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**Biotechnological Inventions – A
Comparison between the Patent Systems of
Europe and the United States**

Christine Reiter

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Abstract

Reaching everything from medicine to the food industry, biotechnology's impact on society has become a major economic factor and is ever-increasing. In addition to its impressive potential benefits, biotechnology carries serious risks, especially regarding security and ethics. The European Patent Convention includes statutory restrictions regarding morality and public policy, while today's U.S. laws in contrast, try to avoid morality restrictions in patenting biotechnology and U.S. agencies generally grant patents without regard to moral concerns. Not long ago, the U.S. Patent Act included a morality doctrine which had a restrictive effect on biotechnology.

The new U.S. approach applies to micro-organisms, plants, and animals where moral concerns were not considered at all before the United States Patent and Trademark Office. It is not clear, if the moral questions re-emerged referring to the Newman/Rifkin patent application, claiming an animal-human chimera, since the application was finally rejected on the grounds that human beings do not constitute statutory subject matter under 35 U.S.C. § 101. This line of argumentation was a break from the developed case law concerning living matter. The attempt to keep ethical concerns out of the U.S. patent laws stands on very shaky grounds.

Another problem arises from the fact that both patent systems, in Europe and the U.S., are relying on the term "human" as a borderline for patentability but none of them define the term "human" which leads to ambiguities. An interesting approach came up, defining a human being not by its biological criteria but rather by its intellectual capabilities. However, this approach is still in its infancy.

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“Imagine a world without cancer, heart disease, or arthritis. Or imagine that the same world could produce food crops able to flourish in salt water and disease-resistant poultry that grow twice as big on the same amount of food. Biotechnology research and development could very well lead to such a world.”¹

1. Introduction

It is a dream-come-true; biotechnology is an applied science with an ever-increasing impact on society. Gene technology is one area of biotechnology, which now applies to a wide spectrum of fields ranging from the medical to the food industry. For example, biotechnology has led to important new applications in the therapy of hereditary diseases, the production of modern pharmaceutical products and vaccines, and ultimately, the breeding of transgenic animals inter alia for drug development. By allowing for the creation of insect- and virus-resistant plants, biotechnology has become an essential part of agriculture. In the environmental field, biotechnology has brought about the development of pollution-eating microbes capable of numerous functions, such as cleaning hazardous waste or extending the shelf-life of fruits and vegetables. Another well-known application of biotechnology is DNA fingerprinting in forensic research.²

Although biotechnology offers an impressive range of benefits, it also introduces serious risks which cannot be overlooked. The critics of biotechnology raise ethical questions and security concerns. Among the concerns is a fear that biotechnology will introduce new

¹ Robert Bohrer, *A Guide to Biotechnology Law and Business* 3 (2007)

² See Joseph Straus, *Genpatente* [Gene Patents] 10ff (1997); see also Tatjana Kleine & Klingelhöfer Thomas, *Biotechnologie und Patentrecht- Ein aktueller Überblick* [Biotechnology and Patent Laws - A Current Review], *Gewerblicher Rechtsschutz und Urheberrecht* [hereinafter GRUR] 1, 1 (2003); see also Elizabeth Hecht, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy over Transgenic Animal Patents continues*, 41 Am. U.L.Rev. 1023, 1036ff (1992); see also Merges Robert, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD.L.Rev. 1051, 1053ff (1988); see generally NC State University, *Biotechnology and its Applications*, available at <http://www.ces.ncsu.edu/depts/foodsci/ext/pubs/bioapp.html> (last visited June 11, 2008)

dangers, such as the uncontrolled or unintentional insemination of genetically engineered organisms. Genetically-engineered organisms could lead to irreversible damage to the ecosystem or could negatively influence the health of human beings, animals, and plants. There are also unsolved ethical questions. Gene technology is at odds with some religious views that regard living organisms as the “Creation of God” and therefore followers of some religions reject any form of human intervention. To make matters worse, much is still unknown about the long-term consequences of gene technology. Furthermore, there is a potential for eugenics, and thus discrimination, against biological diversity on the basis of gene and genomic analysis. Last but not least, the production of transgenic animals could create a novel form of suffering in animals and reduce them to manipulable objects.³

a) Definition of Biotechnology

The definitions of biotechnology are numerous due to the extensive reach of this field of science, but in my mind—and for the purposes of this paper—the following is the most appropriate: “*Biotechnology is a set of technologies that use biological molecules and cells to make products, solve problems, and do research, based upon an understanding of cellular and molecular structure and processes*”.⁴

Under its broadest definition, biotechnology is a discipline that applies biology to human needs.⁵ As early as 10,000 years ago people carried out selective cross-pollination of crops and domestication of animals. The Sumerians and Babylonians already knew how to make beer through processes of fermentation around 4,000 B.C.⁶ In this paper I will narrow down the meaning of biotechnology to a more modern set of disciplines centered around genetic

³See, e.g. Thierry Calame, *Öffentliche Ordnung und gute Sitten als Schranken der Patentierbarkeit von gentechnologischer Erfindungen* [Public Policy and Morality as Bars on Patentability regarding Gene Technological Inventions] 9ff (2001); see generally Biotechnology Industry Organisation, *There's more to biotechnology than science and business*, available at <http://www.bio.org/speeches/pubs/bioethicsbrochure.pdf> (last visited June 10, 2008)

⁴Victoria Sutton, *Law and Biotechnology* 4 (2007)

⁵See, *id.*

⁶*Id.*, at 11

engineering which can be defined as “a technique involving the introduction of changes to the DNA molecule of a living organism without the intervention of natural means of reproduction.”⁷

b) History of Biotechnology

Oswald Avery set the cornerstone of gene technology in 1944 when he discovered that DNA is the material comprising genes and chromosomes. On this basis, James Watson and Francis Crick published their theory of the double helix, while in 1966 Marshall Nirenberg described the genetic code of human beings and in the 1970s Stanley Norman Cohen and Herbert Boyer engineered the first recombinant DNA. In 1985 Kary Mullis discovered the Polymerase Chain Reaction which enables amplification of DNA in vitro in only a few hours. These groundbreaking achievements are only highlights of the vast gene technology research of the last century.⁸

In light of these rapid developments, biotechnology has become a major economic force.⁹ In the U.S., biotechnology has become a billion-dollar industry and has stimulated the establishment and growth of hundreds of businesses.¹⁰

Consequently, there is an intense need for a strong and reliable patent system so businesses can recoup the high costs research which is required in this field.¹¹ The biotechnology industry is a high-risk investment, and patents are important in order for attracting much-needed investors.¹² The European Union became aware of this seminal branch of industry and

⁷ Gateway to the European Union, *European Commission Report of 7 October 2002 on the development and implications of patent law in the field of biotechnology and genetic engineering*, available at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2002&nu_doc=545 (last visited June 19, 2008)

⁸ Kleine, *supra* note 2, at 2.

