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Moral exclusions in European biotechnology patent law

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Abstract

Biotechnology patent law raises moral issues since it concerns living material and the European Biotech Directive therefore contains exclusions for inventions that are contrary to “ordre public” or morality under Article 6.

The purpose of this paper is to discover the scope of the moral exclusion in the Human, Animal and Plant fields of biotechnology patent law and to discuss the problems regarding the specified moral exclusions found in Article 6(2) of the Biotech Directive.

The analysis shows that the moral exclusion scopes differ between these fields and that there is a more narrow moral protection for plant inventions. The broadest protection is found concerning human related inventions. The analysis also shows that the human moral exclusion scope is quite uncertain since there are different interpretations regarding this field.

The specified moral exclusions under Article 6(2) of the Biotech Directive create uncertainty regarding the moral exclusion. The fact that the biotechnology field is a fast developing area, with large potential for creating medical benefits for human beings, makes it inappropriate to include too specified moral exclusions in the European biotechnology patent law.

Key words: *Moral exclusions*, *Biotechnology*, *Patent law*, *Europe*, *Ethic*

Abbreviations

Biotech Directive	European Parliament and Council Directive on the legal protection of biotechnological inventions
CTD	Clinical Trials Directive
CPVR	Community Plant Variety Rights Regulation
ECJ	European Court of Justice
EGE ogy	European Group on Ethics in Science and New Technol-
EPC	European Patent Convention
EPO	European Patent Organisation
TRIPs	Trade Related Aspects of Intellectual Property Rights

1. Introduction

1.2 Purpose

The *raison d'être* of the biotechnology industry is the manipulation of living organisms. This however is also the main reason for the controversy of biotechnological patenting. Since modified gene can form patentable inventions if the criteria of inventiveness and industrial applicability are met, living organisms are in principle patentable. The discussion is interesting since our previous understanding of life is challenged under the impact of this technological perspective, which regards living material with inheritable characteristics as objects of exclusive rights. This raises moral issues within the biotechnology patent regulation, since living subject matter is given a different ethical concern than mechanic ones and this has created new ethical problems within the patent field. The moral debate and exclusions under the European patent law are therefore worthy of an analysis.

I find the problem interesting since it combines two different systems of ideas, ethics and technique, within the patent structure. The patent system is a technical field created to promote inventions rather than solve moral problems and the harmonisation of these two systems of ideas is therefore not obvious.

It can also be added that no system of ethical regulation is perfect, if only for the reason that ethics is not an exact science but means for applying moral beliefs, which further complicates the task. It has therefore been argued that the patent system "*must be related to the world of commerce rather than to the realm of philosophy…*"[1]. It has simultaneously been argued that the patent system is not a mere technical issue that can be seen as morally neutral, but that ethics forms an integrated part of patent law since the idea of patenting is to exclude others from accessing information and thereby affects the relation between different interests.[2]

However the European patent system aims to keep a balance between the inventors' interests and the interests of society and therefore includes moral exclusions under Article 53(a) EPC and Article 6 of the Biotech Directive. These Articles state that inventions shall be considered unpatentable if their commercial *exploitation would be contrary to "ordre public" or morality,* and moral issues are therefore to be considered in the biotechnology patent field.

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[1] Stated by the US Supreme Court, Sigrid Sterckx, 2001:175
[2] Peter Drahos, E.I.P.R 1999:9:442

The aim of this study is to examine the scope of the moral exclusions in biotechnology patent law in respect of the application of the exclusions to Humans, Animals and Plants. This is done through an analysis of the diverging interpretations that have emerged and the range of legal considerations relevant to the resolution of the differences.

The analysis of the moral exclusion in biotechnology patent law demonstrates a vague and uncertain scope of exclusions and shows that Article 6(2) of the Biotech Directive has created new ethical questions instead of solving them. Since ethical considerations may change over time I will also discuss the question if the general moral exclusion in Article 6(1) of the Biotech Directive is to prefer without the further guidelines found in Article 6(2).

1.2 Method and Material

I will use a traditional legal method in this paper and I will apply a subjective and teleological interpretation method since I believe that the intention and purpose of the law is important when considering the moral exclusions within the biotechnology patent law. According to the traditional legal method the law is the primary source when interpreting juridical problems and the political values are to be judged as secondary. However, law cannot be separated from politics or power.[3] And political objectives have had an important influence upon the Biotech Directive.

My starting point is therefore that the overall legal frameworks, in particular the EU Legal Order and the EPC Patent System, both have distinctive legal features that bear on the legal construction of the moral exclusion articles within the Biotech Directive. I will therefore analyse a range of legal and extra-legal sources that are relevant to the interpretation of the biotech Directive under each legal system. In particular, the paper considers:

- The text of the Biotech Directive, including the Recitals
- Preparation acts regarding the Biotech Directive
- The text of the European Patent Convention (EPC), including the Rules
- The EPO case law
- The policies and practice of the European Patent Office (EPO)
- The Opinions of the European Group on Ethics in Science and New Technology (EGE)
- The wider principles of EU law under which the Biotech Directive has legal effect

Judicial decisions and preparation acts have a subordinate function within the hierarchy of sources. Although judicial decisions are to be utilised as a subsidiary mean for

[3] Malcom Shaw, 2003:75

the determination of rules of law rather than as an actual source of law, judicial decisions can be of great importance. I will use these sources to clarify the moral exclusion scope in the biotechnology patent field. However, the reader should consider the limit of these examines since the EPO at several times stated that the case law concerning patent and moral exclusions shall be regarded in a case-by-case view. Each new patent has to be examined on its own merits and therefore one cannot deduce a patent policy from a single case. I will nevertheless try to conduct some analyses from the case law of the EPO since the principles produced in the case laws are repeated and referred to by the EPO itself.

There are disagreements as to the value of a customary system in international law. But the essence of custom is that it could constitute evidence of a general practice accepted as law.[4] I will therefore take into account the EPO custom[5] in my analysis.

A special rule prevails over a general rule, and the law later in time will have priority[6]. Thus, I will consider the Biotech Directive as the main source, even though I will also consider the EPC since I think that the legislative changes are important for the understanding of the moral exclusions found in the European patent law.

1.3 Delimitations

My paper analyses the moral exclusions within the European Biotechnology Patent Law under the Biotech Directive and the EPC. I consider European patents that have been delivered by the EPO since it at present is the only legal body to deliver European patents. Thus I do not take into account patents delivered only by national courts, even if some references are made. References are also made to the TRIPs agreement, but only to illustrate differences between these systems and the European one.

There is a difficulty in deciding the scope of the moral exclusions within the biotechnology patent law since biotechnology patents operate within both the EU and the EPO legal system. However since the Biotechnology Directive has been implemented[7] into the EPC and since 26 out of 27 EU Member States[8] have signed the EPC, I consider the "moral articles" under the two systems to be equivalent and that the two systems can be analysed together. This is also stated by the ECJ in the *Neth-*

[4] Malcom Shaw 2003:69
[5] "The concept of patentability in the European patent law must be as wide as possible",
Document IV2071/61-E
[6] Malcom Shaw, 2003:116
[7] The Administrative Council of the EPO implemented the Biotech Directive through Chapter VI in Part II of the EPC Implementing Regulations in September 1999 into European patent law.
[8] Malta is the only Member State which has not signed the EPC

erlands case, where the court stated that the differences in wording between the exclusion provided for under Article 53 EPC and in Article 6 of the Biotech Directive should not give rise to differences in assessing whether one and the same invention is contrary to "ordre public"[9]. Still, the differences that have occurred between these two systems is a part of the analysis of my essay.

While analysing the moral exclusions within the biotechnology patent law I have been required to consider some related articles, even though these are not directly "moral articles" since moral issues raised under the patent law often have been of a general character related to the question of "patenting on life". Thus the articles 4 and 5, concerning the exclusion of patentability related to Humans, Animals and Plants will be considered to enable the scope of moral exclusions.

I have tried to delimit the biotechnical parts since I am not at all an expert on biotechnology and since the purpose of this essay is to analyse the moral exclusions. However, since it is a technical field it has been necessary to make some technical references, in order to enable an understanding of the scope of the moral exclusion within the system.

The case law parties related to Human, Animal and Plant exclusions are quite detailed since I find it important to reproduce the wording of the decisions in order to understand the moral debate and scope regarding biotechnology patents.

1.4 Terminology and Definitions

Biotechnology can be given an extremely wide definition and can refer to "*any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals or to develop micro organisms for specific uses*"[10] The basis of modern biotechnology is the ability to cause genetic recombination using molecular means, as opposed to sexual means[11].

1.5 Disposition

Chapter 2 is descriptive and explains the European patent system and the criteria for patentability within Europe. Chapter 3 is both descriptive and analytical and describes the origin and ethical debate related to the moral exclusions under European patent law, both related to the EPC and the Biotech Directive. Chapter 4-6 analyse the law and case law related to Human, Animal and Plant moral exclusions under the biotechnology patent law, to determine the ethical scope within these fields. Chapter 7

[9] ECJ, Case C-377/98, *Netherlands vs. European Parliament*, para 62
[10] Anthony McInerney, E.I.P.R 1998:1:14
[11] Li Westerlund, 2001:9

analyses the usefulness of a moral exclusion article that includes specified guidelines for unpatentability in a fast developing area such as biotechnology, since the analysis in the previous chapters demonstrates the vague and uncertain scope found in the law.

2. The European Patent System and Patentability

The purpose of the patent system is to encourage the development of science and technology, and increased innovation is thought to lead to subsequent economic growth and prosperity.[12]

2.1 Administration

The European Patent Office (EPO) grants European patents for the contracting states[13] to the European Patent Convention (EPC). The EPO was set up by the contracting states to the EPC with the aim of strengthening co-operation between the countries of Europe in the protection of inventions. This was achieved by adopting the EPC which makes it possible to obtain patent protection in several or all of the contracting states by a single patent grant procedure. Also, it establishes standard rules governing the treatment of patents granted by this procedure.[14] Thus a patent granted by the EPO may be registered in any of the states adhering to the Convention, avoiding the multiplication of applications for the inventor.[15]

In September 1999 the Administrative Council of the EPO incorporated the Biotech Directive into European patent law. unclear its practice through Chapter VI in Part II of the EPC Implementing Regulations. The interpretation of these rules by the EPO operates within the legal framework established by the EPC system which is a legal order independent from the EU legal order. Thus the Biotech Directive operates within two distinct and separate legal frameworks without inter-institutional links or procedures to integrate the two legal frameworks. This is due to the fact that the EPO is not subject to control by the EU in respect of its finances or procedures. There is therefore no integrated European judicial system to resolve differences of interpretation between these two systems.[16]

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[12] Peter Drahos, E.I.P.R 1999:9:445
[13] Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Grece, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Netherlands, Poland, Portugal, Romania, Slovania, Slovakia, Spain, Sweden,Switzerland, Turkey, United Kingdom,
[14] www.european-patent-office.org/epo_general.htm, 27/12/06
[15] www.european-patent-office.org/epo_general.htm, 27/12/06
[16] www.nottingham.ac.uk/law/StemCell Project/summary.htm, 20/12/06

Any person may oppose to a patent delivered by the European Patent Office by addressing the EPO directly, or via a national court[17].

2.2 Objectives and limitations

Patent law in general aims to promote technical innovations and the distribution of the products. The inventor recieves exclusive rights to control the commercial exploitation of its invention for some years and in return the inventor discloses detailed description of the invention, making the new knowledge available to all. A discovery thereby enables others to further develop the achieved knowledge. The aim is to define the conditions of a "social contract" between the inventors and society. On one hand inventors are able to be granted financial rewards and thus share profits with industrialist. And on the other hand inventors are obliged to disclose information on useful inventions for the benefit of the public good. This means that the purpose of a patent is to strike a balance between different interests. The patent system aims to keep a balance between the inventors' interests and the interests of society. That is why a fair balance between both interests, meaning that the scope of the claim of the patent must be proportional to the scope of the effectively described applications of the inventions, has an ethical dimension.[18]

A patent provides the patent holder with exclusive commercial rights that protect against exploitation of the invention by others. The patent right is timelimited to twenty years from the date of filling in the application[19] under the EPC. The right is also limited in space and the patent is only valid in the jurisdiction of the patent office by which is granted.

A patent is not a legal title granting the inventor the exclusive right to exploit his or her invention, nor it is a right of ownership. It is a negative right, to exclude others, and thereby a legal title granting its holder the exclusive right to stop others from using or making the invention. If a third party wants to use an invention protected by a patent a licence is normally required from the patent holder. The granting of a patent is neither an authorisation for the use of the invention and this principle is also found in recital 14 of the biotech Directive which states that "*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 or commercial purposes*" Consequently, it is not the patent law's task to replace or render superfluous national, European or international law that may impose restrictions or prohibitions, or which concerns the monitoring of research or the use or commercialisation of its results. In the biotech-

[17] This is a difference to the US, where only third parties whos interest are directly damaged by the patent can oppose it, The European Group of Ethics and New Technology (EGE), Opinion 16, p9
[18] EGE, Opinion 16, p12
[19] Article 63 EPC

nology_field this is especially important from the point of view of requirements of public health safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards.[20] Thus the legislation governing patents cannot replace instruments for monitoring conformity with the rules on ethics commonly accepted by society. Whether or not research, commercial use or marketing is permitted, is dealt with by other kinds of regulations, and is not under the jurisdiction of patent regulation.[21]

A patent application contains a description of the invention and one or more claims. The claim is an essential part of the patent as it defines the scope of the rights given by the patent to the patent holder. Thus the claim defines what a third party may or may not do without a licence from the patent holder and the EPO has stated that whether or not a claimed patent should be excluded from patentability in particular depends on the wording of the claim[22].

