing morality is the finding of a body of norms which are generally accepted as standards of behaviour. Whether morality could (and should) be
based on the perception of a majority of the public (cultural morality) is a contentious issue, not least because the method is considered to be faulty in terms of ethics. The finding of morality is also hampered by the fact that the EPO has refused different kinds of evidence of morality, e.g. opinion polls (rightly so, where they were not executed properly), which leaves the issue of substantiation of facts, as well as recognition of arguments, open in the majority of decisions, a fact discussed in Section 13.10. The finding of morality is held to require the rebuttable presumption test, which is true as far as the invention in question concerns human biological material. Concern for human dignity, for instance, is a factor that should never be compromised and hence, is sufficiently significant to not be outweighed by benefits of any kind. To the extent that moral approaches are identifiable in the tests, they are clearly utilitarian (balancing tests) or dignitarian (rebuttable presumption).

According to the analysis in Sections 13.6.4 and 13.6.5, the use of the different tests in relation to ordre public or morality concerns respectively is not openly advocated by the EPO, and neither are the moral approaches discussed from the point of view of forming theoretical bases for the decisions. The only situation where the use of a specific test is expressly preferred is the balancing test in relation to animal inventions. The creation of such a test by the EPO (in Oncorhynchus I, the T 19/90 test) was later codified in Article 6(2)(d) of the Biotech Directive, albeit with some minor modifications.

Despite the absence of express recognitions, the analysis shows that these two types of tests are actually used. However, the conclusions have to be treated with caution. This study points to the fact that an elucidation from the EPO with regards to the identification of and use of the tests is necessary. This is important not least from the perspective that the use of the tests seem to depend on the character of the material in the invention. Where animal or plant inventions are examined in relation to Article 53(a) EPC, the utilitarian balancing tests are preferred. In relation to inventions concerning human biological material, the results are not as clear, but it seems as if the balancing test cannot be used to the same extent as for other types of inventions. If the rebuttable presumption test is preferred, the situation necessitates clarification.

When a test is performed, the outcome must necessarily be judged against a standard which decides whether or not the invention should be excluded from patentability on the basis of ordre public or morality concerns. In this study, two specific standards relative to the level of immorality required by the morality exclusion are identified in EPO case law, namely, abhorrence and unacceptability. The abhorrence standard requires that the invention should be regarded by the public in general as so abhorrent that the granting of patent rights should be inconceivable. This standard is predominantly used by lower divisions. The

1389 See the reasoning in e.g. Section 13.6.3.2, 13.6.7 and 15.8.
unacceptability standard stems from the definition of morality in PGS, and consists of an assessment of whether the public in general would find the invention unacceptable in the light of conventionally accepted standards of conduct of European culture. Whereas the difficulties of basing a standard on cultural morality are discussed elsewhere in the study, the fact that the two standards – abhorrence and unacceptability – denote different levels of perception is important. Abhorrence is, by nature, a stronger criterion than unacceptability.

In this thesis the relation between the tests and standards has been investigated in Sections 13.6.4 to 13.6.6. The suggestion that the use of the identified tests requires adherence to a specific standard is not evident. Even though it is held in doctrine that the balancing test must adhere to an unacceptability standard and the rebuttable presumption test to a standard of abhorrence, this particular allocation of respective tests in accordance with a specific standard is not reflected in the EPO case law. Even if it would not be logically possible to balance factors to the point of abhorrence, and that unacceptability cannot be the outcome of a rebuttable presumption test, it is still necessary to identify the preferred level of immorality that the patent system is able to handle, against the background of its function and aim.

Furthermore, it is possible to see the outcome of the tests (i.e. balancing of factors or assessment in accordance to a rebuttable presumption) as providing the required answers in themselves, and not requiring a specific standard. As discussed in Section 13.6.4, the position of the EPO is not clear in this regard, and the opinions of commentators as to the interpretation of these issues indicate a large degree of disagreement.