⁹ See, e.g. Biotechnology Industry Organization, *Biotechnology Industry Facts*, available at <http://www.bio.org/speeches/pubs/er/statistics.asp> (last visited June 8, 2008)

¹⁰ E.g. Jasmine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe and Japan: How much Patent Policy is Public Policy*, 34 *Geo. Wash. Int'l L. Rev.* 223, 224 (2002)

¹¹ E.g. Enerson Benjamin, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 *Cornell L. Rev.* 685, 688f (2004)

¹² E.g. Chambers, *supra* note 10, at 225.

in response adopted “Directive 98/44/EC on the legal protection of biotechnological inventions” (hereinafter Directive 98/44/EC) on July 6, 1998 after a ten-year debate in the European Council and the European Parliament.¹³ Directive 98/44/EC’s major purpose was to harmonize the biotechnology patent laws across all Member States of the European Union. By harmonizing the European patent laws, the law aimed to establish a competitive European market place for inventors and investors in the biotechnology sector as well as to create a clear legal framework to address ethically questionable inventions.¹⁴ The adoption of this Directive was necessary because the European Patent Convention (hereinafter EPC) only offers a harmonized application *process*; this means that once the European patent is granted by the European Patent Office (hereinafter EPO), the patent is treated like a national patent for which the respective national law is applicable. The main provisions of Directive 98/44/EC are also incorporated into the Implementing Regulations to the EPC (hereinafter EPC-Regulations) in 1999 and can be found in the Rules 26 to 29. Additionally Rule 26 (1) sets forth that Directive 98/44/EC shall be used as a supplementary means of interpretation. Notably, Directive 98/44/EC is only binding on European Union Member States but not on the EPO Contracting States. Nevertheless, there is a large overlap between the European Union Member States and the EPC Contracting States. Because all the key biotechnology provisions have also been implemented in the EPC Regulations, the majority of the EPC Member States are affected by Directive 98/44/EC.¹⁵

2. Biotechnology and the Legal Dimension of Ethical Concerns

Especially regarding biotechnology, the question of morality has often arisen in Europe as well as in the United States. While Article 53 (a) of the EPC sets forth that European patents

¹³ Richard Flammer, *Biotechnologische Erfindungen im Patentrecht: Eine Analyse der EU-Richtlinie* [Biotechnological Inventions in Patent Law: An Analysis of Directive 98/44/EC] 22ff, (1999)

¹⁴ *Id.*, see also *Introduction* to Directive 98/44/EC

¹⁵ E.g. Gregory Hagen & Sebastian Gittens, *Patenting Part-Human Chimeras, Transgenics and Stem Cells for Transplantation in the United States, Canada, and Europe*, 14 Rich. J.L. & Tech. 11, 72 (2008)

shall not be granted to inventions the commercial exploitation of which would be contrary to “ordre public” or morality, the U.S. Patent Act does not contain any express statutory restrictions concerning morality or public policy. Instead, the U.S. Patent Act requires utility, which has been interpreted to include a morality doctrine and has had an exclusive effect comparable to the morality limitation of the EPC .¹⁶

a) Ethical Reflexion in the U.S. Patent System

This morality doctrine can be traced back to Justice Story’s judgment in *Lowell v. Lewis*¹⁷ in 1817 where he asserted that “*all that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society*”.¹⁸ Justice Story also gave examples of inventions which are barred from patent eligibility because they lack morality, for instance, an invention to poison people, promote debauchery or assassination.¹⁹ In the nineteenth century, the morality doctrine was often applied to prevent gambling devices or instruments of fraud from gaining patent eligibility.²⁰ In *Ex parte Murphy*²¹ (1977), the United States Patent and Trademark Office (hereinafter PTO) turned away from the morality doctrine. Instead, the PTO regularly granted patents for gambling devices for two main reasons: (1) gambling was no longer seen as immoral, and (2) the PTO became more wary of denying patents on the basis of a vague moral standard, which it saw was subject to significant changes over time.²² In *Ex parte Murphy* the court held that “. . . the Patent and Trademark Office should not be the agency which seeks to enforce a standard of

¹⁶ See Valerie Phillips, *Half- Human Creatures, Plants & Indigenous Peoples: Musing on Ramifications of Western Notions of Intellectual Property and the Newman-Rifkin Attempt to Patent a Half- Human Creature*, 21 Santa Clara Computer & High Tech. L.J. 383, 417ff (2005); see also, Donald S. Chisum & Craig Allen Nard & Herbert F. Schwartz & Pauline Newman & F. Scott Kieff, *Principles of Patent Law* 750f (3rd ed., 2004); see also Calame, supra note 3, at 65; see generally Mark Jagels, *Dr. Moreau has left the Island: Dealing with Human-Animal Patents in the 21st Century*, 23 T. Jefferson L.Rev. 115 (2000)

¹⁷ 15 F. Cas. 1018 (D. Mass. 1817)

¹⁸ E.g. Chambers, supra note 10, at 230.

¹⁹ Phillips, supra note 16, at 422.

²⁰ Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* 45 (2005)

²¹ 200 U.S.P.Q. 801 (Bd. App. 1977)

²² Merges, supra note 2, at 1063.

morality. . . .”²³ In *Whistler Corp. v. Autotronics, Inc.*²⁴ (1988) the PTO decided that a radar detector whose only use was to break the law, did not fail the utility requirement.²⁵

Although the morality doctrine almost disappeared in order to keep in line with the modern perspective of the U.S. patent system,²⁶ the PTO “exhumed” the doctrine at a media advisory on April 2, 1998, where the PTO stated “*inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement*”²⁷ of the U.S. Patent Act.²⁸ However, it is still unclear whether the moral utility doctrine thus re-emerged in U.S. patent law since ultimately it was not used as a legal ground to reject the patent application for a human/nonhuman chimera. Former PTO Commissioner Bruce Lehman declared in 1998 that an invention may meet the utility requirement simply by presenting a scientifically plausible use for the invention.²⁹