One distinguishes Claim on Product and Claim on Processes or Methods. In the biotechnology field a Product Claim may concern a substance (like a chemical composite) or a composition matter (like a cell line). The protection given by such patents include the right to prevent third parties from making, selling, using or importing the product. A process claim concerns the activity exercised upon biological material to affect a process or a method. The protection given by such a patent includes the right to prevent third parties from using the process and using, selling or importing the product obtained by this process. The protection does not cover the same product which has been obtained otherwise. Thus a product claim provides stronger protection for the patent holder and more restrictions in relation to further use and research than a process claim.[23]

2.3 Criteria

A patent, both under EPC and the Biotech Directive has to fulfill the three criteria of *novelty*, *inventive step* and *industrial application*[24]. Thus a patent may be granted only if these requirements are met. Prior knowledge is known as the "*state of the art"* and a novelty requires an advancement of what is considered to be the "*state of the arts*" in its field. Another aspect of novelty is that there must not be publications of the invention before the filling in date of the application. Regarding the inventive step the invention must neither follow logically from what is already known nor be obvious to anyone familiar with the field concerned. The invention must also be applicable in

[20] OJ C 295, 7.10.96, p12
[21] EGE, Opinion 16, p6
[22] T 290/86, *ICI/ Cleaning Plaque*, OJ. EPO 1992, 414, para 3.2
[23] EGE, opinion 16, p 6-7
[24] Article 52(1) EPC

any type of industry, including agriculture.[25] Further the claims contained in the application must describe the invention sufficiently clearly to enable those "ordinary skilled in the art" to practice the invention instructed by the description.[26]

2.4 Discovery

The distinction between discovery and invention in the biotechnological field is complicated by the fact that "*the traditional distinction between discovery (not patentable) and invention (patentable) involves, in the field of biotechnology, a particular ethical dimension*" regarding patenting of inventions involving elements of human origin.[27]

The manipulation of living matter poses significant challenges for patent law because these inventions do not fit as neatly into the classic model, as do those of mechanical nature, since biotechnology products and processes are closely related to phenomena existing in the nature. From a legal point of view, patent law addresses the issue of discovery by drawing a distinction between the non-patentable discovery, of something that already exist independently in the nature, and a patentable invention, which requires a significant element of human intervention.[28] Thus a patent can be granted to materials that already exist in the nature if they are claimed in a different form than its natural existence, as material existing in other than its natural context, for example in purified, isolated or recombinant forms.

The Opposite Division of the EPO has stated that mere finding of something freely occurring in the nature is not an invention[29], since an invention must have technical character, i.e. constitute an industrially applicable technical solution to a technical problem. Thus the concept of invention, contrary to discovery, used in the biotechnology patent law can therefore be given the meaning of a technical solution.[30]

The exclusion of the patenting of discoveries derives from the idea that the patent system is meant to promote the innovation of products and processes rather than abstractions. The purpose of the distinction is to force the discoverer into the field of practical application and workmanship.[31]

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[25] Oliver mills, 2005:7
[26] Article 83 and 84 EPC
[27] The European Group on Ethics in Science and New Technology (EGE), Opinion No 8
[28] Li Westerlund, 2001:47
[29] V 8/94, Relaxin, para 5.4, OJ EPO 6/1995
[30] Li Westerlund, 2001:49
[31] ibid

2.5 Exclusions and Exceptions

There are also exclusions and exemptions from patentability in Europe[32]. Diagnostic, therapeutic and surgical methods are excluded from patenting to obtain the sharing of medical knowledge and know-how for the benefits of patients.[33] Also, there is recurrent traditional academic exemption in Europe that allows further research without paying a licence to the inventor if the research is not commercial. There is also often a compulsory licence that may be granted if the patent protection is contrary to the common good.[34]

The most important exclusions, regarding the content of this paper, are patents excluded if their publication or exploitation is in conflict with "ordre public" or morality. The concept refers mainly to the respect of human dignity, which is at the roots of human rights, and is mentioned in Article 1 of the Charter of Fundamental Rights. The EPC refers to "ordre public" and morality in Article 53(a) and the Biotech Directive in Article 6. The Biotech Directive has also specified some exclusions in Article 6(2) to provide national courts and patent offices with a general guide to interpreting the reference to "ordre public" and morality, even though they cannot be presumed as exhaustive[35]. This list of moral exclusions contained in Article 6 of the Biotech Directive has also been transposed into Rules 23(d)*a-d* of the EPC.

[32] Article 52(2)-(4), Article 53 EPC, and Article 5 and 6 Biotech Directive
[33] This does not concern products or drugs used for medical purposes
[34] EGE, Opinion 16, p8
[35] Recital 38 in 98/44/EC

3. The origin of the European biotechnology patent legislation and the ethical debate within the European patent law

When the European patent law was introduced thirty years ago it was impossible to discern the scope of biotechnological research and even less foresee the range of possible applications and the various ethical and other problems that might arise[36].

3.1 Purpose

The European Commission saw a need to adopt and harmonise patent law to biological innovations in order to stimulate the industrial development and investments within the European Union.[37] The European Commission's White Paper from 1985 stated that differences in intellectual property laws among Member States had a direct and negative impact on the intra-Community trade.[38] Thus, the original purpose of the 1998 EU Biotechnology Directive was to establish legal certainty in the biotechnology inventions area within the European Community and to help European biotechnology companies to become more efficient in promoting innovation and attracting investment. In addition, the Biotech Directive took into account ethical considerations.

3.2 The ethical debate in the creation of the Biotech Directive

The first European Commission proposal of 1988, which was essentially technical and legal in nature, was the first text ever rejected by the Parliament under the conciliation procedure in 1995. This was basically because of different interpretations of ethical problems, in particularly the questions of the patentability of parts of the human body and the genetic manipulation of the human body.[39] Biotechnology raises moral questions particularly because it affects living matter and it is therefore explic-

[36] OJ C 295, 7.10. 1996, page 11
[37] COM/97/446, Rec. 1 and 3
[38] COM/93/700, final
[39] OJ C 295, 7.10. 1996, page 12

itly said in the motivation in the Preparatory Acts[40] to the Biotechnology Directive that it is necessary to, in a suitable way, implement the ethical dimension into the Directive. There were four main areas in the first draft that were complained about and to which the Commission had to improve; a clearer distinction between invention and discovery, exclusions from patentability of the human body and the parts thereof in their natural state, exclusion from patentability of germ line gene therapy on humans out of respect of human dignity and extension of farmer's privilege on the livestock breeder.[41]

However, the biotechnology had an overall positive comprehension because progresses in biotechnology was said to increase yields and develop crops resistant to unfavourable climatic conditions, which may be important in third-world countries, and to be one of the most innovative and promising technologies in the medical and veterinary field.[42].

The Economical and Social Committee therefore proposed that the article considering the patentability exclusions in the Biotech Directive should be based on Article 27(1) of the TRIPs[43] agreement which states that "*a patent can be obtained for any invention, product of process in any biotechnological area, provided that its new, implies an inventive activity and is capable of being applied in industry*", before it in Article 27(2) states the exclusions from this right. On the other hand, the fact that Article 6 of the Biotech Directive lacks such a reference can be seen as an indication of a larger importance to the exclusions from patentability in the Biotech Directive than in the TRIPs agreement since the permission to the patentability of biological matter is found in recital 15 of the Biotech Directive. This is further stated by the different formulations of the exclusion from patentability. According to Article 27(2) TRIPs the Members "*may* exclude from patentability inventions commercial exploitation which is necessary to protect "ordre public" or morality". Yet, in Article 6 in the Biotech Directive an invention "*shall* be considered unpatentable where their commercial exploitation would be contrary to "ordre public" or morality".

The way and scope in which Article 27(2) is implemented to provide limits on patentability is thereby left to each Member State to decide as a mediation from the widespread disagreement on the issue of patentability exceptions under the TRIPs agreement.[44] Thus the fact that the Biotech Directive diverges from the international standard of intellectual property rights could demonstrate the importance given to the moral issues within the biotechnology field. Yet, Article 27(2) of the TRIPs agreement did influence the Biotech Directive and that is why Article 6 refers only to *exploitation* and not *publication*[45], compared to Article 53(a) EPC. The emphasis is clearly on the commercial exploitation of the invention to make clear that "ordre

[40] COM/97/446
[41] OJ C 295, 7.10.96, p12
[42] OJ C 295, 7.10.96, para 1.2.2 and 3.1.2.1
[43] TRIPs – Trade Related Aspects of Intellectual Property Rights
[44] Richard Ford, E.I.P.R 1997:6:315
[45] COM/97/446 final, comments to article 6

public" and morality are to be judged considering the use for an industrial application of the invention and to limit morality to commercial situations.

The changes made in the wording between the Commission's second proposal and the final recital 39 of the Biotech Directive additionally strengthened the ethical importance since the final version states that:

"*ordre public" and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this fields and their relationship to living matter. Such ethical or moral principles shall supplement the standard legal examination under patent law regardless of the technical field of invention.* And thereby excludes the sentence "*these considerations do not, however, change the nature of patent law as a primarily technical body of law*".[46]

This can be seen as a sign of the importance given to the moral questions in the Biotech Directive. The recital only points out ethical and moral principles, which are important to consider, in the Directive and makes no references to the technical body of law. It could also be argued that this should only be seen as a way to make the recital clearer, but since the rest of the text corresponds with the proposal it can be seen as a justification for the first argument.

Furthermore, Article 7 of the Biotech Directive refers all ethical evaluation to the Commission's European Group on Ethics in Science and New Technology. The group can also be consulted when biotechnology is to be evaluated at the level of basic ethical principles on patent law.

3.3 Relation between the Biotech Directive and the EPC

During the legislation process the Parliament held that ethical questions had to be confronted with great attention but that this could not be used as pretext for inaction. This was due to the fact that the EPC was not considered suitable to this new technique; neither concerning the technical nor ethical problems emerged within the field.[47]

Ethical questions had not been a concern to the European patent law before the biotechnology technique emerged and the classic example of an innovation that is to be considered as immoral is that of a letter bomb. This dates back to the implementation of the EPC. Since the patent field was not related with ethical problems the predominant view according to historical document relating to the EPC was that "*the concept*

[46] OJ C 296, 8.10.96, p 6
[47] 98/44/EC, Rec. 4

of patentability in the European patent law must be as wide as possible[48]". As a result, the exceptions to patentability have been narrowly construed.

This is also revealed in the EPC Substantive Examination guidelines to Article 53(a)[49] where the EPO indicated a narrow approach, affirming that this article probably would be invoked only in rare cases were it is clear that the public in general would find the invention "*so abhorrent that the grant of patent right would be inconceivable*". If it is clear that this is the case, objection should be raised under Article 53(a), otherwise not.

To better handle this new technology the Administrative Council of the EPO inserted a new Chapter VI entitled "Biotechnological inventions" in Part II of the EPC Implementing Regulations in September 1999, and thereby implemented the requirements of the Biotech Directive in European patent law. The EPO was not subject to a formal obligation of implementation of its legislation, but brought it into line with the Biotech Directive primarily in order to comply with the requirement for uniformity in harmonised European patent law.[50]

The ECJ stated in the *Netherlands* case that it is necessary to leave it up to Member States to assess whether a biotechnology invention can be considered valid in the terms of the ethical, sociological, or philosophical context of each country. It is therefore within the discretion of each Member State to deem whether the use of certain patents may be contrary to ordre public.[51] However, since EPO has implemented it, the Biotech Directive makes moral judgement concerning biotechnology patents a question to the EPO boards as well.

3.4 Implementation difficulties

Due to the moral controversies generated by the "patent on life" debate across Europe, the national implementation of the Biotech Directive became a delayed process in many countries. Even though Article 15 of this directive required the Member States to implement it in 2000, only seven Member States had done so in year 2003. Consequently, infraction proceedings were brought against several Member States[52]

[48] Document IV/2071/61-E, page 5, point 2
[49] EPO guidelines C-IV 3.1
[50] Information from the European Patent Office concerning the amendement of the Implementing Regulation to the European Patent Convention, 1 July 1999, See OJ EPO 1999, 437.
[51] ibid, para 38
[52] France, Belgium, Luxembourg, Germany, Austria and Italy

for non implementation.[53] However, today all member states have finally implemented the Biotech Directive in their national laws.[54]

This controversy was also demonstrated by the fact that the Netherlands shortly after the resolution prosecuted the validity of the directive of moral grounds in the ECJ. The Biotech Directive was judged valid and the court also stated that it sufficiently ensures that the human dignity was safeguarded.[55]

[53] Stem Cell Patents: European Patent Law and Ethics Report, p. 23-24, www.nottingham.ac.uk/law/StemCellProject/project.report.pdf, 20/12/06
[54] European Commission State of Play of the Implementation of Directive 98/44/EC, http://ec.europa.eu/internal_market/indrop/docs/invent/state-of-play_en.pdf, 03/01/07
[55] ECJ, C-377/98, *Netherlands vs. European Parliament*, para 77

4. Biotechnology patents and human moral exclusions

Biotechnology raises ethical issues because the use of living matter and different questions and problems arise within different biotechnology fields. Do human, animals and plants need the same moral protection or are there different scopes of morality and "ordre public" exclusions among these subjects? What do the laws and cases tell us? I will try to answer these questions by examining each field separately.

4.1 Law

It was essentially problems relating to patentability of the human body that rose controversy in the initial draft of the Biotech Directive. The initial draft had used the words "*exclusion of the human body as such*". This caused misunderstandings of whether or not a gene or a microorganism could be patented in their own right.[56] Since this was the article that concerned the most controversial point of the previous Directive the Commission changed the article to "*the human body and its elements in their natural state shall not be considered patentable inventions*[57]". Nevertheless, also this text had to be transformed since the Economic and Social Committee argued that this wording did not remove all uncertainties.[58] The text, finally implemented, in the Biotech Directive in Article 5(1) was "*the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions*". The revised version was also criticised for not excluding human embryo from patentability, specifically since the wording "*human body*" could be interpreted as not including the embryo.