In sum, the theoretical construction of the tests and standards does not hold up against their practical application by the EPO. Whereas it would be desirable that the EPO displayed awareness of this theoretical framework and clarified the applicability of the moral approaches (i.e. tests) and whether these are relative to the standards identified, the conclusions in this study nevertheless points to a specific choice of standard.

Even though unacceptability is the preferred notion in a majority of the decisions, it is imperative that abhorrence should be the preferred level. Abhorrence as the relevant criterion fits into the purpose, objectives and function of the patent system in a superior fashion than unacceptability. The standard of unacceptability invites an assessment of factors which are in many cases difficult to substantiate, assess or even examine in the light of the mandate put upon the patent system, i.e. the experts at the patent authorities. The criticism of cultural morality as the basis for decisions is indicative of the deficiencies with this particular standard. Even if abhorrence is based on the same type of public perception as unacceptability, it is easier for the patent examiners to identify.

1390 See Sections 13.6.2, 13.6.5 and 13.6.6.
Another factor is imperative, namely the presumption for patentability which stems originally from Article 4ter of the Paris Convention. This presumption seems to be lost today, not only by the complete detachment from law that is advocated by the EPO in the assessment in relation to Article 53(a) EPC, but also in the discussion of commercial exploitation of the invention. Even if national law cannot have a bearing on the EPO interpretation, due to factors relative to the functioning of the European Patent Organisation, regulation by higher norms should be indicative of morality or *ordre public*. But, to exclude an invention on the basis of morality or *ordre public* in the EPO, when national laws do not prohibit the making or use in question of the invention, would indicate that these laws are immoral or constitute a breach of morality or *ordre public*. Even if the EPO does not have an ex officio responsibility to investigate the state of legislation in every Member State, an indication by a party in an appeal proceeding that this is the case should definitely have an impact on the decision under the morality exclusion. In fact, in this study it is advocated that the EPO should use its investigative possibilities and take national legislation into account to a greater extent under the morality exclusion, in order to avoid a situation in which patentability is denied even though the invention is free to use on the market. With a level of abhorrence as a threshold for the application of the morality exclusion this situation is avoided to a greater extent than with a level of unacceptability.

The outstanding issue is thus the tests and the assumption that the balancing tests are not possible to use against a standard of abhorrence (which goes well with the rebuttable presumption test). But the standard of abhorrence is, just as unacceptability, based on a standard which is reached through an assessment of public perception. To the extent that the balancing tests relate to a standard at all, it seems as if neither abhorrence nor unacceptability is possible to use. It is rather so that the results of the balancing tests are not possible to measure against a public perception standard, since the outcome of such balancing exercise is the outweighing of one set of factors in relation to another set of factors in relation to a total set of consequences. Thus, the result of this study is that the balancing tests are not possible to use in relation to a certain standard, but the result of such test is a utilitarian interest rationale. This conclusion also supports the notion that the only test that can use a certain standard is the rebuttable presumption test, and that standard needs to be one of abhorrence. An abhorrence standard ensures that the examination under the morality exclusion does not interfere with the regulatory system. It also fits in with the presumption of patentability that is also visible in the EPO decisions, where very few patents have actually been excluded on the basis of the morality clause.