Despite the uncertain status of the morality doctrine, the current U.S. law does contain some isolated statutory exclusions that suggest the morality doctrine has survived. For example, the U.S. Patent Act itself stipulates in Section 181 that if the publication or disclosure of an invention might be detrimental to national security, the invention can be kept secret and be withheld. Additionally, 42 U.S.C. Section 2181(a) sets forth that “*no patent shall be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.*”³⁰ The real purpose of these provisions are

²³ *Ex parte Murphy*, 200 U.S.P.Q. 801, 801 (Bd. App. 1977)

²⁴ 14 U.S.P.Q.2d 1885 (N.D. Tex. 1988)

²⁵ Dana Visser, *Who’s Going to Stop Me from Patenting My Six-Legged Chicken? An Analysis of The Moral Utility Doctrine in the United States*, 46 Wayne L. Rev. 2067, 2072 (2000)

²⁶ *Id.*

²⁷ U.S. Patent & Trademark Office, *Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998)* available at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm> (last visited June 10, 2008)

²⁸ See Scott Bennett, *Chimera and the Continuum of Humanity: Erasing the Line of Constitutional Personhood*, 55 Emory L.J. 347, 358f (2006)

²⁹ Enerson, *supra* note 11, at 693.

³⁰ Robert Harmon, *Patents and the Federal Circuit* 63 (8th ed. 2007)

not moral but rather are security concerns about keeping technology out of the hands of those who would misuse them.³¹

b) Ethical Reflexion in the European Patent System

The terms morality and “ordre public” used in the EPC are tailored to exclude exceptionally abhorrent inventions from patent eligibility.³² “Ordre public” represents the essential values prevailing in society³³ and is formed by statutory rules, in contrast to morality.³⁴ The statutory rules can be found in the constitutions of the European states, in international treaties such as the European Convention on Human Rights, and in all kinds of penal provisions aimed at maintaining law and order.³⁵ All these regulations are similar in that they protect basic values like human dignity, individual integrity, public safety, and the environment.³⁶ “Ordre public” and morality are related to each other; a breach of “ordre public” is always combined with a breach of morality.³⁷

In T 356/93,³⁸ the European Patent Office held that *“the concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation.”* In short, morality represents factual rules which have obtained acceptance through social conduct.³⁹

³¹ Merces, supra note 2, at 1067.

³² E.g. Gerald Paterson, *The European Patent System* 441 (2nd ed. 2001)

³³ Calame, supra note 3, at 133.

³⁴ Ulrich Schatz, *Öffentliche Ordnung und gute Sitten im europäischen Patentrecht- Versuch einer Flurbereinigung* [Public Policy and Morality within European Patent Law], GRUR Int. 879, 880 (2006)

³⁵ *Id.*; Rüdiger Rogge, *Patente auf genetische Informationen im Lichte der öffentlichen Ordnung und der guten Sitten* [Patents on Genetic Information in the light of Public Policy and Morality], GRUR 303, 304f (1998)

³⁶ E.g. *The European Patent Convention: A Commentary* 88 (Singer Margarete ed., 3rd ed. 2003)

³⁷ Calame, supra note 3, at 135.

³⁸ European Patent Office, Boards of Appeal Decisions Database, *T 356/93*, available at <http://legal.european-patent-office.org/dg3/biblio/t930356fp1.htm> (last visited June 15, 2008)

³⁹ Schatz, supra note 34 at 885.

In determining whether an invention falls into the definition of being contrary to “ordre public”, the inventor’s intentions for exploitation can be considered. Under European law, if the intended exploitation contravenes basic value provisions or infringes on morality, the patent must be denied. If the invention can be exploited in both legal and illegal ways, the illegal exploitation may not be placed under the control of the inventor. However, a patent for an invention may not be rejected merely because an invention could also be exploited in an illegal way.⁴⁰ To give a few concrete examples, a patent application for a letter bomb must be rejected; there is no imaginable legal way to use this invention. In contrast, an application for a method to break open safes can be patented because a legal use is possible, for example by a locksmith in case of emergency.⁴¹

Whether a claimed invention constitutes an exception to patentability within the meaning of Article 53(a) EPC has to be determined in each particular case on its merits, based on the concepts of "ordre public" and morality as defined above and accordingly on the concept of utility. In the following pages, I will discuss the application of these concepts to biotechnological inventions relating to plants, animals, and human beings.

c) Conclusion

In Europe as well as in the U.S., it is consistently pointed out that neither the EPO nor the PTO are appropriate forums to debate and regulate ethical, social, or moral concerns arising from science and research.⁴² Patent law should be independent from these kinds of issues in

⁴⁰ *Id.*

⁴¹ Singer ed., supra note 36, at 88.

⁴² See, e.g. Enerson, supra note 11, at 720; *contra* European Patent Office, Boards of Appeal Decisions Database, T 19/90, available at <http://legal.european-patent-office.org/dg3/biblio/t900019ep1.htm> (last visited June 15, 2008): “Under the heading "Considerations under Article 53(a) EPC" in the contested decision, the Examining Division argued that patent law is not the right legislative tool for regulating problems arising in connection with genetic manipulation of animals. The Board considers, however, that precisely in a case of this kind there are compelling reasons to consider the implications of Article 53(a) EPC in relation to the question of patentability. The genetic manipulation of mammalian animals is undeniably problematical in various respects, particularly where activated oncogenes are inserted to make an animal abnormally sensitive to carcinogenic substances and stimuli and consequently prone to develop tumours, which necessarily cause suffering. There is also a danger

order to fulfil its task of promoting progress and innovation.⁴³ Policy makers should decide whether a particular technology should be excluded from patent protection or prohibited in general. Policy makers are the appropriate decision makers because they have a duty to balance risks and benefits for society, set boundaries, and establish regulations.⁴⁴ A patent only offers an inventor the right to exclude others from making, using, or selling his invention for a limited time.⁴⁵ The patent serves as an economic incentive and as a means to recoup the initial costs of developing the invention.⁴⁶ The denial of a patent does not legally prohibit the inventor from continuing any research and development in ethically questionable areas. In sum, the EPC includes statutory restrictions regarding morality and public policy, in contrast to the U.S. practice of keeping questions of morality separate from the patent process and generally granting patents for biotechnology without regard for moral concerns.⁴⁷

3. Patentability of Living Matter

a) The Legal Situation in Europe

In principle the EPC does not exclude living matter from patent protection. Before the EPC came into effect, there were several patents granted for inventions involving living matter in Europe.⁴⁸ According to the wording of Article 53 of the EPC, one cannot patent plant and animal varieties, nor can one patent essential biological processes for the production of plants and animals. However, animals or plants *as such* (in particular in another form of

that genetically manipulated animals, if released into the environment, might entail unforeseeable and irreversible adverse effects. Misgivings and fears of this kind have been expressed by a number of persons who have filed observations with the Board under Article 115 EPC. Considerations of precisely this kind have also led a number of Contracting States to impose legislative control on genetic engineering. The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other.”