The exclusions to "*processes for cloning human beings*", "*processes for modifying the germ line genetic identity of human beings*" and "*uses of human embryos for industrial or commercial purposes*" are in the Biotech Directive law under Article 6(2)*a-c* excluded as contrary to "ordre public" or morality. Thus these inventions shall be seen as so abhorrent to the public in general that the grant of patent right would be inconceivable.

The recitals to the Biotech Directive clarify the exclusions under article 6(2) by explaining a process for cloning human beings to be defined "*as any process, including techniques of embryo splitting, designed to create a human being with the same nu-*

[56] OJ C 295, 7.10.96, p12
[57] OJ C 296, 8.10.96, p7
[58] OJ C 295, 7.10.96, p14

clear genetic information as another living or deceased human being"[59] and "*processes to produce chimeras from germ cells or totipotent cells of humans and animals*"[60]. Moreover, the use of human embryos for industrial or commercial purposes must be excluded from patentability in any case when such exclusion does not affect inventions for therapeutic or diagnostic purposes that are applied to the human embryo and are useful to it. [61]

Recital 16 of the Biotech Directive affirms that the patent law must be applied in order to respect the fundamental principles safeguarding the dignity and integrity of the person. It is therefore important to assert the principle that the simple discovery of a part of the human body cannot be patented since a mere discovery cannot be patented. However, genes that have been isolated and purified can no longer be said to exist in nature since they are the result from a process and may therefore be regarded as inventions and not discoveries, even if the structure of that element is identical to that of a natural element. Article 5 of the Biotech Directive thus makes clear that an invention based on an element isolated from the human body or produced by means of a technical process susceptible to industrial application, is not excluded from patentability since it is the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body[62].

If an invention is based on biological material of human origin or if it uses such material, 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[63]. This recital was more detailed in the proposition from the Parliament since it demanded name, address and proof of approval from the person in the patent application. This was regarded as contrary to the European protection of personal integrity[64] and was therefore rejected. Recital 26 attempts to embed the general principle of free and informed consent of the donor of body material as is proclaimed in Article 22 of the Convention on Human Rights and Biomedicine[65], in the context of biotechnology patenting.

The EPC has implemented the exclusions under Article 6(2)*a-c* of the Biotech Directive under Rule 23(d)*a-c*. The only difference between the two texts is that the EPC has implemented the recitals texts, which explain a process for cloning[66] and adds that therapeutic or diagnostic purposes in the use of human embryos are accepted[67] in the paragraphs. This could be explained either by the fact that the Guidelines for Exami-

[59] 98/44/EC Rec.41
[60] 98/44/EC Rec. 38
[61] 98/44/EC, Rec. 42
[62] 98/44/EC Rec. 20
[63] 98/44/EC, Rec. 26
[64] 95/46/EC, OJ L 281, 23.11.95
[65] Convention on Human Rights and Biomedicine, 1997
[66] recital 41 of the Biotech Directive
[67] recital 42 of the Biotech Directive

nation in the EPO are much more diminutive than the Directive since it has not implemented all recitals, or that the EPO wants to define the limit of these exclusions.

4.2 Case law

4.2.1 The Relaxin case

The first case related to moral exclusions in the human biotechnology field was judged under the EPC before the Biotech Directive was implemented. Therefore the questions were considered without any special biotechnology text references.

The *Relaxin* case[68] considers a patent claim for a DNA fragment encoding a human protein from human tissues taken from a pregnant woman. The patent was opposed on the grounds that the subject-matter of the patent was not patentable and that it offended against "ordre public" or morality under Article 53(a) EPC.

The argument that the subject-matter was not patentable due to lack of novelty and inventive step can also be seen as ethical considerations against the patent. The opponents contested the patent because the gene encoding relaxing was always present in the female body and therefore should not be seen as an invention, but rather discovery. The opponents requests were denied since the EPO established that the proprietor had developed a process for obtaining the relaxin and the DNA encoding it, and had thereby isolated and applied the gene for industrial use.

Theopponents argued that the isolation of the DNA relaxin gene from tissue taken from a pregnant woman was immoral since it constitutes an offence against human dignity to make use of a particular female condition, such as pregnancy, for a technical process oriented towards profit. They further found that the patenting on human genes violated the human right to self-determination and could be seen as a form of modern slavery since it involved the dismemberment of women and their piecemeal being sold to commercial enterprises. Finally they argued that it was intrinsically immoral to patent human genes since this meant that human life was being patented.

The Opposition Division established that Article 53(a) is to be invoked only in rare and extreme cases for inventions which universally would be regarded as outrageous and they referred to Guidelines C-IV 3.1 to test whether or not it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. [69] They further stated that Article 53(a) constitutes an exception to the general principle and that the boards of appeal repeatedly have found

[68] V8/94 Relaxin, OJ EPO 6/1995
[69] V 8/94 Relaxin, para 6.2.1

that such exceptions are to be narrowly construed[70]. The Opposition Division confirmed that a patenting of the DNA would be abhorrent to the overwhelming majority of the public if it were true that the invention involved patenting of human life, an abuse of pregnant women, a return to slavery and the piecemeal sale of women to industry. However, they rejected this argument since the woman who donated the tissue consented to do so within the framework of gynaecological operations, and since other human tissue or materials such as blood or bones have been isolated and patented. The Opposition Division added that these practices are perfectly acceptable to, and even welcomed by, the vast majority of the public.[71] Subsequently they settled that the assertions concerning slavery and the dismemberment of women to be a fundamental misunderstanding of the effects of the patent since no woman was affected by the present patent, but that it only confers its proprietor the right to exclude third parties from commercially using the patent invention.[72]

The Opposition Division further said that the allegation that human life had been patented was unfounded since DNA is not life but a chemical substance carrying genetic information.[73] The Opposition Division finally regarded the broad argument of the immorality of patents on human genes in general. They argued that it could not be said that a majority of the European states were against gene patenting since there was an uncertainty and disagreement within the European Union's institutions and Member States. The EPO further refused to carry out a referendum to find out the concerns of the public since the burden of proof lies on the opponent in opposition proceedings and because there is not a condition in the EPC that only those inventions actively approved by the public should be patented.[74] The Opposition Division also pointed out that views expressed by the public in referendum tend to depend upon how the question is being asked.[75]

Finally, the patent was granted since the Opposition Division found that the invention did not offend widely-accepted moral standards of behaviour, nor that there was a clear consensus amongst member of the public in the contracting states that patenting human genes was immoral.[76]

4.2.2 The Edinburgh case

This case[77] refers both to the EPC and the Biotech Directive, through Rule 23(d)*c*. The University of Edinburgh was granted a patent for laboratory methods that could

[70] ibid. Para 6.2.2, The Opposition Division refer to T 19/90 and T 320/87
[71] ibid, para 6.3.1
[72] ibid, para 6.3.3
[73] ibid, para 6.3.4
[74] ibid. Para 6.5
[75] ibid. Para 6.4.4
[76] ibid. Para 6.6
[77] European patent No. EP 0695351, with the title "*Isolation, selection and propagation of animal transgenic stem cells*"

be used to isolate embryonic stem cells from more differentiated cells in a cell culture in order to obtain pure stem cell cultures.[78] The patent claims were technically exemplified with mouse embryonic stem cells, but the patent application used the expression *animal* in the application, which can refer to humans, and the patent holder was therefore granted the right to make, use, and sell human beings created in its laboratory, even though this was not the intention of neither the University of Edinburgh nor the EPO.

The patent was opposed by the governments of Italy, Germany, Netherlands, Greenpeace and the European Parliament for being contrary to "ordre public" and morality according to Article 53(a) EPC and not in compliance with Rule 23(d)*c* of the Implementing Regulations for the Biotech Directive. Therefore, the aforementioned claims were held insufficient as far as embryonic stem cells were concerned. However the Opposition Division decided to maintain the patent with modified claims, including stem cells per se, having denied embryonic stem cells.[79]

The Opposition Division subsequently considered whether the claim would have contravened Rule 23(d)*c*[80] in the absence of a disclaim. The Opposition Division questioned whether Rule 23(d)*c* must be interpreted in a narrow or broad fashion to be substantial . That is, whether the intention of the legislator was to ban the patenting of uses of embryos as such (the narrow interpretation), or to ban the patenting of uses of human embryos together with the stem cells being retrieved therefrom by destruction of the embryos (the broad interpretation). The conclusion was that only a broad interpretation of Rule 23(d)*c* could have been intended.[81] Thus the intention was judged to be to prevent patents of human embryos, not only on industrial and commercial uses, but also regarding patents on human embryonic stem cells retrieved therefrom by destruction of human embryos, regardless of whether the application reveal direct use of the human embryo or not.

The Opposition Division decided to list which kinds of stem cell that would fall within the acceptable claims of the patent. This list includes pluripotent and mulipotent stem cells isolated from adults and cells isolated from foetal tissues obtained after pregnancy termination.[82]

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[78] Emil Ekström, 2004:89
[79] EPO Press release, Munich 24 July 2002
[80] which prohibits the patenting of uses of human embryos for industrial and commercial purposes, equivalent to Article 6(2)c of the Biotech Directive
[81] Interloctury decision of Opposite Division dated 21 July 2003 concerning European patent 0695351, p22
[82] R. Stephen Crespi, E.I.P.R 2006:11:572

4.2.3 The *WARF* case

The decision of the Opposition Division in the Edinburgh case was followed in the Wisconsin Embryonic Stem Cells (WARF) case[83]. This claim was directed to a culture of cells with a list of desired characteristics. The claim was silent as to the derivation of the cells and there was no process claim to the methods used to achieve this. This case also involved the question of the scope of Rule 23(d)*c*, as in the Edinburgh patent.

In relation to the issue of patentability under Rule 23(d)*c* in conjunction with Article 53(a) EPC, it has been determined that a two step examination has to be performed. The first test is whether the wording of the relevant individual subsection is suitable to Rule23(d), and secondly a so-called "real" Article 53(a) test that must be applied if the invention under examination survives the first test.[84] The outcome of the Rule 23(d) test may therefore be either additional or alternative to an objection under Article 53(a) EPC itself, as developed by the case law.

The Technical Board also noted that there were no unified moral standards in Europe on human embryonic stem cells[85]. The correct approach in this respect was therefore to undertake the balancing test[86], i.e. to make a careful weighting of the moral objections on the one hand, and the invention's usefulness to mankind on the other.[87]

The Technical Board remitted the question on the value of the word "use" in Rule 23(d)*c* EPC to the Enlarged Board, since it could lead to the conclusion that only claims which directly claim use of human embryos for industrial or commercial purposes fall under the exclusion. The Board also questioned whether Rule 23(d)*c* EPC forbids patent claims directed to products (here human embryonic stem cell cultures) that can be prepared exclusively by a method which necessarily involves the destruction of the human embryos from which this product derived, if the said method is not part of the claim.[88] The Enlarged Board of Appeal has not yet given its judgement.

4.2.4 The Netherlands case

In the *Netherlands*[89] case, the Netherlands questioned the validity of the Biotech Directive and the case was judged by the ECJ. The Netherlands argued that the patentability of isolated parts of the human body provided for by Article 5(2) of the

[83] T 1374/04 – 3.3.08, WARF
[84] ibid, p5, para x
[85] ibid, p10, para x
[86] The balancing test was settled in the Onco-Mouse decision, T 19/90, OJ EPO 1990, 476
[87] T 1374/04 WARF, p12
[88] T 1374/04 WARF, para 36
[89] ECJ, Case C-377/98, 9 Oct 2001

Biotech Directive, reduces living matter to a means to an end and thereby undermines human dignity.

The Court settled that the respect of human dignity was provided for in Article 5(1) of the Biotech Directive, which provides that the human body at the various stages of its formation and development cannot constitute a patentable invention[90]. It also states that the elements of the human body are not patentable in themselves and their discovery cannot be the subject of protection under the patent law.[91] Additional security is offered in Article 6 of the Biotech Directive[92] and the Court therefore found that the Biotech Directive frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and human dignity thus safeguarded.[93]

4.3 Reflections

The exclusions referred to in Article 6(2)*a-c* of the Biotech Directive can be understood as an indication for the importance given to these exclusions out of respect for human dignity, since these concerns were the main reason to the rejection of the initial document. However, it can also be seen as a sign of a rather narrowly constructed exclusion to patentability regarding "ordre public" or morality since these paragraphs are located under Article 6(2) and not under Article 5 of the Biotech Directive. Eventhough the exclusions mentioned in Article 6(2) cannot be seen as exhaustive,[94] it exemplifies that an objection under Article 6 has to be of the same importance to be excluded from patentability. In other words, an invention has to be at a potential threat of a rejection of the Directive by the European Parliament to be excluded.

In the *Relaxin* case the Opposition Division failed to make clear how it could be measured that an invention is an abhorrence. The test was only applied in a negative way, stating that the invention was not abhorrent. Article 6(2) *a-c* can be seen as a guideline to abhorrence. But since the recital 38 states that this list is not exhaustive it indicates that there could be other exclusions concerning issues related to the human body inventions. This makes the case law quite unclear.

Furthermore I don't find it to be an adequate argument against surveys that:

[90] ibid, point 71
[91] ibid, point 72
[92] ibid, point 76
[93] ibid, point 77
[94] 98/44/EC, Rec.38

"there is no provision in the EPC that only those inventions actively approved by the public should be patented…(since) it is arguable that numbers of patents granted… may well be objectionable to parts of the public[95]".

Since the EPO earlier has stated that it is only in limited cases in which there appears to be an overwhelming consensus that the invention is immoral, that it should be excluded from patentability. Whether or not there are objections from *parts* of the public is therefore irrelevant. Furthermore, an "*active disagreement*" against a patent claim is different to "*active approval*". So even if it is not a patent condition that an invention is actively approved, an active disagreement could be an obstacle since the question is how to establish the "widely-accepted moral standards of behaviour" requested.