The question of tests and standards has not, due to the lack of case law on the issue, been treated by either the CJEU or the WTO panels. No apparent conclusions can be drawn regarding the question of compatibility between the legal systems in this respect. It is also natural since the purpose of the European
Patent Organisation is to create a common examination and granting system for European patents, whilst the other entities handle questions of legal interpretation on a different level.
The analysis in Chapter 16 has exposed a possible discrepancy between the requirements of Article 27.2 TRIPS and the corresponding provisions in Article 53(a) and Rule 28 EPC as well as Article 6 of the Biotech Directive. The main conflict exists with regard to the interpretation of the requirement that the prevention of commercial exploitation must be necessary to protect *ordre public* or morality, and consequently for the exclusion of inventions from patentability. Such a necessity requirement is neither expressly confirmed in the text nor in the case law of the corresponding provisions in European patent law. As mentioned, there are two competing opinions as to the content of this necessary to prevent-approach: requiring a corresponding prohibition in national law (prohibition approach) or requiring an assessment of the necessity of such approach (necessity approach). Both approaches could be found inconsistent with the current state of the law as interpreted by both the CJEU and the EPO, although the prohibition approach represents the strongest deviation due to the required national prohibition as a basis for the application of the exclusion. A second aspect of the EPO and CJEU interpretations of the morality exclusions is the breadth of scope awarded to the concept of commercial exploitation, especially with regard to the inclusion of developmental aspects within the scope of assessment. Against the background of established WTO case law on the concept of exploitation, it is conceivable that such breadth of interpretation is not compliant with the understanding of the concept of commercial exploitation in the WTO framework.

Since no definite answer as to the question of compliance to Article 27.2 TRIPS is possible until such time as a DSS decision provides guidance to its interpretation, this analysis will be based upon a presumption of non-compliance with Article 27.2 TRIPS on behalf of the European morality exclusions in the Biotech Directive, which the conclusions in Section 16.4 also indicates.

The Member States of the EU are also Members of the European Patent Organisation, which in addition has a number of non-EU Member States as members. The European Patent Organisation Member States are also Members of the WTO, with the exception of Serbia and the microstates of Monaco and San Marino. There are thus overlaps in membership to the extent that

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1392 Serbia is an EU Candidate country and a WTO Observer government (in the process of application and accession to both organisations). See European Neighbourhood Policy and Enlargement Negotiations, ec.europa.eu/enlargement/countries/detailed-country-information/serbia/index_en.htm (20 April 2015), WTO Members and Observers, www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (20 April 2015)
the majority of the European states are members of the EU, the European Patent Organisation and the WTO. The EU is also a WTO Member in its own capacity.

This institutional web of membership will affect the national states to the extent that if a state which is a member of all three organisations is subject to (possibly) differing interpretations from the organisations, it will naturally affect this member’s obligations in relation to the organisation with a differing interpretation compared to the one that the state chooses to follow in its national system.

As explained in Section 10.3.2, the European Patent Organisation is not a WTO Member and is not formally bound by TRIPS, even if EPO case law points to at least an intent to adhere to the international framework, as far as common concepts are created. The deviation of EPO case law from an interpretation of Article 27.2 TRIPS would not entail any consequences for the European Patent Organisation, but its individual Member States would have to choose to adhere to either interpretation and face the consequences of non-compliance with either TRIPS or the EPC. Even if the Member States have not agreed to a formal harmonisation in terms of the EPC, they have chosen to do so by means of national decisions. The outcome of non-compliance with the principles established by the EPO does not seem to lead to any severe effects, and is mostly an issue for national law, e.g. in the case that a Member State fails to validate a European patent under the requirements of EPC. As will be discussed next, a breach of TRIPS obligations could lead to a DSS panel proceeding, which seems, in comparison, to entail more serious consequences.

As outlined in Chapter 9, EU law takes precedence over national law in the harmonised fields (in accordance with the EU Treaties and general principles of law) and EU Member States have a duty to set aside national provisions which are incompatible with EU law. Furthermore, national law has to be interpreted to avoid conflicts with EU law. National courts and authorities are consequently bound by the CJEU interpretation of e.g. the Biotech Directive, and the failure of a Member State to adhere to the obligations could result in measures being taken within the EU legal system. The specific character of the EU legal system is of such a nature that the recognition of EU legislation as part of national legislation is much stronger than other types of obligations stemming from the conclusion of international agreements in general. At least this is the position taken by the CJEU.