⁴³ See e.g. *Ex parte Murphy*, 200 U.S.P.Q. 801, 801 (Bd. App. 1977)

⁴⁴ See e.g. Hecht, supra note 2, at 1060ff.

⁴⁵ E.g. Chisum, supra not 16, at 3.

⁴⁶ See *id.*, at 66ff.

⁴⁷ Munzer Stephen, *Human-nonhuman Chimeras in Embryonic Stem Cell Research*, 21 Harv.J.Law & Tec 123, 175 (2007)

⁴⁸ Georg Benkard, *Europäisches Patentübereinkommen* [European Patent Convention] 399 (2002)

appearance besides varieties) are not excluded. The case law of the EPO also supports this literal construction of the Article. For example, the EPO specifically refuses to rule out that certain inventions can be eligible for patents—inventions within the animate nature,⁴⁹ plants and seeds as living matter,⁵⁰ and claims which do not set forth specific plant varieties even though they also embrace plant varieties.⁵¹ Art. 53(b) EPC applies to certain classes of animals, but not to animals *as such*.⁵²

Furthermore, Article 3 (2) of Directive 98/44/EC states that biological material which is isolated from its natural environment or produced by means of a technical process may be patented even if it previously occurred in nature. Article 4 (2) expressly sets forth that inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. These provisions can also be found in Rule 27 of the EPC-Regulations.

b) The Legal Situation in the U.S.

In the United States, *Diamond v. Chakrabarty*⁵³ established that living matter is patentable under 35 U.S.C. § 101. Prior to that landmark decision, living organisms were not eligible for patents since they were considered to be products of nature and were unable to satisfy the requirement of novelty.⁵⁴ In *Diamond v. Chakrabarty*, a patent was granted for a genetically engineered bacterium designed to break down multiple components of crude oil.⁵⁵ At first, the patent application for the bacterium was rejected on two grounds: (1) that microorganisms are “products of nature,” and (2) that they do not represent statutory subject matter under 35

⁴⁹ European Patent Office, Boards of Appeal Decisions Database, *T 49/83*, available at <http://legal.european-patent-office.org/dg3/biblio/t830049ep1.htm> (last visited June 15, 2008)

⁵⁰ European Patent Office, Boards of Appeal Decisions Database, *T 356/93*, supra note 39

⁵¹ European Patent Office, Enlarged Board of Appeal Decisions, *G 1/98*, available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/4831A04A31133EA6C12572C8006DFE59/\\$File/g980001.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/4831A04A31133EA6C12572C8006DFE59/$File/g980001.pdf)

⁵² European Patent Office, Boards of Appeal Decisions Database, *T 19/90*, supra note 43

⁵³ 447 U.S. 303 (1980)

⁵⁴ Thomas Magnani, *The Patentability of Human-Animal Chimeras*, 14 Berkeley Tech. L.J. 443, 447 (1999)

⁵⁵ Chisum, supra note 16, at 776.

U.S.C. §101.⁵⁶ The Board of Appeal affirmed this decision on the second ground and argued that in face of the legislative history relating to the 1930 Plant Patent Act, where Congress extended patent protection to certain asexually reproduced plants, Congress could not have intended to cover living matter within the U.S. Patent Act since doing so would render the Plant Patent Act unnecessary.⁵⁷ Finally, the Court of Customs and Patent Appeal found in favor of the patent applicant.⁵⁸ In making its decision, the Court reasoned that in deciding to use such extensive terms as “manufacture” or “composition of matter” as well as the word “any” in 35 U.S.C. § 101, Congress intended to give the patent laws a wide scope.⁵⁹ The Court went further along this line and construed the four categories laid down in 35 U.S.C. § 101 as “...*anything under the sun that is made by man*”⁶⁰ but also clarified that “*laws of nature, physical phenomena, and abstract ideas*”⁶¹ are not eligible as patentable subject matter.⁶² The applicant’s invention did not constitute a law of nature, physical phenomena, or an abstract idea since it was a microorganism which does not occur in nature, in contrast to the invention in the case *Funk Brothers Co. v. Kalo Inoculant Co.*,⁶³ where the applicant claimed that a mixed culture of naturally occurring bacteria is capable of inoculating the seeds of leguminous plants.⁶⁴ The Court states that “...*their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.*”⁶⁵ Accordingly, the significant distinction between patentable and not patentable is “... *not between living or inanimate things but between products of nature or human made inventions*”.⁶⁶ The invention is not nature’s

⁵⁶ *Id.*

⁵⁷ *Id.*, at 777.

⁵⁸ *Id.*

⁵⁹ *Id.*, at 778.

⁶⁰ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)

⁶¹ *Id.*

⁶² Chisum, *supra* note 16, at 778.

⁶³ 333 U.S. 127 (1948)

⁶⁴ Chisum, *supra* note 16, at 779.

⁶⁵ *Funk Brothers Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)

⁶⁶ *Chakrabarty*, 447 U.S. 303, 313 (1980)

handiwork but man-made.⁶⁷ As a result, non-naturally occurring man-made living microorganisms constitute patentable subject matter under 35 U.S.C. § 101.

Moreover, the Plant Patent Acts of 1930 and 1970 cannot be seen as obstacles to patenting living matter since they were enacted as a response to the U.S. Patent Act, which was not designed to meet the specific needs for plant patent protection (e.g. the requirement of a written description). Furthermore, nothing in the wording or history of the Plant Patent Acts of 1930 or 1970 indicates that they were created to address that 35 U.S.C. § 101 does not encompass living matter.⁶⁸ This landmark decision paved the way for patenting genetically modified organisms and thereby opened the door for the U.S. biotechnology industry.⁶⁹ After *Diamond v. Chakrabarty*, patents were also granted for multi-cellular living organisms such as genetically engineered oysters⁷⁰ or the cancer-prone “Harvard Onco-mouse.”⁷¹

c) Conclusion

As a result, living matter in general is patentable under both the EPC and the U.S. Patent Act, with the latter offering the widest scope of protection for biotechnological inventions worldwide.⁷²

3.1 Plants

a) The Legal Situation in Europe

Article 53 (b) EPC excludes plant varieties from patentability as well as essentially biological processes for the production of plants. As stated before, this does not mean that plants *as such* are ineligible for patent protection.⁷³ The same as is set forth in Article 53 (b) EPC is also stated in Article 4 (1) of Directive 98/44/EC but the Directive also adds in paragraph (2) that

⁶⁷ *Id.* at 310.