The Biotech Directive can be consider to have enlightened the field significantly considering the exclusions under the human biotechnology field. Article 6(2)*a-c* states human related inventions which must be excluded from patentability because of ethical considerations. That this field is quite descriptive is not surprising since these questions were the most important when creating the Biotech Directive.

However, even if the field is clearer under the Biotech Directive there is still some moral uncertainty concerning the human moral exclusion scope. This concerns the question of gene sequences, stem cells and the exclusion found in Article 6(2)*a-c*.

Regarding gene sequences, the Commission decided in 2005 not to take a position on the validity of transposition according to the choice between classic and limited scope of protection for gene sequences. The informal Group of Experts argued that there were no objective reasons to create a specific regime of purpose-bound protection in this field other than the classic protection. In particular legal and technical experts felt there were no differences between DNA sequences and chemical substances which would justify different treatment as regards to the scope of patent protection.[96] However, the question was raised by the fact that the human gene sequences have been isolated from the human body, which implies that they should be given different treatment to chemical substances on ethical grounds. This is also behind the transposition of the Biotech Directive in French national law where purpose-bound protection is provided for inventions concerning material isolated from the human body.[97]

Another argument which was discussed regarding the scope of protection for gene sequences was the economic question of whether it is more valuable to society to allow the first inventor a broad scope of protection, so that others building on this invention have to seek a licence, or if a patent on a gene sequence should be limited in scope to allow future uses of such sequences to be patented freely. This question

[95] V 8/94 Relaxin, para 6.5
[96] COM/2005/312, final, para 2.2
[97] COM/2005/312, final, para 2.1

was linked to the freedom of research, even though certain research exemptions already exist in patent law.[98]

Additionally, the exclusions found in Article 6(2) of the Biotech Directive and Rule 23(d) have raised questions regarding the scope of the moral protection vis-à-vis how broadly or narrowly the protection shall be estimated and how useful these specifications are. The question has also been raised whether the Biotech Directive specifically addressed the patentability of stem cells I will therefore consider these exclusions more carefully below.

4.3.1 Stem cells

The patenting of inventions involving human stem cells raises specific questions related to fundamental ethical principles since it is prohibited to make profit from the human body and its elements according to the charter of Fundamental Rights which is based on the principle of non-commercialisation of the human body.[99]

A stem cell has the potential to give rise to all or most of the many different cell types that make an organism, whereas other cells have a limited development pathway and can only "differentiate" into certain predetermined cell types with predetermined functions.[100] Furthermore, three different types of stem cells can be distinguished according to the source from which they are retrieved. Thus, there are Adult stem cells, Stem cells of foetal origin and Stem cells of embryonic origin.[101]

A distinction can be drawn between totipotent stem cells, which are capable of developing into a human being, and pluripotent stem cells, which are not capable of this.[102] In the light of the Commission's analysis in its report from 2005[103] it appears that totipotent stem cells should not be patentable on grounds of human dignity. The conditions of the Biotech Directive are clear in relation to totipotent stem cells, since each cell could develop into a human being on its own and thereby would be banned under Article 5(1).

The European Group on Ethics considered that there was no ethical reason for a complete ban on patenting of inventions relating to stem cells or stem cell lines. But the Group argued that the rapid development of biotechnology in the stem cell area made it appropriate to consider and clarify some questions which could not have been taken into account in 1998 when the Biotech Directive was drafted.

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[98] COM/2005/312, final, para 2.1
[99] European Group on Ethics in Science and New Technologies (EGE), Opinion 16, 7 May 2002, p12-13
[100] http://stemcells.nih.gov/info/basics/, 20/12/06
[101] EGE, Opinion 16, p4
[102] COM/2005/312, final, para 2.2
[103] COM/2005/312, final

The Group mentioned that one option would have been to forbid patenting of stem cells or stem cell lines, but argued that this would be contrary to public interest (especially patients) and to the EU choices as expressed by the Biotech Directive. They further stated that there was a basic ethical dilemma due to the fact that patents can both encourage scientific progresses and damage access to health care because of the need of a licence.[104] The Group on Ethics therefore found it is necessary to secure the right balance between the inventors interest and the society's interest in the sense that one task for the community is to secure ethical principles and values in the context of conflicts between stake-holders such as patients and patients association, inventors and researchers, donors, industry, investors, healthcare providers and social insurance providers.[105] Therefore, they found no ethical obstacles to patenting of processes involving human stem cells if they fulfilled the requirements of patentability but added that only stem cell lines which have been modified so that they acquire characteristics for special industrial application can be granted a patent.

On the contrary, stem cell lines which have not been modified cannot be patented since the industrial application is not fulfilled and since such isolated cells are so close to the human body that their patenting may be considered as a form of commercialisation of the human body. Neither do they consider unmodified cell lines as patentable product since they have a very large range of potential undescribed use and such a patent would therefore be too broad[106].

However it is important to remember that these human stem cells shall not be taken from embryonic stem cells since processes which would lead to use of human embryos for industrial or commercial purposes are excluded as contrary to "ordre public" or morality in the Biotech Directive. This principle is also in line with the principle of non commercialisation of the human body. Nevertheless, the Group of Ethics considered it to be ethically acceptable to grant patents for inventions which allow the transformation of unmodified stem cells from human embryonic origin into genetically modified stem cell lines, or specific differentiated stem cell lines, for specific therapeutic or other use to be ethically acceptable[107].

Furthermore it is interesting to note that the European Group on Ethics mentions that there is a risk that women may be submitted to excessive pressure to donate since the process requires the use of human oocytes to produce stem cells and that this raises a question about the patentability of these processes.[108] It can be seen as contradictory to the Relaxin case law where the EPO settled that there could be no ethical concerns related to the women used in the procedure.

[104] EGE, Opinion 16, p14
[105] EGE, Opinion 16, p15
[106] EGE, Opinion 16, p15
[107] EGE, Opinion 16, p16
[108] EGE, Opinion 16, p13

4.3.2 Unpatentable inventions under Article 6(2)*a* and Rule 23(d)*a*: Cloning

There are three different types of cloning procedures, namely Human Adult DNA cloning, Therapeutic cloning (to create human organs), and Embryo cloning of Humans (artificial twinning).[109] A process for cloning human beings is defined in recital 41 of the Biotech Directive defined as "*any process, including techniques of embryo splitting, designed to create human being with the same nuclear genetic information as another living or deceases human being*".

It could be argued that this wording suggests that the exclusion is confined to processes for human reproductive cloning. If the wording should be regarded as broader, and also included exclusions for therapeutic cloning, one would have to treat the term *human embryo* and *human being* equivalent, and according to the European jurisprudence within the ECHR there is not such a consensus across Europe.[110] However, the European Group on Ethics argues that the Biotech Directive does not bring clarification to the specific question of applying the prohibition of patenting only to reproductive cloning or also to cloning for stem cells and that there is a diversity of approaches between member states cloning for stem cells and the analyse of the exclusion scope is therefore unclear. [111]

There is a widespread international understanding that it is ethically wrong to clone a human being. There are religious, philosophical or social objections. Nevertheless some interesting questions can be raised concerning the possibility for lesbian couples or for couples, where the man is sterile, to use adult DNA cloning to produce a child. An ovum from a woman would be coupled with a cell from the other's body and thereby they would both contribute to the child. Even though the technique is not yet there (since the child cells would have the same age as the donor and subsequently a reduced life) the fact that abortions and in vitro fertilisation (IVF) technology, which was controversially and unethical in the beginning now is accepted could show that the concerns can change over time. [112] One can also consider if there is a point in having explicit exclusions to "ordre public" and morality since these concerns may change over time and thereby force changes in the Biotech Directive. Thus, one could imagine that this would make Europe lag behind in the development of these procedures since there would be no economical benefits to the inventor.[113] However, it could be stressed that none of these applications meet the criterion of industrial application, which prohibits the patentability of a method of treatment of the human body by surgery or therapy or of diagnostic practised on the human body.[114]

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[109] Belle Kingsley Etame, 2004:72
[110] www.nottingham.ac.uk/law/StemCellProject/project.report.pdf, p55, 20/12/06
[111] EGE, Opinion 16, p17
[112] Belle Kingsley Etame, 2004:78-79
[113] even though the importance of the patent for the development of this field is discussed
[114] Article 52(4) EPC

Additionally, since the patent office does not regulate the use of the technology, but only the exclusions for third parties to exploit an invention, this exclusion from patentability could make the technique allowed but not a patent and cloning procedures would be common heritage.

The fact that the European countries find it important to state the exclusion from patentability for inventions concerning human cloning procedures may be a result of the genocide in the Second World War, as well as the spectre of eugenics[115] and social control through manipulation of human genes that is made possible through genetic and reproductive technologies. This approach is also reiterated in a case[116] regarding synthetic antigens for the detection of AIDS-related diseases from 2004 where the Enlarged Board states that practical examples under Article 53(a) arise from the fact that not everything can be done to human being which can be done to other living beings. For example, the avoidance of unwanted offspring due to certain properties (such as sex or colour) or for economical reasons, may be legitimate for domestic animals whereas when applied to human beings it would be contrary to "ordre public" or morality. The Board thereafter added that this might give rise to the need of a specification to "non-humans" in the patent application to further clarify the patent claim.

4.3.3 Unpatentable inventions under Article 6(2)*b* and Rule 23(d)*b*: modifying germ lines

Recital 38 affirms that processes or use which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals are excluded from patentability.

Somatic cell gene therapy attempts to affect the somatic cells of a patient, to cure or prevent a number of genetic as well as acquired diseases, in such a way that the genetic alteration will exist only in the cells of that person and not to be passed on to descendants. As long as the gene therapy involves only the treatment of somatic cells, which cannot cause genetic alterations which would be passed on, the method is ethically acceptable and Article 6(2)*b* will not come into question. Germ line gene therapy on the other hand will transmit changes. The technique is performed on the patients reproductive cells (germ cells) and the genetic alternation will exist in all cells of the organism and would be passed on to each of the offspring of the treated patient. The fundamental ethical aspects raised are linked to the respect of human dignity and the dividing line between therapy proper and eugenics and is at the present state therefore not acceptable. [117]

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[115] Eugenics means the science of producing healthy and intelligent children with the aim of improving the general characteristics of the human race

[116] G 2/03 *Genetic System Corporation*, para 2.4.1

[117] EGE, Opinion 4, para 1.7

It has been argued that it is regrettable that processes for modifying the germ-line identity of human beings are excluded from patentability since there are a number of diseases, which are inheritable and perhaps one day could be cured by germ-line therapy. One can therefore reason that it is conservative and short-sighted to exclude a process which might have such a substantial benefit to mankind from patentability.[118]

4.3.4 Unpatentable inventions under Article 6(2)*c* and Rule 23(d)*c*: Human embryos

Procedures involving directly or indirectly the human embryo are controversial in the sense that they are based on presupposition of the beginning of human life and the question if there should be an absolute or relative protection of human life in its different stages.[119]

However, the most promising research on stem cells has centred upon embryonic stem cells, which researchers believe may be used to treat diseases like cancer, Alzheimer's diseases, diabetes, HIV, Parkinson's and heart diseases.[120] Human embryonic stem cells are of particular interest because they have the potential to differentiate into all cell types of the body and are at present the only pluripotent stem cell that can be readily isolated and in culture grown in sufficient numbers to be useful.[121]

As seen above totipotent stem cells should not be patentable according to the Commission[122]. However for the pluripotent embryonic stem cells the situation is more complex and there was no immediate answer to the question of the patentability of these embryonic pluripotent stem cells. Since the fact that the Biotech Directive provides for Member States to refuse patents on grounds of "ordre public" or morality under Article 6(1) made the Commission decide that it was premature to give further definition or provide for further harmonisation in this area.[123]

The rejection of the Edinburgh patent on pluripotent embryonic stem cells was regarded to the wording in the patent application but a division has emerged between the EPO and the policy and practice of some national patent offices in Europe. This interpretation of Article 6(2)*c* has led to exclusions from patentability to totipotent human embryonic stem cells only and processes to obtain cells from human embryos, but allows patent on pluripotent human embryonic stem cells and other processes.[124]

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[118] Robin Nott, E.I.P.R 1998:9:349
[119] EGE, Opinion 16, p13
[120] EGE, Opinion 15
[121] COM/2005/312, final, para 2.2
[122] COM/2005/312, final
[123] COM/2005/312, final, para 2.2
[124] Practice Note from the UK patent office, Stem Cell Patents: European Patent Law and Ethic Report, 2006:12, www.nottingham.ac.uk/law/StemCellProject/project.report.pdf, 20/12/06

Other national patent offices (e.g. Sweden[125]) which lack a formal policy have adopted a practice of granting patents on pluripotent human embryonic stem cells.

These different approaches have, regarding a research on patent applications, made the applicants even more unsure about the scope of the exclusion under Article 6(2)*c* and the result is that they seek to protect their claim by trying different wording strategies.[126]

This demonstrates that there is a legal uncertainty regarding the scope of the moral exclusions of use of human embryos under Article 6(2)*c*. Thus the national patent offices, which have granted patents involving use of pluripotent human embryonic stem cells, assume that Article 6(2)*c* shall be narrowly constructed, giving considerable weight to the qualification expressed in the article stating that only *industrial* and *commercial* use are forbidden. The EPO has made a different interpretation of this article (through rule 23(d)*c* and has so far taken the view that the exclusion should be broadly constructed and thereby bar not only totipotent human embryonic stem cell but also pluripotent human embryonic stem cells. The reason given for such a wide interpretation is that Article 6(2) of the biotech Directive, if interpreted narrowly, will be unnecessary with Article 5(1) of the Biotech Directive.[127]

This view has been criticised on the grounds that the Recital 39[128] in the Biotech directive indicates that moral standards are to *correspond* to ethical and moral principles recognised in a Member State and that this wording indicates that the patent offices were not intended to become separate moral institutions under the Biotech Directive. But that it has to draw the applicable moral principles and norms from the moral principles recognised and reflected in the national laws, regulations and constitutional traditions of Member States, and to supplement their examinations according to these. This could be interpreted as it is doubtful whether national patent offices or the EPO may refuse a patent on the basis of a general moral norm under Article 6(1) of the Biotech Directive when this moral norm is not recognised as immoral in a member State. One perspective is therefore that the logical consequence, regarding to human embryo patents, cannot be a legal basis for the EPO to refuse such an application on moral grounds, as long as at least one Member State has adopted laws authorizing the relevant use of human embryos.[129]

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[125] Swedish patent No. SE 526490, Granted for a patent of a method of differentiation of pluripotent human embryonic stem cells into haematopoietic cells. The Swedish Patent Office considered the application to fall outside the scope of the exclusion of use of the human embryos for industrial and commercial purposes under Article 6(2)c of the Biotech Directive.