The conclusions relative to the function of the WTO legal system are found in Section 8.2. The WTO sources of law consists of the WTO treaties and a specific custom characterised as a system of ‘subsequent practice’, where the

norms developed within the organisation follow a discernible pattern of a sequence of acts implying a specific interpretation of an agreement. Such subsequent practice is not directly applicable to WTO judicial decisions, but adopted reports are nevertheless seen as an important part of the WTO acquis and should be taken into account where relevant. But the decisions are not of an erga omnes character, since they are exclusively binding on the parties to the dispute and not legally binding outside that particular relation. Still, the interpretation of a panel or Appellate Body of Article 27.2 TRIPS would, against the background of the function of the WTO system, have effects also outside the specific dispute, depending on how general the findings are. They would definitely provide guidance for subsequent decisions and also in relation to WTO Members, despite the absence of formal erga omnes character.

WTO Members are required to follow the WTO rules as binding rules of international law. The effects of WTO law on their Members’ national systems are subject to the constitutional principles in the domestic legal system, which is decisive for e.g. the decision to grant international rules’ direct effect in national law. Even if Article 27.2 TRIPS would not be granted direct effect in the system in question, the principle of consistent interpretation (as found in Articles 26-27 VCLT) nevertheless requires the interpretation of domestic law in accordance with international obligations.

Since the EU is a WTO Member in its own right, alongside the EU Member States which are also WTO Members in their own right, a specific legal situation is created with regard to the EU and its Member States, i.e. a situation of mixed competences. From the perspective of the EU, incorporated international law is placed on a rank below EU primary law (but above secondary law), which means that Directives in general are of a lower norm category than the international rules. This entails the effect that the provisions of the Biotech Directive, including Article 6, are subject to Article 27.2 TRIPS in terms of norm hierarchy within the EU legal system.

The particular situation of mixed competences in relation to TRIPS, as analysed in Section 9.5.2, has been subject to an interesting legal development. The division of competences between the EU and its Member States with regard to TRIPS was originally held by the CJEU to depend on whether the Union had retained competence in the specific field in question, by harmonisation efforts. Thus, by the enactment of the Biotech Directive the EU became fully competent in relation to its Member States in the field of biotechnological patents. In addition, the introduction of Article 207 TFEU has established EU authority in full with regard to the whole field of commercial aspects of IP. The develop-
ments have led to the situation where the original mixed competence between the EU and its Member States in relation to TRIPS now rests exclusively with the Union. The possibility for individual Member States to decide on the incorporation of TRIPS in accordance with the constitutional principles of their choice is consequently not present anymore. Thus, the EU needs to conform its secondary law (at least) to the obligations following from TRIPS, or it could face a DSS dispute if another WTO Member reacts to a perceived non-compliance.

Since the EU Member States are still WTO Members in their own right, they need to adhere to the obligations following from TRIPS also as individual states. In a situation where EU law is found non-compliant with TRIPS, a EU Member State which by force of the EU law follows the interpretation of the CJEU, could (at least formally) be found to violate its TRIPS obligations in relation to WTO and consequently be subject of a DSS panel proceeding. The other option, i.e. to adhere to the WTO interpretation of Article 27.2 TRIPS, would entail a risk of breach of EU law for the EU Member State. The WTO membership on behalf of the EU, thus, puts its Member States in a precarious position, to say the least.

As outlined in Section 8.2.2, a non-European WTO Member that considers the interpretation of Article 6 of the Biotech Directive to be non-compliant with Article 27.2 TRIPS could initiate a panel proceeding. The outcome of the panel (or on appeal, the Appellate Body) decision must be adopted by the DSB. Failure to comply with the conclusions of an adopted report could lead to the Member having to pay compensation, and ultimately the application of concessions or other obligations of the agreement could be suspended in relation to the party in breach of its obligations under TRIPS.