⁶⁸ Chisum, *supra* note 16, at

⁶⁹ *E.g.* Phillips, *supra* note 16, at 392.

⁷⁰ *Ex parte Allen*, 846 f.2d 77 (Fed.Cir.1988)

⁷¹ U.S. Patent No. 4,736,866 (filed June 22, 1984)

⁷² Chambers, *supra* note 10, at 226.

⁷³ European Patent Office, Boards of Appeal Decisions Database, *T 356/93*, *supra* note 39

“inventions which concern plants ... shall be patentable if the technical feasibility of the invention is not confined to a particular plant variety.” This provision is identical with Rule 27 (b) of the EPC-Regulations. Rule 26 (4) of the EPC-Regulations defines the term “plant variety” as:

any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

- defined by the expression of the characteristics that results from a given genotype or combination of genotypes,*
- distinguished from any other plant grouping by the expression of at least one of the said characteristics,*
- considered as a unit with regard to its suitability for being propagated unchanged.*

Article 5 of Council Regulation 2100/94 on Community plant variety rights dated July 27, 1994⁷⁴ and Article 1 of the International Convention for the Protection of New Varieties of Plants (hereinafter UPOV), which was signed as early as 1961, define “plant variety” the same way. The UPOV and the Community plant variety rights document offer intellectual property rights which are tailored to the specific needs of plant breeders and provide a more appropriate way to protect plant varieties than a common patent. The plant variety rights offer a protection for all of the genetic information of a plant variety, which can be distinguished from others through its genotype (entirety of all genes in one organism) and whose genetic information can be passed onto the next generations within natural hereditary transmission.⁷⁵

The reason for excluding plant varieties from patent eligibility under the EPC was the existence of the UPOV and the UPOV’s prohibition against dual protection.⁷⁶ In the 1991

⁷⁴ The Community plant variety right is an industrial property right valid throughout the Community granted by the Community Plant Variety Office seated in Angers, France and co-exists with the national regimes in the member states of the European Union. (*See* Community Plant Variety Office, *Its mission*, available at <http://www.cpvo.eu.int/default.php?res=1&w=986&h=566&lang=en&page=ocvv/mission.html> (last visited June 16, 2008))

⁷⁵ Benkard, *supra* note 48, at 402.

⁷⁶ *E.g.* Benkard, *supra* note 48, at 400.

revision of the UPOV, the dual protection prohibition was overruled but the EPC provision remained in force.⁷⁷

The Enlarged Board of Appeals of the EPO stated that the extent of the EPC's exclusion of plant varieties corresponded with the plant variety right protection.⁷⁸ In conclusion, a patent is not available for a specific plant variety but can be granted if the application is for a plurality of plants which also encompasses plant varieties since the UPOV and the Community Plant Variety Right do not offer protection for technical inventions that can be implemented in several plant varieties.⁷⁹ Moreover, plant cells are not covered by the term "plant variety" and are patentable subject matter under the EPC.⁸⁰ Within the plant variety protection, it is irrelevant how the plant variety was produced; therefore, genetically engineered plant varieties are also excluded from patentability.⁸¹

b) The Legal Situation in the U.S

The U.S. also recognizes that the utility patent may not be the best-tailored intellectual property right for plants varieties, especially not to fulfil the U.S. requirements of an enablement and written description.⁸² On this ground, the Plant Patent Act of 1930⁸³ (hereinafter PPA), which extended plant protection to certain asexually reproduced plants, and the Plant Variety Patent Act of 1970⁸⁴ (hereinafter PVPA), which extended protection to certain sexually produced plants, were enacted to ease these requirements.⁸⁵ On the other

⁷⁷ E.g. Singer ed., supra note 36, at 93.

⁷⁸ European Patent Office, Enlarged Board of Appeal Decisions, *G 1/98*, supra note 51

⁷⁹ *Id.*

⁸⁰ European Patent Office, Boards of Appeal Decisions Database, *T 356/93*, supra note 39

⁸¹ European Patent Office, Enlarged Board of Appeal Decisions, *G 1/98*, supra note 51

⁸² See Scott Locke, *Intellectual Property for the Botanist and the Plant Breeder: An Overview of Protection Afforded by Plants Patents and Plant Variety Protection Certificates*, 6 Chi.-Kent J. Intell. Prop. 198, 199f (2007)

⁸³ 35 U.S.C. 161-64 (1994 & Supp. V 1999)

⁸⁴ 7 U.S.C. 2321-2583 (2000)

⁸⁵ Locke, supra note 76, at 199f.

hand, these Acts do not offer as broad protection as a utility patent does.⁸⁶ This fact has made plant breeders feel discriminated against.⁸⁷ Furthermore, at the time of enactment of the PPA it was not clear if plants were also eligible for patent protection under 35 U.S.C. § 101.⁸⁸ In *ex parte Hibberd*⁸⁹ as well as in the Supreme Court decision *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*,⁹⁰ it was held that plant variety protections are offered as an alternative to utility patents but they do not impede the applicant from also receiving a utility patent for his invention.⁹¹ Hence, plants or plant varieties can be protected simultaneously under the U.S. Patent Act, the PPA, and the PVPA. This is a significant difference concerning plant protection between the system in Europe and the United States, since plant varieties are expressly excluded from patentability under the EPC.

c) Patentability of processes to produce plants in the U.S, and Europe

The U.S. Patent Act does not establish any restrictions on the patentability of processes if they fulfil the general requirements (novelty, non-obviousness, utility, disclosure, written description, and best mode). As stated in *Diamond v. Chakrabarty*, the decisive criterion for whether an invention is patentable is that the invention has to be man-made and not just represent a product of nature. Consequently, a man-made product which does not occur in nature is patentable under 35 U.S.C. § 101, irrespective of whether it is produced by means of genetic engineering or by traditional breeding methods.⁹² In contrast, Article 53 (b) EPC excludes from patentability processes that are essentially biological for the production of plants and animals. Consequently, processes used in the production of plant and animals that

⁸⁶ Chisum, supra note 16, at 804.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ 227 U.S.P.Q. (BNA) 443

⁹⁰ 534 U.S. 124 (2001)

⁹¹ Locke, supra note 76, 211 f.