[126] Porter G, Denning C, Plomer A, Sinden J, Torremans P, The patentability of human embryonic stem cells in Europe, Nature Biotechnology 24, 2006:653-655

[127] Denis Schertenleib, E.I.P.R 2004:5:209

[128] ”Whereas ”ordre public” and morality correspond in particular to ethical and moral principles recognised in a Member State…”

[129] www.nottingham.ac.uk/law/StemCellProject/project.report.pdf, p 51, 20/12/06

Furthermore Article 6(2)*c* leaves open the question of patentability of cells obtained from donated embryos, and does not state precisely which embryos are subjected to exclusion. Some consider that non viable embryos (which cannot lead to a birth) such as those created, for example by a somatic cell nuclear transfer (cloning) is not covered by this exclusion.

Human embryo stem cells inventions are still a rather open debate and the Edinburgh patent case showed that there is a strong opinion in the EU against these kinds of patents. At the same time the national legislations differ and the Commission in their 2005 report concludes that there is no uniform view amongst European societies on the point in time from which the life of human embryo should be protected[130]. The differences within EU still exists and the EPO's practice in the WARF case note that the legal situation regarding the interpretation of Rule 23(d)*c* EPC is not mapped out completely.[131]

Although the wording in Article 6(2) of the Biotech Directive was intended to guide the interpretation of the general moral exclusion in Article 6(1), the emerging range of diverging interpretations under Article 6(2) have spread substantial uncertainty on the scope of exclusions, most notably under Article 6(2)*c*. The reading of Article 6 of the Biotech Directive concerning the exclusions is therefore unsure, leaving room for speculations, the opposite of the objectives of the Biotech Directive.

4.4 Summary

The first proposal of the Biotech Directive was rejected by the European parliament because it did not sufficiently take into account the moral issues concerning the human biotechnology field.

Inventions which uses *processes for cloning human beings*, *processes for modifying the germ line identity of human beings* or which *uses embryos for industrial or commercial purpose* shall not be patentable according to Article 6(2)*a-c* of the Biotech Directive. The respect of human dignity is provided for in Article 5(1) of the Biotech Directive, which confers that the human body at the various stages of its formation and development cannot constitute a patentable invention. The prohibition of making profit from the human body is grounded on the principle of non-commercialisation of the human body.

Some further definitions have been made concerning the content of Article 6(2)*a-c* and further exclusions related to the human body. Totipotent stem cells shall not be patentable on grounds of human dignity, according to Commissions analysis in its

[130] Human embryo stem cell report, www.nottingham.ac.uk/law/StemCellProject/project.report.pdf
[131] T 1374/04 WARF, para 20 e-f

report from 2005. Neither shall isolated stem cell lines, which have not been modified, be patented since the industrial application is not fulfilled and since such isolated cells are so close to the human body that their patenting may be considered as a form of commercialisation of the human body. Contrarily pluripotent and mulipotent stem cells isolated from adults, and these cells isolated from foetal tissues obtained after pregnancy termination, can be patentable if they acquired characteristics for industrial application.

However, the interpretation of the moral exclusions concerning the human body and the Article 6(2)*a-c* is not totally clear and different interpretations exist concerning how broad or narrow these exclusion scopes shall be regarded. For example, the Commission in 2005 decided not to take a position on the validity of transposition according to the choice between classic and limited scope of protection for gene sequences. Furthermore, the question was raised whether the Biotech Directive specifically addresses the patentability of stem cells or not. The EPO also noted that there was no uniform moral standard in Europe on human embryonic stem cells, which affects the scope of the moral exclusion.
A large division has emerged concerning the question of patent on pluripotent embryonic stem cells. The EPO estimates them as unpatentable since it has established that Rule 23(d)*c* shall be interpreted in a broad way, which means a ban on patenting uses of human embryos together with the cell being retrieved therefrom by destruction of the human embryo stem cell. Contrarily the policy and practice of some national patent offices in Europe allow patent on pluripotent human embryonic stem cells and other processes, since their interpretation of Article 6(2)*c* has led to exclusions from patentability to totipotent human embryonic stem cells only and processes to obtain cells from human embryos.

Much of the difficulties concerning the moral exclusions under Article 6(2)*a-c* refer to the fact that these types of inventions also have potential to create benefits for human beings. Human embryonic stem cells are of particular interest because they have the potential to differentiate into all cell types in the body and are at present the only pluripotent stem cell that can be readily isolated and grown in culture in sufficient numbers to be useful. For example, embryonic stem cells might in the future be used to treat diseases like cancer, Alzheimer's diseases, diabetes, HIV, Parkinson's and heart diseases.

5. Biotechnology patents and animal moral exclusions

5.1 Law

The Balancing-test in Article 6(2)*d* in the Biotech Directive is intended to reduce the burden on patent examiners of balancing the ethical aspects of an invention by excluding "*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 animal resulting from such process"*. Earlier under the Article 53 EPC other kinds of benefits, such as purely economical, could have been sufficient.[132] However, even though this states the balancing-test set out in the *Onco-Mouse* case (see below) it remains difficult to determine the exact scope of the Article since there are difficulties in interpreting the imprecise wording used in the Article. Particularly the wording "substantial benefit" and "likely to cause them suffering" are imprecise. Although the "substantial benefit" is unclear the Rec. 45 of the Biotech Directive at least gives some guidelines for the "medical benefit" (read medical) by referring to "*any benefit in terms of research, prevention, diagnosis or therapy*". However the interpretation could be even more difficult in view of the added phrase "likely to cause them suffering" in the sentence. How is this phrase meant to be interpreted? That any pain would immediately require a substantial benefit or that the level of pain sustained by the animal is estimated on a sliding scale against a range of substantiality?[133] Personally, I find the latter alternative to be the most likely and rational interpretation of the Article 6 (2)*d* because it is difficult, if not impossible, to estimate subjective sentiments, and an unquestionable (or at least clear to the majority) level of pain therefore simplifies the explanation of the Article.

The Biotech Directive is rather silent regarding further exclusions related to the animal field in biotechnology. The only one stated is that animal varieties or essentially biological processes for the production of animals shall not be patentable[134]. However, inventions which concern animals shall be patentable if the technical feasibility of the invention is not confined to a particularly animal variety according to Article 4(2) of the Biotech Directive. The same exclusions and acceptance regarding animal patents are found in Article 53(b) EPC. The restriction to patentability under Art. 53(b) EPC, first half-sentence, does not extend to the products of a micro-biological

[132] Andreas Neuendorf 2004:109
[133] Amanda Warren, E.I.P.R 1998:12:446
[134] Article 4(a) EC/98/44

process which are patentable under Art 53(b) EPC, second half-sentence. Thus patents are held to be granted for animals produced by a microbiological process according to Article 53(b) EPC and Article 4(3) of the biotech Directive.

Furthermore, national laws, regulations and practices must determine the degree and the conditions of the animal variety rights, since there is no Community legislation on animal variety rights.[135] The Biotech Directive does not interfere with the provision of national patent law whereby processes for treatment of the animal body by surgery or therapy and diagnostic methods practised on the animal body are excluded from patentability according to recital 35.

5.2 Case law

5.2.1 The Onco-Mouse case

The HARVARD/Onco-Mouse[136] case is one of the most well known cases referring to article 53(a) EPC. The Case considers a European patent application[137] filled in by researchers from Harvard for transgenic-produced mice whose germ and somatic cells contained an activated onco-gene sequence that was introduced into the mouse at its embryonic stage. The result of the genetic modification was an increase of the probability for the mice to develop malignant tumours. The purpose was to use the Onco-mice in research, for example in the evaluation of anti-cancer drugs.[138]

The Examining Division of the EPO first refused the patent application in July 1989. Article 53(a) was discussed, even though the application was refused on the ground that the subject matter was excluded from patentability under Article 53(b), and the Examining Division concluded that patent law was not the correct legislative tool for regulating problems arising in connection with genetic manipulation of animals.

However, the Board of Appeal was of a different opinion concerning Article 53(b) and they also considered that "*precisely in a case of this kind there are compelling reasons to consider the implication of Article 53(a) in relation to the questions of patentability*"[139]. The reason for the opposite opinion of the Board of Appeal was that they estmated that the mice suffering caused by the developing of tumours and the danger that genetically manipulated animals could cause if released into the general environment, were reasons enough to consider if the patent would be contrary to "ordre public" or morality. The Board of Appeal additionally stated that the decision

[135] 98/44/EC Rec. 51
[136] T 19/90 HARVARD/Onco-Mouse, O.J. EPO 1990, 476; (1990) E.P.O.R. 501
[137] European patent application No. 85 304 490.7
[138] David Thomas and Georgina A. Richards, E.I.P.R. 2004:3:97
[139] T 19/90 point 5

to whether or not Article 53(a) EPC is barred from patenting an invention mainly depends on a careful weighing up off the suffering of animals and possible risks to the environment on one hand, and the invention's usefulness to mankind on the other.[140] On this basis, the Board of Appeal remitted the application to the Examining Division for further prosecution thought it was the task of the department of first instance to examinee these matters in the Onco-mouse case.

The Examining Division stated that although the development of new technologies normally are afflicted with new risks, they should not generally lead to a negative attitude vis-à-vis new technologies, but rather to a careful weighing up of the risks on one hand and the positive aspects on the other. It is the result of this consideration that should be the determining factor in whether a new technology should be used or not. They concluded that the question of morality arises if higher life forms are involved in the new technology because not only the risk but also the possible harm, which is inflicted on such higher life forms must be considered. Therefore, inventions which are made in connection with the new technology and which are to be patented under the EPC, must satisfy the requirements of Article 53(a) EPC.[141] This means that for each individual invention, the question of morality has to be examined and possible detrimental effects and risks have to be weighed and balanced against the merits and advantages.

The Examining Division then examined this balancing test in the *Onco-Mouse* case stating that there were three different interests involved; the basic interest of mankind to remedy widespread and dangerous diseases, the environment protection against the uncontrolled dissemination of unwanted genes and that cruelty to animals must be avoided. The Examining Division concluded that the latter two aspects might well deem an invention as immoral and therefore unacceptable unless the advantages, i.e. the benefit to mankind, outweigh the negative aspects.[142]

The Examining Division considered particularly four considerations; the invention's usefulness to mankind on the basis of the frequency of cancer diseases, the reduced numbers of animals required, the scientific communities' positive opinion concerning animal testing procedures in cancer research and the factor that Onco-mice tests were to be used exclusively in the laboratory under controlled conditions by qualified staff. They added that the risk of an uncontrolled release was practically limited to intentional misuse or blatant ignorance on the part of the laboratory personnel carrying out the tests and the mere fact that such uncontrollable acts are conceivable could not be a major determinant for deciding whether a patent should be granted or not but the business of specialised governmental authorities.[143] On balance the Examining Division concluded that the present invention could not be considered immoral or contrary to "ordre public". The provision of a type of test animal useful in cancer research and giving rise to a reduction in the amount of testing on animals together with

[140] ibid, point 5
[141] V 6/92 point 3 II. (Decision of the Examining Division) O.J. EPO 1990, 476
[142] V 6/92 point 4
[143] ibid

a low risk connected with the handling of the animals by qualified staff can generally be regarded as beneficial to mankind. A patent was therefore not denied for the Onco-Mouse on the grounds of Article 53(a) EPC. They further stated that the above considerations in the Onco-Mouse balancing-test applied only in this case and that a different conclusion might be reached in other cases applying Article 53(a) EPC. The Examining Division therefore decided in the applicant's favour.

5.2.2 The Onco-Mouse II case

The decision was later appealed and the Onco-Mouse case was finally settled in July 2004, after over ten years of proceedings. The final result was that the Technical Board narrowed the scope of the patent to only include mice, but did not revoke it entirely.