As explained in Chapter 16, the compliance with Article 27.2 TRIPS of the interpretation of Article 6 of the Biotech Directive by the CJEU could be called into question. The TRIPS obligations should not be subject to conflicting regulation from the EU. But as the study in Section 9.5.3 shows, there is little or no possibility of direct legislative review of EU (secondary) law by the CJEU in the case of TRIPS. This is because WTO law in general, including TRIPS, lacks direct effect which is a precondition for an agreement to have a constitutional function within the Union. The reason for such stance is that WTO law is based on reciprocal and mutually advantageous arrangements, and not of a character which requires strict compliance with the primary obligations.

Even if the application of the principle of consistent interpretation to the Biotech Directive in relation to TRIPS could result in an indirect adherence to Article 27.2 TRIPS, this option is not expressly recognised. In essence, this leaves the individual EU Member States in a legal vacuum, without any possibility to influence or remedy the interpretation of the CJEU in case of non-compliance with TRIPS. In such case, the only remaining option is to rely on the goodwill of the non-European WTO Members to not initiate panel pro-
ceedings against a single state. However, Straus is sceptic towards the likelihood for non-European Members to let such non-compliance pass: ‘[I]t has to be observed that a patent granting practice, which would result in excluding from patent protection under Article 53(a) EPC, inventions the exploitation of which is allowed by law, would doubtlessly also be questioned internationally under Article 27 TRIPs. Nobody would be willing to see his/her inventions used freely in foreign countries under such a pretext.’

From the point of view of the current situation of (TRIPS-plus) FTAs, as described in Section 8.1, non-compliance with Article 27.2 TRIPS could well be an important factor in the negotiations between individual WTO Members, a situation which a single EU Member State cannot improve or challenge in the current legal situation. The terms of functioning of the EU, in regard to its TRIPS obligations, depicts a system which is quite static and sealed off from external influence. In the case of biotechnological patents, this situation puts the EU Member States in a legal dilemma.

An often proposed solution to the patent law dilemma of incorporating ethical considerations into the assessment under the morality exclusions is to conform the ethical standards of *ordre public* or morality to the state of the regulatory legislation of the invention concerned. Some EU Member States (and a number of non-EU states) have, for instance, aligned their patent morality exclusions (and especially the national embryo exclusions) to relevant medical legislation by express references in the law. These references were created as a result of the implementation of the Biotech Directive, as outlined in Section 14.4, but reflect an approach which has been noticed earlier in the practice of some patent authorities. The adaptation of decisions of patentability (with regard to moral assessments) to the existing regulatory framework, especially where e.g. pre-ethical review is required, shows a tendency to rely on moral evaluation already established, albeit in a different context than patent law. This conformity of the patent law morality assessment to the regulatory framework is, in fact, anticipated by the TRIPS prohibition approach as concluded in Chapters 16 and 18.

As exposed in Sections 16.2 and 16.3 the proviso (i.e. the regulation in the morality exclusion that the existence of national prohibitions on exploitation should not impact on the assessment) has been interpreted as a reason for complete detachment of the decision of patentability under the morality exclusion from the regulatory framework. From the perspective of the relation between patent and regulatory law, the criticism of the apparent discrepancy between the denial of patentability and the permissive regulatory approach to commercially exploit such inventions necessitates a discussion regarding three vital aspects of this relationship.

*First*, if a correspondence between patent morality and regulatory prohibitions are sought, it is important to identify the basis of the regulatory assessment. The decisions in the regulatory system should naturally only be relevant for the patent morality assessments where the basis for such decisions is *ordre public* or morality concerns. In this thesis, as established in Section 3.3, it is presumed that the concept of the regulatory framework targets legislation and authorisation procedures with the aim of protecting the safety (including health) of humans, animals, plants and the environment, as well as protection of ethical principles (in a broad sense) in e.g. research and the application of biotechnology. From this perspective, a relevant connection is assumed.