⁹² Sommer Tine, *Patenting the Animal Kingdom? From Cross-Breeding to Genetic Make-Up and Biomedical Research* IIC 165 (2008)

are not essentially biological are patentable. It is important to note that this provision only relates to the production of plants and animals and not to plant and animal varieties.

What did the drafters of this provision mean by “essentially biological”? In accordance with the drafting of the provision, the term “biological” was used as the opposite of “technical”,⁹³ this can be seen as a stress on the “technical character,” which an invention must have in order to be patentable under the EPC.

Whether a process constitutes a non-essentially biological process is a question of the totality of human intervention and its impact on the result achieved.⁹⁴ The requirement “non-essentially biological” is not fulfilled merely by “a” human intervention, such as the artificial pollination of plants, nor is it at issue whether such intervention is qualitative or quantitative.⁹⁵ A process is deemed to be non-essentially biological if it does not occur in nature or coincide with classical breeding methods.⁹⁶ This is also laid down in Article 2 (2) of Directive 98/44/EC on the legal protection of biotechnological inventions which states that “*a procedure for the breeding of plants and animals shall be defined as essentially biological if it is based on crossing and selection*”. This is similar to Rule 26 (5) of the Implementing Regulations to the EPC which stipulates that “*a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.*” To give a concrete example: a process for the production of transgenic animals with an increased susceptibility to cancer due to insertion of an oncogene into the genome constitutes a non-essentially biological process (“Harvard Onco-mouse”)⁹⁷ and is patentable, since the process includes at least one fundamental technical step, which could not be carried

⁹³ *Id.*

⁹⁴ European Patent Office, Boards of Appeal Decisions Database, *T 0320/87*, available at <http://legal.european-patent-office.org/dg3/biblio/t870320ep1.htm>

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ European Patent Office, Boards of Appeal Decisions Database, *T 19/90*, supra note 43

out without human intervention and which has a decisive effect on the final result⁹⁸ This contrasts with the typical process performed by an animal breeder who seeks to produce animals with desired characteristics by selecting animals with these specific or dominant characteristics and breeding them.⁹⁹

Not only are non-essentially biological processes for the production of plants and animals eligible for patentability within the EPC, but so are “*microbiological processes or the products thereof*” as is expressly stated in Article 53 (b). The reason for expressly excluding microbiological processes from the exception to patentability is the key role that they play in the development of drugs.¹⁰⁰ Moreover, micro-organisms can hardly be classified as plants or animals.¹⁰¹ According to the Boards of Appeal, micro-organisms are “*not only bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory, including plasmids and viruses.*”¹⁰²

According to the case law of the Boards of Appeal of the EPO, the phrase “*microbiological processes or the products thereof*” constitutes an “*exception to the exception*”¹⁰³ that plant and animal varieties are excluded from patent protection.¹⁰⁴ Therefore, patent protection is accessible to plant and animal varieties if they are produced by microbiological processes.¹⁰⁵

This construction is disputable due to the background of the provision (it was created as a counterpart to the plant variety protection of the UPOV).¹⁰⁶ The UPOV requires that a plant

⁹⁸ European Patent Office, Boards of Appeal Decisions Database, *T 356/93*, supra note 39

⁹⁹ Sellers Michael, *Patenting Nonnaturally Occurring, Man-Made Life: A Practical Look at the Economics, Environment, and Ethical Challenges Facing Animal Patents*, 47 Ark. L. Rev. 269, 270 (1994); Sommer, supra note 86, at 153.

¹⁰⁰ Mills, supra note 21, at 72.

¹⁰¹ Berkard, supra note 48

¹⁰² European Patent Office, Boards of Appeal Decisions Database, *T 356/93*, supra note 39

¹⁰³ Paterson, supra note 32, at 449.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*, European Patent Office, Boards of Appeal Decisions Database, *T 356/93*, supra note 39

¹⁰⁶ Paterson, supra note 32, at 449.

variety shall be new, distinct, uniform, and stable,¹⁰⁷ irrespective of the way the plant variety is produced. Hence plant varieties made by microbiological processes should also be unpatentable. Therefore, the phrase “*microbiological processes or the products thereof*” should be interpreted as relating to the production of plants and animals and not as an exception to the general provision which renders plant and animal varieties unpatentable. The Enlarged Board of Appeal of the EPO stated in its decision G 1/98¹⁰⁸ that a plant variety which was created by genetic manipulation is excluded from patentability because plant varieties are not eligible for patent protection regardless of the way they were created (here moving away from the notion that the phrase “*microbiological processes or the products thereof*” should be construed as an exception to the unpatentability of plant varieties). However, it argued that processes of genetic engineering are not the same as microbiological processes since the parts of living beings used for the genetic modification of plants do not constitute micro-organisms. This last statement was redundant in the Enlarged Board’s line of argumentation because the Enlarged Board had already held the position that all plant varieties were to be excluded regardless of how they were created. Hence, there should have been no reason to indicate that this variety was not created by a microbiological process. After arguing that processes of genetic engineering can not be equated with microbiological processes, a distinction between these kinds of processes had to be made. Rule 26(6) of the Implementation Regulations to the EPC defines a microbiological process as “*any process involving or performed upon or resulting in microbiological material.*” As stated above, human, animal and plant cells also fall into the category of micro-organisms according to the case law of the EPO. According to the Oxford Dictionary of Biology, cells are “*structural and functional units of most living organisms*”¹⁰⁹ and also represent parts of living beings. Moreover, case law has established that “microbiological processes” include the manipulation

¹⁰⁷ UPOV Article 5

¹⁰⁸ European Patent Office, Enlarged Board of Appeal Decisions, *G 1/98*, supra note 51

¹⁰⁹ *Oxford Biology Dictionary* 111 (Elizabeth Martin & Robert Hine, eds., 6th ed. 2008)

of micro-organisms by genetic engineering.¹¹⁰ On the basis of these facts, the argument of the Enlarged Board of Appeal is not clear at all.