The Technical Board stated that Rule 23(d)*d* EPC is not incompatible with the principle of narrow construction of exclusions or with the previous law[144]. They further stated that the "balancing test" in Rule 23(d)*d* EPC only requires three matters to be considered: animal suffering, medical benefit and the necessary correspondence between the two in terms of the animal in question and the level of proof shall be the same for both animal suffering and substantial medical benefit, namely a likelihood.[145]

The Board also affirmed that the balancing test used in the first Onco-Mouse case[146] still is appropriate in animal manipulation cases. This test differs in several aspects from the test in rule 23d(d) EPC, most importantly by allowing matters other than animal suffering and medical benefits to be taken into account, such as degree of suffering, environmental risks and the possibility of non-animal alternatives.[147] It was said in the earlier Onco-Mouse case that that a decision under Article 53(a) EPC would depend mainly on the balancing test, and the Technical Board therefore stated that this allows for other considerations to be taken into account and further that the balancing test under Article 53(a) offers a test for use in both "ordre public" and morality cases.[148]

5.2.3 The Leland Stanford case

The *Leland Stanford* case was the first on this issue since the Biotech Directive was integrated into the Guidelines for Examination in the EPO in 1999, and like the *Onco-Mouse* case the *Leland Stanford* case also concerns a patent for a modified

[144] T 315/03, Onco-Mouse II, OJ EPO 2006, 15, Reasons, section 7
[145] ibid, Reasons, para 9.1-3
[146] T 19/90
[147] T 315/03, Onco-Mouse II, para 10.6
[148] ibid, para 10.5 and 10.7

mouse. Stanford University was granted the patent by EPO for an immunocompromised mouse implanted with human tissue constituting an animal-human chimera. The production technique involved taking cells and tissues from aborted fetuses or children under the age of three years.[149]

The patent was opposed by the claim that it would be fundamentally unethical and against the general moral of Western society to grant patents on life and that animals were not to be placed on the same level as industrial products. They also found the preparation of the chimeras of the patent ethically unacceptable, as was the use of human foetal cells and tissue from children. Furthermore, the opponent claimed that it was undesirable from an economic and social point-of-view, as patenting animals would increase the cost of medicines by causing dependency in the medical research area.[150]

The Opposition Division applied both an unacceptability-test and a balancing-test, known from the Onco-Mouse case. In the unacceptability-test the Opposition Division considered the question weather it was ethically unacceptable to introduce human foetel cells into an animal organism or not, and thus regard animals as industrial objects. The Opposition Division argued that animals are patentable according to Article 4(2) and 6(2)*d* of the Biotech Directive and in the corresponding Rules 23(d)*d* EPC if the technical feasibility of the invention is not confined to a particular animal variety and if the invention confers a substantial medical benefit to man or animal, if the result of the modification is likely to cause the animal suffering. They therefore claimed that it could not be considered contrary to the general moral of the western society to patent modified animals since there exists legislation on such patenting.

The Opposition Division then applied the balancing-test. They stated that the test applies to all patents concerning animals, and not only to genetically modified animals, according to the "spirit of the rule" 23(d)*d* EPC.[151] The Opposition Division did not consider the economical argument from the opposing parties since 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 of restricting the field of patentable subject matter accordingly.[152]

Since economical aspects were not to be considered in the determination of the moral integrity of an invention the only issue to evaluate was if there was a "substantial medical benefit" or not. The Opposition Division judged that there was likely to be a great medical benefit from the invention such as ways of providing human cells or organs for transplant in the future and by providing the only available animal model for HIV-I infection.[153] The Opposition Division additionally considered the potential

[149] Andreas Neuendorf 2004:102
[150] EPO, Opposition Division, *Leland Stanford,* 16 aug 2001, (2002) E.P.O.R. 2, para 44
[151] ibid. para 46
[152] ibid. Para 49
[153] ibid. Para 47

risk that the opponent referred to being associated with the particular transplantation. The Opposition Division saw it as a weak argument, given that the EPO is not vested with carrying out the task of monitoring and estimating such risk and thus referred this responsibility to the regulatory authorities.[154] The potential benefits outweighed therefore the negative aspects according to the Opposition Division and the patent was granted.

5.2.4 The Artemis case

The 2005 Artemis case[155] once again concerned mice genetics. The applicant wanted to grant a patent for a conditional gene trapping constructed for the disruption of genes, i.e. a change in the genetic identity of mice. The Technical Board concluded that there was no balance between the likely suffering and likely substantial medical benefit to man or animal. For this reason, the subject matter fell within the category of exceptions to patentability according with Rule 23(d)*d* EPC and this part of the patent claim was therefore denied. [156]

5.3 Reflections

The Board of Appeal has asserted from the *Onco-Mouse* case the general principle that the exception to patentability under Art. 53(b) EPC applies to certain categories of animals, but not to all animals as such. In interpreting the term "animal varieties" the board in this decision emphasised the narrow interpretation to be given to the provision of Article 53(b) EPC.

As seen above, there were in particular three different interest to be considered in the morality balancing test; those of mankind in remedying dangerous diseases, protection of the environment and those of animal suffering in testing. The *Onco-Mouse* case, as well as the *Leland Stanford* case, reduced general moral consideration to specifics, which makes the scope of the interpretation narrower.

A difficulty raised by the use of a balancing-test is the question whether it always is possible to rank the outcomes in terms of the sum of welfare. There can be ethical objections to the utilitarianism that is used in the *Onco-Mouse* case as it sacrifices the interest of a person with the aim, not just to protect but to increase the aggregated welfare. This is also problematic with respect to rights because a valuation must be done to estimate the different principles.[157]

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[154] ibid. Para 47
[155] T 606/03- 3.3.08 ARTEMIS,
[156] ibid, para 4
[157] Andreas Neuendorf 2004:104

Moreover the method used in the balancing-test has been a mixture of known and unknown quantities. In the *Onco-Mouse* case the "known" side was the element of suffering to the mice and the "unknown" was the risk to the environment. These quantities were weighted against the possible (but still "unknown") advantage in the treatment of cancer in human beings. The criticism of this utilitarian calculus focuses on the fact that the examiners give a reduced weight to "cost items" of the equation and a broad weight to benefits regardless of whether they are known quantities[158]. Thus the known fact of mice suffering is weighted down as the uncertain advance in medical knowledge is weighted up. The unknown medical benefit was regarded but not the unknown environment risk, because the EPO did not feel capable of properly estimating the risks. Weighing known and unknown quantities against each other is difficult per se since there is no evidence for the unknown outcome. [159] So even if I find the *Onco-Mouse* judgement fair, it would have been desirable for the EPO to give the known facts a broader weight in view of its certainty, and also a more equivalent estimating of the two unknown facts. The EPO should make a more serious consideration of the potential benefits as well as the potential risks. The fact that potential benefits are estimated while the potential risks are not adds up to a very loose approach that makes the whole process arbitrary.

The result of the *Onco-Mouse* judgement was further criticised for the failure by the Examining Division to consider the morality of every possible application of the patent. The opponents gave an example of an "Onco-Giraffe", who would fall within the scope of "all non-human mammals" claimed by the patent. The assumed impossibility of using transgenic giraffes as test models would thereby shift the balance against patenting since the animal welfare considerations would be given a more important substance.[160] The objection that transgenic animals in general pose unethical inference with evolution was entirely ignored by the Examining Division.[161] The basis for the narrowing in the *Onco-Mouse II* case to contain only mice, can therefore be seen as important since the applicants will have to show the use of all the animals for which they are claiming a patent can lead to a benefit.

It is also interesting that the balancing test under Article 53(a) is wider than the test under Rule 23(d)*d*. The Board stated that in cases falling within Rule 23(d)*d* EPC it inserts an objection under Article 53(a) EPC which, depending on the facts and outcomes of the test, may be either additional or alternative to an objection under Article 53(a) EPC itself as developed in case law.[162] This shows that one shall first regard the strictly medical benefits and animal suffering, and if this is not enough to reject the patent the opponent can, under Article 53(a), refer to further facts.

This demonstrates that the Biotech Directive actually has a narrower scope of animal protection in regards to the case law under the EPC. The Technical Board's analysis

[158] ibid. p.105
[159] ibid, p.108
[160] Amanda Warren E.I.P.R 1998:12:447
[161] ibid
[162] T 315/03, Onco-Mouse II, para 10.1

of the *Onco-Mouse II* case can be seen as an improvement of the earlier one but can still be criticised for their confusion regarding whether the degree of suffering is relevant to the Art 53(a) test and its dismissive treatment of opinion pools[163] and case law evidence from other jurisdictions[164] relating to the *Onco-Mouse* case.

The position of the Examining Division in the *Onco-Mouse* case demonstrates that the balancing-test must be judged in each single case and the wording "substantial benefit" therefore remains unclear until the case law better defines the law. Besides, the intention of the Biotech Directive was to establish conformity of practice. The legislation of the balancing-test stated within the *Onco-Mouse* case without any further guidelines than the case law of the EPO can therefore be seen as a failure to give guidelines to national courts in judging exclusions from patentability regarding animals.

The moral exclusion from patentability regarding animals therefore must be regarded as narrowly constructed, even thought Article 6(2)*d* Biotech Directive and Rule 23(d)*d* in the Guidelines for EPO explicitly make references to animals and moral exclusions. Regarding exclusion related to "patent of life", the Board of Appeal from the *Onco-Mouse* case has asserted the general principle that the exception to patentability under Article 53(b) EPC applies to certain categories of animals, but not to animals as such. Furthermore, the moral exclusion which exist is only related to animal suffering and is to be considered narrowly constructed since the Examine Division stated that animal suffering must be related to benefits for human mankind and that the exclusion therefore has to be narrowly constructed since animal testing regarding diseases are widely accepted within Europe. Even though the EPO has showed that the animal suffering really is regarded.

5.4 Summary

Inventions which concern animals shall be patentable if the technical feasibility of the invention is not confined to a particularly animal variety according to Article 4(2) of the Biotech Directive. This general principle was also asserted in the *Onco-Mouse* case, where the EPO further emphasised the narrow interpretation to be given in the interpretation of the term "animal varieties".

The question of morality arises since higher life forms are involved in biotechnology and hence the possible harm which is done to such higher life forms must be considered. Article 6(2)*d* Biotech Directive and Rule 23(d)*d* in the Guidelines for EPO explicit make references to animals and moral exclusions, stating that *"processes for*

[163] T 315/03, para 10.10, refers to T 356/93
[164] The Canadian Supreme Court refused the patent for the Onco-Mouse in 2002 based on its interpretation of the word *invention* and additionally referred to the serious moral and ethical implications of the subject-matter, see E.I.P.R 2006:1:59

modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefits to man or animal shall be excluded from patentability". This exclusion applies to all patents concerning animals, and not only to genetically modified animals, according to the "spirit of the rule" 23(d)*d* EPC. However, the moral exclusion from patentability regarding animals must be regarded as narrowly constructed since Rule 23(d)*d* EPC is said to be compatible with the principle of narrow construction of exclusions and with the previous EPC law.

The *Onco-Mouse* case created a "balancing-test" to enable an examination of the morality exclusion concerning animal inventions. This balancing-test has been incorporated into in Article 6(2)*d* of the Biotech Directive to reduce the burden on patent examiners of balancing the ethical aspects of an invention. Compared with the "balancing-test", created by the EPC case law, the balancing-test under the Biotech Directive has been narrowed regarding the scope of animal protection. The Rule 23(d)*d* EPC only requires three matters to be considered: animal suffering, medical benefit and the necessary correspondence between the two. The level of proof shall, according to Rule 23(d)*d,* be the same for both animal suffering and substantial medical benefit, namely a likelihood. Nonetheless, the EPO has stated that the balancing-test under Article 53(a) can be additional since one shall first regard the strictly medical benefits and animal suffering, and if this is not enough to reject the patent the opponent can under Article 53(a) refer to further facts.

A difficulty raised by the use of a balancing-test is how to determine the exact scope of the Article since there are difficulties in interpreting the imprecise wording used. Particularly the wording "substantial benefit" and "likely to cause them suffering" are imprecise. Another question is whether it always is possible to rank the outcomes in terms of the sum of welfare. Especially since the method uses a mixture of known and unknown quantities, which is difficult given that there is no evidence for the unknown outcome.

The *Onco-Mouse II* case stated that the applicants have to show that the use of all the animals for which they are claiming a patent, can lead to a benefit.

6. Biotechnology patents and plant moral exclusions

6.1 Law

Recital 10 in the Biotech Directive states that considerations should be taken to the potential of the development of biotechnology for the environment, and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of grounds, whereas the patent system should be used to encourage research into, and the application of, such processes. This can be seen as an overall positive view of biotechnology in the plant field, which is further strengthened by the fact that this domain is the only one (out of these three) which does not consider any exclusion under Article 6(2).

Article 4(1) of the Biotech Directive states that plant varieties are excluded from patentability, whereas Article 4(2) states that inventions which concern plants are patentable provided that the application of the invention is not technically confined to a single plant variety. The definition of a plant variety is its whole genome, and as a result it possesses individuality, and is clearly distinguishable from other varieties, whereas a plant grouping is characterised by a particular gene (and not its whole genome) and is therefore not excluded from patentability, even if it comprises new varieties of plants.[165] However, according to recital 32 of the biotech Directive, an invention should be excluded from patentability if it consists only in genetically modifying a particular plant variety even if the genetic modification is the result of biotechnological processes.

This article is an improvement of the first proposal since the Economic and Social Committee demanded more detailed explanations considering the relationship between plant variety rights and protection by patent. This was particularly important regarding questions about the patentability of plants and the combination of these two different forms of protection and it therefore wanted a reference to the concept of plant varieties to remove this conflict. The Committee also argued that it was important to make it clear in the wording that it was an exclusion from patentability of plant varieties and animal breed per se without prejudice to the patentability of plants or animals when the application of the underlying invention is not technically limited to specific plant or animal varieties.

[165] Rec. 30 and 31 of 98/44/EC, referring to the protection of new varieties.

The Community plant variety rights regulation (CPVR) can be seen as a dual system of protection to the plant patent protection.[166] There is however a difference in how the moral exclusions are addressed since the CPVR follows the structure that the:

"*exercise of the rights may not violate any provisions adopted on the grounds of public morality, public policy or public security, the protection of health and lift of humans, animals or plants, the protection of the environment*"[167].