*Second*, a distinction between permission to use subject matter and permission to commercialise subject matter is necessary if the patent decision is to be aligned with regulatory rules or decisions. As discussed in Chapter 16, the relevant criterion for the assessment of an invention with regard to morality or *ordre
public is commercial exploitation. The fundamental argument for conformity between the systems is that acts which are lawfully performed should not be denied patent protection, as witnessed by e.g. the alignment of national embryo exclusions with research regulation in the wake of the Biotech Directive’s implementation. But the fact that an act is permitted for research purposes should perhaps not be extended to include permission for the commercial exploitation of the invention in the patent law morality assessment. And if a patent is seen as (at least including) a commercial element as discussed in Section 16.1, then this distinction means that the assessment of ethical considerations relative to a permission to conduct research with the material is different from permission to commercialise the results, which is what the patent morality assessment actually targets. If the scope of assessment includes also developmental issues, this distinction is crucial, not least from the point of view of the principle of prior informed consent, where the consent would have to include consent also to ensuing commercialisation.

Third, the supposition that the unpatentability of the inventions in the WARF and Brüstle decisions is not reflected by corresponding regulatory prohibitions must be put in relation to the scope of the legislation in question. In the EU legal order, although permissive regulations on uses of human embryos, procurement of hESCs and commercialisation of this subject matter exists on Community level, the national legislation in the Member States is rather diverse, as discussed in Section 15.7.5. No commonality is achieved on the national level, and different opinions exist as to the actual permission with regard to commercialisation in Community law. Since memberships overlap to a large extent, the situation in the Member States of the European Patent Organisation is similar. But the EPO has, arguably against the background of the burden of investigating the provisions of each Member States’ national legislation, interpreted Article 53(a) EPC rather strictly, providing a large room for manoeuvre for national opinions.1397 This has also been the position of the CJEU, at least in regards to Article 6(1) of the Biotech Directive, as established in Section 15.4.1.

As long as the morality exclusions in these systems are used as an absolute safeguard, with a narrow scope and adhering to a high threshold standard (of abhorrence, as advocated in Chapter 17), the problem of incompatibility between permissive national regulations (with regard to commercial exploitation) and a denial of patentability will not occur. But the interpretations of the EBA in WARF and the CJEU in Brüstle as based on the embryo exclusion in Rule 28(c) EPC and Article 6(2)(c) of the Biotech Directive yields a result where the patent morality assessment is actually stricter than relevant regulatory legislation, indicating that the latter is immoral or contrary to ordre public. In the context of the EU legal order, it may be questioned whether this is a desired result.

1397 See Section 13.5.
In the European Patent Organisation, the result is definitely contrary to established practice of the EPO, which in the past has endeavoured to accommodate national variations in the application of Article 53(a) EPC. From this perspective, this thesis urges the CJEU to align its interpretation of the EU morality exclusion to the applicable legislation on commercialisation, where such exist.

Against the background of the discussion of necessary requirements for an alignment between the patent morality exclusion and relevant regulatory legislation or decisions, another factor is important to consider, namely the mandate and competence of the patent authorities. As seen in the decisions involving especially risk assessment in relation to plants, the EPO has held that patent offices are placed in the crossroads between science and public policy, which could lead to an overlap of roles between patent offices and regulatory bodies. Patent offices’ competence in the field of risk assessment for e.g. the testing of genetically modified plants or animals, or agrochemicals, could consequently be questioned. It is furthermore evident from the decisions that a failure to substantiate facts by evidence was a contributing factor with regard to the decision of patent grant.

Still, the findings show that despite questions about mandate and evidence the Boards and Divisions are actually making assessments of the kind that perhaps could and should be handled by the regulatory authorities instead. Considering that the main task of the patent offices is to handle the formal and substantive requirements for patentability, in particular the novelty and inventive step of the invention, this competence is well suited for assessing the exploitation of the invention on the market. But other types of patent-external assessments of the kind that the morality exclusion seems to require, should not entail the effect that the patent authorities suddenly becomes omniscient entities competent to make any kinds of assessment. This, however, does not mean that the patent offices are not competent to judge moral issues. It means that the scope of assessment awarded to the patent morality clause should be held within the constraints of the patent system. Decisions made elsewhere, by the qualified regulatory authorities, should as far as possible be used to supplement the patent authority in the assessment according to the morality exclusion.