Case T 356/93 prompted the question of whether one microbiological step in a process involving several stages would render the whole procedure a “microbiological process”. It was concluded that a technical process including a microbiological step is not automatically a “microbiological process” irrespective of the decisive impact the microbiological step has on the final result.¹¹¹

All in all, Article 53 (b) EPC and the corresponding case law concerning the patentability of plants lack clarity as a result of vague terms like “essentially biological processes,” “variety” and “micro-biological processes.” The original reason for the exclusion of plant varieties was already rendered redundant in 1991 when the UPOV was revised and the prohibition of dual protection contained therein was rescinded. Moreover the term “essentially biological” is an antonym of technical or a synonym of non-natural; under the EPC a technical character is a prerequisite for the patentability of an invention. A possible solution that could make things clearer for applicants would be to cancel Article 53 (b) and to accept the patentability of plants under the EPC in general while also retaining the specific plant variety rights.¹¹² Under this alternative, applicants could personally choose which system would offer the best scope of protection for their inventions.

Even though an invention concerning plants may manage to pass the hurdle of Article 53 (b) by not falling within the category of plant variety or essentially biological processes, its patent application may still be rejected on the basis of Article 53 (a) which prohibits inventions

¹¹⁰ “...not only traditional fermentation and biotransformation processes, but also the manipulation of micro-organisms by genetic engineering or fusion techniques, the production or modification of products in recombinant systems, etc., i.e., briefly, all activities in which an integrated use is made of biochemical and microbiological techniques, including genetic and chemical engineering techniques, in order to exploit the capacities of microbes and cultured cells. Therefore, as an example, genetic engineering processes carried out on vegetable cells may be defined as ‘microbiological processes’ and their products, namely genetically-modified vegetable cells and their cultures, may be defined as ‘the products thereof’.” (European Patent Office, Boards of Appeal Decisions Database, T 356/93, supra note 39)

¹¹¹ *Id.*

¹¹² Geertrui Overwalle, *Patent Protection for Plants: a Comparison of American and European Approaches*, 39 IDEA 143, 177 (1999)

whose exploitation would be contrary to “ordre public” and morality. With regard to plants, the morality issue came up for the first time in the case T 320/87¹¹³ in 1992.¹¹⁴ The patent application concerned plants whose nutritive value went beyond that of unmodified plants.¹¹⁵ This patent was opposed based on the exclusion on grounds of morality under the EPC. The Opposition Division did not follow this approach and stated that Article 53 (a) only refers to cases which are considered particularly abhorrent.¹¹⁶ Furthermore, these plants serve an important human need, namely to reduce food shortage in the world.¹¹⁷

The concept of “ordre public” encompasses public security, the physical integrity of individuals, and the protection of environment.¹¹⁸ In the decision T 356/93,¹¹⁹ the Board of Appeals stated that a patent for plants can be rejected if the exploitation of the invention is likely to seriously prejudice the environment.¹²⁰ The main concern is that genetically modified plants, once released in the environment, could possibly disturb the ecological balance.¹²¹

Article 6 of Directive 98/44/EC sets forth an exemplary list of activities so as to provide a general guide to interpreting the terms “ordre public” and morality but makes no reference to plants therein. This suggests that there may be a lower standard of morality applied to plants than to animal or human-related inventions, which are expressly mentioned in this list.¹²²

In the United States,, patent opponents pointed out potential risks for the natural ecosystem resulting from the release of genetically manipulated organisms into the environment, but these concerns have never presented an obstacle to granting patent protection for plants.¹²³

¹¹³ European Patent Office, Boards of Appeal Decisions Database, T 320/87, supra note 94

¹¹⁴ Mills, supra note 21, at 61.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ Paterson, supra note 32, at 436; Mills supra note 21, at 62.

¹¹⁹ European Patent Office, Boards of Appeal Decisions Database, T 356/93, supra note 39

¹²⁰ Singer ed., supra note 36, at 89.

¹²¹ Mills, supra note 20, at 15.

¹²² *Id.* at 131f

¹²³ *See, e.g.* Sellers, supra note 99, at 289f.

3.2 Animals

In contrast to the protection for plant varieties, there is no corresponding protection for animal varieties in either the U.S. or in Europe.

a) The Legal Situation in Europe

There are two major provisions relating to animals that are of primary importance within the EPC: Article 53 (a) which excludes inventions from patentability if their commercial exploitation would be contrary to "ordre public" or morality and Article 53 (b) which stipulates that animal varieties and essentially biological processes for the production of animals are not eligible for patenting. The reason for excluding animals varieties and essentially biological processes for the production of animals was the awareness that ordinary patent protection may not be ideal for the traditional breeding of animals and the results thereof, especially with regard to the requirement of reproducibility.¹²⁴

According to the Board of Appeals of the EPO "*the exception to patentability under Article 53(b) EPC applies to certain categories of animals but not to animals as such.*"¹²⁵ This principle also arises from the provision in Article 4 (2) of Directive 98/44/EC, which provides that inventions relating to animals can represent patentable subject matter if the technical feasibility of the invention is not restricted to a particular animal variety.

With respect to legal certainty it was argued that the principles relating to plant varieties should also be applied to animal varieties even though an intellectual property right to protect animal varieties does not exist.¹²⁶ In light of this, interpreting the term "animal variety" in a narrower way than "plant variety" would also be justifiable.

In fact the exact meaning of the term "animal variety" raises problems due to differences in the official languages of the EPC. Article 177 (1) EPC stipulates that the languages English,

¹²⁴ Singer ed., supra note 36, at 97.

¹²⁵ European Patent Office, Boards of Appeal Decisions Database, *T 19/90*, supra note 43

¹²⁶ *E.g.* European Patent Office, Enlarged Board of Appeal Decisions, *G 1/98*, supra note 51

French, and German shall be equally relevant. The problem is that each official language uses different terms (“animal varieties” in English, “races animales” in French and “Tierarten” in German): each of them illustrate a different taxonomic class of animals.¹²⁷ The German term which can be translated as “animal species” gives Article 53(b) the widest possible exclusionary effect and encompasses the other terms “variety” and “races”. Strict application of Article 177(1) EPC “*would lead to the absurd result that the outcome of an Article 53(b) EPC objection would depend on the language of a case, with German having the highest taxonomic order "species" and thereby offering the widest objection.*”¹²⁸ Very likely this was not the original intention of the drafters of the EPC.

In T 90/19 the Board of Appeal ignores that literal problem by simply stating that the “Harvard Onco-mouse” obviously refers to a taxonomic category of animals higher than “species” which illustrates the broadest definition that could be given to the animal exclusion in Article 53(b) EPC.¹²⁹

Concerning the exclusion of essentially biological processes for the production of animals, I want to refer to the examples above in conjunction with plants.

b) The Legal Situation in the U.S.