By this stipulation the law once granted brings together the concepts of morality, public policy and the exercise of rights. This clearly indicates that a plant variety right, once granted, does not permit the rights holder to use that right for any purpose whatsoever but that Member States could choose to restrict the exercise of that right by national legislation.[168] Thus, instead of determining morality by references to grant, determination over the exercise of the right once granted moves the question of morality away from intellectual property right per se. This is in strong contrast to the operation of the patent system where a determination of morality lies in respect of he grant of the right itself, and the question of morality impinges upon the existence of the intellectual property right.[169]

Recital 27 of the Preamble of the Biotech Directive states that a patent application should, where appropriate, include information on the geographical origin of the material and this can indicate that the Biotech Directive shares the public concerns about the contribution of, for example, indigenous communities to the identification of the therapeutic proprieties of native plants.[170]

There is a difference in the wording between Article 27(2) of TRIPs and Article 6(1) of the Biotech Directive. The Article 27(2) TRIPs excludes inventions, which are "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*". I find the wording in Article 27(2) TRIPs to be clearer concerning the plant life protection, than the rather vague Biotech Directive, in view of the lack of references to these in the text since Article 6(2) of the Biotech Directive gives no perceive to plants and environment. Even though the TRIPs agreement with its "may exclude" in reality is less protective. The only references maid to the environment protection in the Biotech Directive is found in recital 14, which states "national, European or international law may impose restrictions from the point of view of the requirement of *public health, safety, environment protection, animal welfare*".

[166] Oliver Mills, 2005:140
[167] Community Plant Variety Rights Regulation, Article 13(8)
[168] Margaret Llewelyn ,E.I.P.R 1997:3:123
[169] Oliver Mills, 2005:159
[170] Geertrui Van Overwalle, 2002: 218

6.2 Case law

6.2.1 The PGS case

The *Plant Genetic Systems* case [171] (*PGS*) concerned a plant cell that was made more resistant by genetic engineering. Article 53(a) and 53(b) EPC were relevant to the case and the patent claim was opposed by Greenpeace on the grounds that the grant of a patent for plant life forms and the exploitation of the patent was contrary to morality and/or "ordre public" and that the processes for their production were not patentable according the concept of "plant varieties".

The appellants' arguments were that plant genetic resources were the heritage of mankind and hence should remain available to all without restrictions, and that the exploitation of the invention could result in serious irreversible environmental risks since the treated plants themselves could become weeds or that the herbicide-resistance could spread to other plants and as a result the ecosystem could be damaged. Greenpeace made references to scientists, industry and opinion pool and a survey to demonstrate that the public opinion was against patenting of genetically engineered, herbicide-resistant plants as technical invention.

The Technical Board of Appeal had to start to define the concept of morality and "ordre public" since it was apparent from the historical documentation of EPC Working Party that "*there was no European definition of morality and "ordre public*" and that these interpretations should be a matter for European institutions.[172]

They declared that it was generally accepted that the concept of "ordre public" covered the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. And accordingly to article 53(a) EPC, inventions which are likely to breach public peace or social order (for example through acts of terrorism) or to seriously prejudice the environment should therefore be excluded from patentability as being contrary to "ordre public".[173]

The Technical Board then regarded the concept of morality and stated that it is related to the belief that some behaviour is right and accepted whereas other behaviour is wrong. This belief is founded on the totality of the accepted norms which are deeply rooted in a particular culture, which for the purpose of the EPC is the culture inherent in European society and civilisation. Thus, accordingly to Article 53(a), inventions of which exploitation is not in conformity with the conventionally-accepted standards of conducts pertaining to this culture should be excluded from patentability as being

[171] T 356/93 *Plant Genetic Systems*, OJ EPO 1995, 545
[172] T 356/93 PGS, para 4
[173] ibid, para 5

contrary to morality.[174] The Technical Board further added that this qualification makes it clear that the estimation is not dependent upon any national laws or regulations.[175]

The Board made clear that it does not consider surveys and opinion polls to reflect the "ordre public" concerns or moral norms in the European culture referred to in Article 53(a) EPC since they easily can be influenced or controlled and tend to reflect only specific interests. Further, since each case must be considered separately[176], surveys and opinion polls have to be made ad hoc on basis of specific questions in relating to the particular subject-matter claimed, which was regarded as scarcely feasible. However, even if such a survey or opinion poll was made showing that the majority of the population of some or all of the Contracting States opposed the patent for a specified subject-matter this cannot serve as a sufficient criterion for establishing that the said subject matter is contrary to "ordre public" or morality.[177]

The Board sustained the examination of whether it was likely that the patent claim seriously would prejudice the environment or be contrary to the conventionally accepted standards of conduct of European culture. The questions concerning the environmental consequences were referred to the "ordre public" issue and the questions regarding the dominion gained by man over the natural world were referred to morality concept under Article 53(a).

The Technical Board argued that plant genetic engineering technique can be used for destructive purpose and that it would be against "ordre public" or morality to propose a misuse or a destructive use of these techniques, but that this was not the situation in the relevant case.[178]

When regarding the "ordre public" exclusion concerning environmental effect the Board evoked the possibility for other authorities to regulate the exploitation of the technique. It further held that in most cases, the potential risks in relation to the exploitation of a given invention for which a patent has been granted cannot be anticipated merely on the basis of the disclosure of the invention in the patent specification, since the nature of the patent protection, which demands novelty, creates a system where a product is most likely to be in the initial phase when the patent application is filled in. The legitimate risk and safety estimation of the exploitation is therefore to be held of competent authorities in a later phase, which are in the position to carry out a realistic assessment of the risk.[179] Thus the threat to the environment that exists is

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[174] ibid, para 6
[175] ibid, para 7
[176] The Technical Board repeated the statement from the *Onco-Mouse* case when it stated that the right approach is to look at the particular facts of each case and examine if these are contrary to "ordre public" or morality, para 13
[177] T 356/93 PGS, para 15
[178] ibid, para 17.1
[179] T 356/93 PGS, para 18.4

only to be considered at the time the decision of the patent is taken by the EPO, in line with the narrowly constructed exceptions under Article 53(a) EPC.[180]

The Technical Board declared that the threats pointed out by Greenpeace were only possible or theoretical threats and consequently "it would be unjustified to deny a patent under Article 53(a) EPC merely on the basis of possible, not yet conclusively-documented hazards"[181].

The Board finally stated that the balancing-test, used in the *Onco-Mouse* case, was not to be applied since the test only was useful in situations where an actual damage or disadvantage exists and added that the test is only one way of assessing patentability with regard to Article 53(a) EPC.[182] The judgement declared the patent valid since granting the patent would not be contrary to "ordre public" or morality within the meaning of Article 53(a).

6.3 Reflections

The Technical Board refers, in the *PGS* case, to the difficulty of estimating the potential risks in the patenting phase and its references to other authorities or bodies. This could indicate a possibility that the EPO could value the arguments in favour of a patent higher than the arguments against, since it takes into consideration the fact that an alternative authority will consider the potential risks once again. This reveals that the exclusions from patentability concerning environmental risks are very narrow. Even if the EPO only shall consider the facts regarding each single patent claim, according to the patent rights, and therefore has ground to barely consider the threat at the application point, the result is that there is almost no environment protection under Article 53(a) EPC or Article 6 of the Biotech Directive. Since the EPO in the Onco-Mouse case also held that it was up to alternative authorities to consider the questions concerning the risk that the mice ended up in the wild, this can be valid for both plant and animal environmental impacts.

The narrow interpretation is additionally strengthened by the fact that it was stated that innovations, which "seriously prejudice the environment", would be contrary to ordre public.[183] I assume that the wording "seriously prejudice the environment" once again could create problems regarding the interpretation of the sentence. First, what prejudices the environment? One could imagine different scopes of damage, even if this destruction according to the *PGS* case has to be a threat on the day the application is examined. And second, what is the difference between "seriously prejudice the environment" and "prejudice the environment"? The exclusion concerned to plants

[180] ibid, para 18.4
[181] ibid, para 18.7
[182] ibid, para 18.8
[183] ibid, para 18.7

under Article 53(a) EPC should therefore be seen as extremely narrow since the threat must be confirmed the day of the examination. Besides, the exclusions regarding plants must further be seen as rather unclear since the wording is relatively imprecise and additionally strengthened by the fact that the balancing-test was not to be considered in cases relative to plant modifications. The fact that plant life is the only subject-matter that has no reference to a subparagraph in Article 6(2) must be seen as a strong indication for a narrow interpretation to exclusions concerning to "ordre public" or morality and shows that the plan protection under the Biotech Directive is the narrowest of these fields of exclusions. One of the reasons may be that the European legislature, in general, does not find any moral problems according to plant patents and a verification for this could be the fact that CPVR has located the moral exclusions outside of the plant variety protection.

The judgement in the *Leland Stanford* case, in which the Opposition Division held that patenting of animals cannot be seen as essentially unethical since there is existing legislation regarding patenting of animals, can in some extent be considered as a contradiction to the judgement in the *PGS* case.[184] Where the Technical Board of Appeal held that "*…national law(s) and regulation(s) approving or disapproving the exploitation of an invention… cannot serve as a sufficient criterion for establishing that the said subject-matter is contrary to "ordre public" or morality*"[185]. That an invention shall not be deemed to be contrary to "ordre public" or morality merely because it is *prohibited by law or regulation* is stated in both Article 53(a) EPC and Article 6(1) of the Biotech Directive. Nevertheless, as a result, national law can be an instrument in favour for a wide scope of patentability but not for exclusions.

This further indicates that the EU-legislation alone has a moral function that the national laws do not have according to the exclusions in Article 6 of the Biotech Directive and Rule 23(d) of EPC. Thus the EU Directive is seen to represent norms of the European Culture but the legislation in single EU Member States does not. However, the Biotech Directive assert in Recital 39 that "*ordre public and morality correspond in particular to ethical or moral principles recognised in a Member State … such ethical or moral principles shall supplement the standard legal examination under patent law*"[186] and gives a value to different national moral principles by this wording. Stating that national laws are not to be considered as sufficient as exclusions regarding to "ordre public" or morality, but national principles do.

The crucial point is how should these ethical and moral principles be identified?

[184] Andreas Neuendorf 2004:106
[185] T 356/93 PGS, para 15
[186] 98/44/EC, Rec. 39

6.3.1 Surveys- advantages and inconveniences

One of the most overlooked aspects of the debate regarding the application of the patent morality criterion is said to be the practicality of a public standard of morality. A solution could therefore be to allow the Patent Office examiners and Patents Courts to have access to surveys and opinion polls as evidence on which the morality decision can be granted. However this has been rejected by the EPO in the *PGS* case, where it also was stated that it would be practically impossible to carry out such surveys on single case basis. Still a practical possibility could be cross-national sampling, which permits for opinions of a cross-section of the European public to be regarded as being representative of everyone.[187]

In the *PGS* case the Technical Board rejected in the value of surveys and opinion polls on the basis that these did not necessarily reflect "ordre public" concerns or moral norms and that the result can fluctuate in an unforeseeable manner.[188] However, it is argued that there is a distinction between values and attitudes. An attitude is a set of beliefs about a specific object or situation, such an attitude towards slavery. A value in contrast is a single belief of a specified kind. It is above attitudes about specific objects and situations, to more ultimate goals that affect how we should judge a wide sweep of objects and situations. Thus the argument given in the *PGS* case is an argument against survey evidence that relates to attitudes, but it is not an argument against the kind of empirical work that social scientist can deliver when it comes to identifying community values deeply rooted in the Member States.[189]

One argument for opinion polls and surveys is that since 1973 the Eurobarometer "has been monitoring the evolution of public opinion in the Member States, thus helping the preparation of texts, decision-making and the evaluation of the European Commissions work" and that *texts* clearly includes legislation.[190] Thus, if opinion pool evidence is a legitimate tool in the formulation of legislative policy at European level, it could also be so in assessing public morality[191]. In so far as surveys do represent essential insights into "abhorrence" values across Europe, they can be useful as part of the evidential basis for the EPO examinees when estimating ethical issues. If one uses scientific methods for collecting and identifying the public opinion it may form part of the evidence since the court can properly assess it. This view has been accepted by UK rules and empirical evidence by market research has also been used in deciding trade mark cases.[192]

However, identification of a brand by the public is far less complex than measuring the public morality in biotechnology, and this indicates that it is the context and not the empirical validity that creates problems.

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[187] Amanda Warren-Jones, E.I.P.R 2006:1:29
[188] T 356/93 PGS, para 15
[189] Peter Drahos, E.I.P.R 1999:9:448
[190] http://europa.eu.int/comm/public_opinion, 03/01/07
[191] David Thomas, Georgina A. Richards, E.I.P.R 2004:3:102
[192] Amanda Warren-Jones, E.I.P.R 2006:1:34

One problem with opinion polls and surveys is that biotechnology applications for patent protection are cutting-edge technology and the dilemma is whether these inventions can be deemed to fall sufficiently within the public's consciousness in order to be instinctively measured.[193] This is somehow also supported by the Eurobarometer from 1996 concerning modern biotechnology, which reports that the greater the level of education, the higher is the percentage of moral acceptability of biotechnology[194]. The levels of both optimism and pessimism increased over the less educated by the better educated and they assumed the risks more fully.[195] This indicates that it might be difficult to find the "deep rooted moral values" that the EPO demands. In addition, the European Commission concluded on the basis of the Eurobarometer that there was no unified attitude to biotechnology in Europe.[196] This makes it even more difficult to estimate the European moral within biotechnology, since both education and nationality[197] have been reported important factors.

Furthermore the EPO approach implies that the standard of morality is related to legal, regulatory and social sanctioned principles, which are judged by a majority of the public as an abhorrence. Still this is somewhat misleading since there is no intention that the public opinion shall be investigated in order to comply with the legal provision regarding to the wording "*whether it is probable…*" in the guidelines and to assess whether an invention would be abhorrent to most people, the examiners probable estimation is an intuitive analysis.[198]

Moreover the Report on Stem Cells, which was regarded by the Commission in their proposition from 2005[199], makes an analysis of the wording *recognised,* in the above discussed Recital 39 of the Biotech Directive, which highlights the need of a correspondence between the concept of "ordre public" and morality and particular ethical or moral principles recognised in a Member States. The report argues that the term *recognised* is significant since it limits the range of sources from which moral norms are to be identified to those sources which are recognize as such in Member States, e.g. national constitutions, laws or regulations, administrative rules of professional Codes of Practice reflecting the relevant moral norms. This would then exclude particular ethical or religious treaties, studies or surveys which have not been incorporated into public policy, and which reflect the sectional interests or the view of particular groups in the society rather than nationally accepted norms.[200]

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[193] Amanda Warren-Jones, E.I.P.R 2006:1:26
[194] The Europeans and Modern Biotechnology: Eurobarometer 46.1, European Commission, 1996:46,
[195] ibid, p28-29
[196] ibid, p.vi
[197] as shown in 4.3.4
[198] Amanda Warren-Jones, E.I.P.R 2006:1:26
[199] COM/2005/312, final
[200] www.nottingham.ac.uk/law/StemCellProject/project.report.pdf, p51

This analysis clearly shows the difficulty in estimating morality and the many different interpretation that can be made of the articles and recitals of the Biotech Directive regarding the moral principles.