Thus, the findings in this thesis support an alignment between the regulatory framework and the patent morality assessment, as far as is possible with regard to the arguments for caution submitted above in this Chapter.

1398 See e.g. Section 13.8.3.3 and 13.11.
1399 See e.g. Section 13.10.
The standards of patent law, especially in such a difficult field as the morality exclusion in the biotechnology domain, where patent law, ethics and biotechnology interact, must be clear, transparent and construed as well as interpreted in a logical manner.

This study indicates that the patent law morality exclusion needs to be kept within strict limits, against the background of the functioning of the patent system, especially in the biotech domain, coupled with the findings with regard to TRIPS compliance. The scope of application of the morality clauses in the respective regional and international systems needs to be sensitive of national approaches to morality and ordre public. A broad interpretation of patent law ethics will lead to a discrepancy between national regulatory legislation and the regional exclusions from patentability in the sense that patentability is withheld on the basis of morality concerns where the invention is free to exploit commercially on the market. Not only is such result probably non-compliant with TRIPS, but it is also contrary to established room of manoeuvre for national approaches to morality and ordre public. If the patent law morality exclusion is not confined within the indicated limits, it will be difficult to justify from a strictly legal point of view. Most importantly, tampering with established patent principles will be detrimental for the patent system because the assessment with regard to the morality exclusion will be difficult to accommodate against the background of the system’s functions and theories of justification. This will also affect the justifications for the morality exclusion as such. Thus, if amendments to the current legal framework are preferred, these must be clarified and explained. Finally, broadening of the scope of the morality exclusion, inviting assessment of more factors under a wider umbrella, may lead to a situation which the patent system is not able to handle simply due to its limited possibilities to practically affect the actual exploitation of inventions in society.

In the search for an optimal function, scope and interpretation of the European morality exclusions, the findings in this thesis put forward the following suggestions:

- The interpretations of the embryo exclusion in Rule 28(c) EPC and Article 6(2)(c) of the Biotech Directive have led to an unclear legal situation with regard to the effects of the general morality clause in Article 53(a) EPC and Article 6(1) of the Biotech Directive. It is necessary that the CJEU, the EBA or the legislator clarifies the preferred approach towards the concept of commercial exploitation, with regard to the scope of factors included within the assessment.
Likewise, an elucidation of the scope of the subject matter under scrutiny is necessary, i.e. the term invention. If a change in practice is not anticipated in relation to the general morality exclusion, then the interpretation of the exemplifying list must be explained and contained within certain limits.

The question whether developmental aspects should be included within the assessment of commercial exploitation is, however, fundamental for the interpretation of all morality clauses generally. For biotechnology inventions, especially of human origin, excluding such aspects from the scope of assessment under the morality exclusion would perhaps yield undesirable results. But the extent to which such aspects shall and will be included, and whether such inclusion should apply to inventions in all technical fields, must be addressed and the limits of the morality exclusions should be clarified. Furthermore, since the compliance of the interpretation of both European morality exclusions with the standards imposed by Article 27.2 TRIPS could be questioned, this perceived discrepancy should be addressed. Explanations as to the accommodation of the current scope of the European morality exclusions are required.

It is finally advocated that the standard required for an application of the morality exclusion should be one of abhorrence, which is in line with the purpose of the provision as one of necessary safeguard against the background of a presumption for patentability also where the commercial exploitation of the invention is prohibited. Since it is established in this thesis that alignment between the patent and regulatory systems is preferable, where possible, a narrow application and high threshold for findings of immorality serves the purpose of keeping the patent system within its confined limits and prevents an overlap of competences. Since it is acknowledged that a broadening of the scope of relevant factors with regard to commercial exploitation could be necessary, at least in some cases, such inclusion of developmental aspects must be coupled with the alignment between patent and regulatory law in order for this to function properly.
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