6.4 Summary

Moral questions were raised concerning plants on the ground that plant genetic resources were the heritage of mankind and hence should remain available to all without restrictions. However, the case law shows that there is a narrowly constructed exception under Article 53(a) EPC concerning plants and the Biotech Directive only excludes plant varieties from patentability. The reason is that plants are not seen as a higher life form and therefore have no explicit moral protection under the Biotech Directive.

The Biotech Directive has an overall positive view to biotechnology in the plant field and states that considerations shall be taken to the potential of the development of biotechnology for the environment, and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of grounds.

The protection according to the “ordre public” exclusion concerning environmental effects is narrow since it only refers to effects that “seriously prejudice the environment”. The threat to the environment that exists is only to be considered at the time the decision of the patent is taken by the EPO, which further limits the exclusion scope. Furthermore, the EPO has referred the responsibility to carry out the task of monitoring and estimating the risk to other regulatory authorities.

The wording “seriously prejudice the environment” is unclear and might create problems regarding the interpretation.

7. A general or specified moral exclusion article

7.1 Is Article 6(2) useful or is only a general moral exclusion, such as Article 6(1), to be preferred?

The principle of protection of human dignity and ethical considerations is one of the main principles in the Biotech Directive, together with the principle of beliefs on positive progresses within the field. The analysis shows that the basic moral issue concern in biotechnology, the general question of "patenting on life", is settled since living subject-matters are patentable if the criteria of an invention is met.

However, the analysis shows that that there still are difficulties regarding the moral exclusions in Article 6 of the Biotech Directive and that the general moral exclusion is vague, as is often the case with general provisions, which are designed to have the greatest relevance in future applications. An examination therefore raises a range of potential interpretation since dignity is a delicate idea when it is transposed into legal language[201], if only for the reason that ethics is not an exact science but means for applying moral beliefs. Nevertheless, regarding these difficulties I believe that there are reasons for having an article which excludes inventions that are contrary to morality and "ordre public", since I personally think that the society should not encourage all kinds of inventions.

However I am sceptical regarding Article 6(2) of the Biotech Directive since the analysis also shows that it has not succeeded in removing the uncertainty regarding the moral exclusions, but has rather created new questions. Additionally, the fact that the biotechnology field probably will extend in the future could come to create new ethical issues that the present Article 6(2) of the Directive has difficulties to handle.[202] Furthermore, the fact that these at present specified moral exclusions may be accepted in the future, if the technology develops further and thereby creates techniques that can be suitable for human kind, can also be an argument for a removal of paragraph 2 in Article 6 of the Biotech Directive.

Besides, the ECJ has recognised that particular circumstances justifying alternatives to the concept of public policy may vary from one country to another and from one

[201] EGE, Report, 23 May 2003
[202] COM/2002/0027, final, para 6

period to another and that it is therefore necessary to allow the competent national authorities an area of options.[203] Even though EPO is not a community institution, the fact remains that even the ethical considerations may change over time and that the exclusions from patentability under Article 6(2) therefore may be accepted in the future. Additionally, since patent protection often is granted years before exploitation occurs, and because morality may change over time, patent morality could become outmoded by the date of the exploitation and this supports the argument that morality exclusions at the patenting stage should be general since this is likely to be more enduring and therefore remains applicable even after a delay between the patent claim and the commercial exploitation.

It can also be argued that the cloning of human beings is a topic on which a high degree of moral consensus exists in the public mind and in these circumstances it can be argued that the matter is so controversial that it will be impossible to claim a patent on a human cloning invention even under a general moral exclusion article of European patent law. Inventions which will be considered as abhorrent will not be granted anyway and the moral protection does therefore exist even without Article 6(2) of the Biotech Directive. Additionally, the validity of the Biotech Directive was declared in the *Netherlands* case[204] where the Court also stated that the Directive framed patent law in rigorous enough terms to ensure that the human body is unavailable for patenting and inalienable and to safeguard human dignity according to Article 5[205]. This could therefore be an argument supporting that articles 5 and 6(1) give sufficient moral protection even without Article 6(2) of the Biotech Directive.

On the other hand, the question can be raised whether it is possible to draft special morality exclusion concepts in ways which are both clear and precise in respect of its meaning and application. The analysis shows that the interpretation of Article 6(2) *a-d* remains unclear, even though it was created as a guidelines to the general article and that the scope of protection not yet is established and that there is no total consensus, on a detail level, within Europe. This could however be an argument for Article 6(2) of the Biotech Directive since it creates a wider harmonisation across Europe, taking in consideration that harmonisation within the patent law was one of the main purposes with the directive.

Another argument for Article 6(2) is that it is quite probable that it might be impossible to delete these references to morality in the biotechnology patent law in the European community at the moment. The *Edinburgh* case together with the moral debate, in the creation of the Biotech Directive, could indicate that Article 6(2) is politically necessary, even if it might not be the best technical solution.

I find the main argument against a specified moral exclusion article to be the potential benefits of biotechnology. Reducing the moral standard to general principles can

[203] ECJ, Case 41/74, Van Duyn vs. Home Office, (1974) ECR 1337, para 18
[204] ECJ, Case C-377/98, Netherlands v. the Parliament, 9 Oct 2001
[205] ibid, point 77

therefore prevent the law in a rapidly developing area such as biotechnology, to become outdated.

7.2 Alternatives to Article 6(2) of the Biotech Directive

Since it is probable that the biotechnology field is too controversial at the moment for a total abandon of the second paragraph of Article 6, I will here discuss some alternatives that could be used as guidelines to Article 6(1) in alternative to Article 6(2) of the Biotech Directive.

First of all, regulations can be differently designed for different stages within the biotechnology field even though they are based on the same set of ethical values. The different stages could be research, patenting and production, usage and marketing. The legislation could therefore differ between these field since judgement is easier to make when one sees the result of research and not beforehand. [206] The strictest regulation is favourable in the production, use and marketing area and the widest regulation in the research field, since one otherwise could miss out on important technology advances. As stated above, I believe that the biotechnology patent law should include an article, which excludes inventions from patentability concerning morality and "ordre public" according to a general exclusion article. But I also find it reasonable not to make it too detailed since I do not find the patent law to be the best regulation to control the risks in relation to its purpose. A patent granted, for example, to embryonic stem cells, does not protect the inventor from laws regulating aspects of the commercialisation and use of this invention. Thus, laws outside the patent system can more specifically target the ethical concerns, whereas a ban on patenting does not since a ban on patents does not prevent an invention or the use of the invention but rather leaves such a use open to anyone.[207]

I find Article 6(2)*d* to be useful as I believe that this is the moral concept which has the less potential to change in the future in view of technical evolution, given that this paragraph already considers potential benefits for humans or animal. Paragraph *d* of Article 6(2) could however instead be incorporated in Article 4(1), which concerns inventions that shall not be patentable.

It has been argued that not all biotechnology patent claims require an ethical evaluation but only those that make claims to human genetic or biological material, i.e. Article 5 and 6(2)*a-c* of the Biotech Directive. As an alternative to Article 6(2)*a-c*, an Ethical Board has been suggested, which would help the EPO in granting theses patents concerning Article 5 of the biotech Directive. The European Groups on Ethics considered such an Ethical Board. Since it found that there might be a need to make ethical evaluations in the course of the examination of patent applications involving

[206] Emil Ekström, 2004:95
[207] Geetrui Van Overwalle, 2002:88

specific ethical dimension. The Group therefore found it desirable that such an ethical evaluation becomes part of the review process of the EPO and that advisory panels of independent experts are set up for this purpose. [208]

A potential guideline for such an ethical panel could be the Clinical Trials Directive (CTD)[209], which is intended to further harmonise the regulatory framework applicable to the European pharmaceutical industry and sets about enforcing an ethical dimension in all clinical trials and in particular those that relate to human biological or genetic material.[210] The Ethical Committee of the CTD will protect, in the broader sense, the well-being and integrity of the subjects of clinical trials. Article 3(2)*a-d* CTD affirms that the key features which are used as conducts in these clinical trials contain; an evaluation carried out by an independent ethics committee, membership of the ethics committee includes non-professionals, the ethical acceptability of proposed trials is considered on an individual basis, the committee's decision is binding not advisory and a relatively rapid and proscribed decision making process.[211] Since these fields resemble according to the subject matter a biotechnology patents ethic committee may be established along the lines of the ethical committee required under the CTD. The advisory panel of independent expert, which the EGE desire, could then use the independent ethics committee under the CTD as a model for the ethical evaluation of biotechnology patents based on the same principles as these ethics committees under the CTD and thus will assure that the patent granted complies with the provision of Article 6 of the Biotech Directive and Article 53(a) EPC.[212]

This idea can however be criticised since one problem with an ethical board is that it is difficult to perceive that such a panel is truly representative. Another critique to this position has been that the European biotechnology industry thereby would be given a competitive disadvantage compared to the US and Japan in view. One solution mentioned to this problem has been to give the granted patents, which have been examined by an Ethical Board, a supplementary protection period as compensation. Nevertheless, it can be argued that this supplementary time will do no good since the patent at the end of the normal 20 years protection often has little commercial value in cutting-edge technology.[213]

However, since the moral exclusions under Article 6(2) are not totally clear, this additional time might not change much in reality, since the present text also can create legal actions against the patent claim. Thus, since it has been established that morality must focus on the industrial application of the invention, any moral consideration needs to be individualised. An Ethical Board could thereby be a solution to the problem on how to judge ethical issues on a single case basis and would then solve the problem that arises between theory and practice regarding the moral considerations in

[208] EGE, Opinion 16,p18
[209] 2001/20/EC, came into force in May 2003
[210] Timothy Sampson, E.I.P.R 2003:9:419
[211] Timothy Sampson, E.I.P.R 2003:9:421
[212] Timothy Sampson, E.I.P.R 2003:9:423
[213] Timothy Sampson, E.I.P.R 2003:9:423

the Biotech Directive. This could further give the public and the European Parliament a more positive view on biotechnology patents since it would provide reassurance that the ethical issues are independently examined.

This could therefore be a politically accepted alternative to Article 6(2) of the biotech Directive, which would also be an advantage since an Ethical Board is more adaptable to moral evolution regarding the biotechnology field than the law, which has to be revised in advance.

Another alternative is to reject paragraph 2 of Article 6 and instead of an Ethical Board further regulate the use of the biotechnology inventions.

8. Summary

The EPO has stated that Article 53(a) constitutes an exception to the general patentability principle and that exceptions are to be narrowly construed. Article 53(a) is to be invoked only in rare and extreme cases for inventions which would universally be regarded as outrageous and considered as so abhorrent that the public in general would regard that the grant of patent rights would be inconceivable.

The EPO has established that the concept of "ordre public" covers the protection of public security and the physical integrity of individuals as part of society. This concept also encompasses the protection of the environment. Simultaneously, the concept of morality is related to the belief that some behaviour is right and accepted whereas other behaviour is wrong. This belief is found on the totality of the accepted norms deeply rooted in the European culture. Article 6 of the Biotech Directive and Article 53(a) EPC make it clear that the estimation of "ordre public" or morality is not dependent upon any national laws or regulations.

Some general estimating rules have been established concerning moral exclusions through the case law. The *Onco-Mouse* case established the balancing-test whereby patentability is excluded on the basis of morality if the likely "benefit" does not outweigh the likely "costs". The *Relaxin* case created the abhorrent-test, which established that patentability is precluded only if the general public finds the invention so abhorrent as to be inconceivable. The *PGS* case established that the balancing-test is not appropriate in all circumstances. The Onco-Mouse case also reduced general moral consideration to specifics, which makes the scope of the interpretation narrower.

The analysis of the case law reveals that the references that can be made to national laws are estimated differently by the EPO. In some cases, references can be made to national laws and in other cases not. Another difficulty is that EPO has failed to make clear how it could be measured that an invention is abhorrence since the abhorrence-test was only applied in a negative way.

The EPO has made clear that it does not consider surveys and opinion polls to reflect the "ordre public" concerns or moral norms in the European Member States since they easily can be influenced or controlled and tend to reflect only specific interests. However, the analysis indicates that it is the context and not really the empirical validity that creates problems.

The EPO finds that the moral exclusion scope differs between the diverse biotechnology fields according to the case laws, and this tendancy has been strengthened after the introduction of Rule 23(d)[214].

It is doubtful if it is justifiable to have explicit exclusions to "ordre public" and morality since these concerns may change over time and thereby force changes in the Biotech Directive.

It has been argued that it is regrettable to make specified patentability exclusions under Article 6(2) since, for example, processes for modifying the germ-line identity of human beings by germ-line therapy perhaps one day can cure a number of diseases which are hereditary. One can therefore reason that it is conservative and short-sighted to exclude from patentability processes which might have such a substantial benefit to mankind.

Additionally, one could imagine that this will make Europe fall behind in the development of these excluded procedures, since there would be no economical benefits to the inventor, and this would be in contrast to the purpose of the Biotech Directive.

[214] A summary to each separate field is found in the corresponding Human, Animal or Plant chapter

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