The U.S. Patent Act is silent when it comes to patenting of animals. As mentioned above, the landmark decision *Diamond v. Chakrabarty* in 1980 established that non-naturally occurring living micro-organisms that are man-made are patentable under 35 U.S.C. §101. In reliance on this, case law expanded patentability from unicellular to multicellular micro-organisms in *Ex parte Hibberd*,¹³⁰ where the Board of Patent Appeals and Interferences of the PTO held that non-naturally occurring man-made multicellular plants are eligible for patentability.

¹²⁷ European Patent Office, Boards of Appeal Decisions Database, T 0315/03, available at <http://legal.european-patent-office.org/dg3/biblio/t030315ex1.htm> (last visited June 15, 2008)

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ 227 U.S.P.Q. 443 (Bd.Pat.App. & Int.1985)

Finally, in *Ex parte Allen (1987)*¹³¹, a method for inducing polyploidy in oysters, which demonstrated increased growth, and the genetically engineered oysters produced by that method, were subjects of a patent application.¹³² Although the application was rejected because the invention did not fulfil the requirement of non-obviousness, the Federal Circuit stated in its decision that the oysters in the claim constituted patentable manufactures or compositions of matter within the terms of 35 U.S.C. §101 because they are not naturally occurring and consequently are encompassed by the wide construction of patentable subject matter laid down in *Diamond v. Chakrabarty*.¹³³ This judgment extended patentability status to higher animals. Shortly after that decision, the PTO released an announcement concerning the patentability of living organisms and clarified that “... *Congress intended statutory subject matter to include anything under the sun that is made by man. The Patent and Trademark Office now considers nonnaturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. ...An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature...*”¹³⁴ The notice expressly referred to the decisions *Diamond v. Chakrabarty*, *Ex parte Hibberd* and *Ex parte Allen*.¹³⁵ In response to that notice by the Commissioner of the PTO, several animal rights groups, individual farmers and animal husbandry groups filed suit challenging the rule promulgated by the PTO.¹³⁶ The background to this suit was the desire to prevent the patenting of animals for moral and economic reasons; animal rights groups opposed animal patenting due to concerns about increased animal suffering and potential environmental risks. Meanwhile, small farmers feared for their

¹³¹ 2 U.S.P.Q.2d 1425 (Bd.Pat.App. & Int.1987)

¹³² *Id.*

¹³³ Sellers, *supra* note 99, at 279.

¹³⁴ 1077 Official Gazette Pat. Office 24 (Apr. 21, 1987)

¹³⁵ Sellers, *supra* note 99, at 281.

¹³⁶ *Id.* at 283ff.

survival as small businesses unable to compete with large corporations who would be able to afford the technology and animal patenting of a new agricultural industry.¹³⁷

Finally, the Federal Circuit held that the plaintiffs lacked standing to sue.¹³⁸ With this decision, the Federal Circuit clarified that the general public does not have an interest in the statutory limitations to patentability and thus avoided addressing ethical concerns regarding the patenting of animals.¹³⁹ This denial of standing means that the only groups which could potentially challenge the validity of animal patents are biotechnology enterprises, who usually welcome the development of animal patenting.¹⁴⁰

The suit did not succeed, but raising the issue of animal patenting had a major public impact, especially regarding the ethical concerns.¹⁴¹ The strongest moral opposition to animal patenting is based on beliefs that it will increase animal suffering.¹⁴² Patent supporters counter that animal suffering can be reduced by the production of genetically engineered disease-resistant animals and that the prohibition of animal patenting would be rather hypocritical in face of the accepted notions of human control of animals in today's society humans buy, sell and eat animals as well as using them for many different kinds of research.¹⁴³

c) The “Harvard Onco-mouse” patent

The policy of the PTO paved the way for the patenting of transgenic animals. In 1988, the U.S. patent for the famous “Harvard Onco-mouse” was granted: this is a genetically engineered mouse which is highly susceptible to cancer, thus facilitating cancer research. The mouse is produced by insertion of a human oncogene into the genome of the animal. This also raised questions concerning the dividing line between human and non-human living matter,

¹³⁷ Hecht Elizabeth, *supra* note 2, at 1025

¹³⁸ Chambers, *supra* note 10, at 299.

¹³⁹ *Id.*

¹⁴⁰ Hecht, *supra* note 2, at 1073

¹⁴¹ *See* Sellers, *supra* note 99, at 290ff.

¹⁴² Hecht, *supra* note 2, at 1025.

¹⁴³ Sellers, *supra* note 91, at 287.

which spurred a public debate in the U.S. as well as in Europe.¹⁴⁴ In contrast to the PTO, the Examining Division of the EPO rejected the patent application for the “Harvard Onco-mouse”, initially on the basis of Article 53 (b) EPC, which excludes animal varieties from patentability. The Board of Appeal disagreed with this overall evaluation and pointed out that according to Article 53(b) animal varieties are unpatentable, but not animals themselves.¹⁴⁵ With reference to Article 53(a), which prohibits issuing patents to inventions contrary to morality or “ordre public”, the Board of Appeal stated that the decision as to “...*whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other.*”¹⁴⁶ Applying this test, the Examination Division came to the conclusion that the potential medical benefits for human beings from the cancer research outweighed the animals’ suffering, as well as the risks concerning the release of genetically modified organisms into the environment.¹⁴⁷ As a result, the European patent for the “Harvard Onco-mouse” was granted.¹⁴⁸ The Board of Appeals’ balancing-test was developed into a statutory concept with subtle differences in Article 6(2) (d) of Directive 98/44/EC, which stipulates that “...*processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes*” are considered to be inventions contrary to “ordre public” or morality and are therefore unpatentable.¹⁴⁹ This provision can also be found in Rule 28(d) of the EPC-Regulations.

¹⁴⁴ Rimmer Matthew, *Intellectual Property and Biotechnology* 89f, (2008)

¹⁴⁵ European Patent Office, Boards of Appeal Decisions Database, *T 19/90*, supra note 43

¹⁴⁶ *Id.*

¹⁴⁷ Rimmer, supra note 144, at 90.

¹⁴⁸ *Id.*

¹⁴⁹ Sommer, supra note 92, at 156.

Of course, patent law cannot prevent animals from being tortured or even killed for the sake of scientific research without any medical benefits, but patent law can contribute to improving the situation by denying the economic incentives that a patent provides.¹⁵⁰

d) Conclusion

In contrast to the U.S. patent system, the EPC contains a legal moral dimension regarding animal patenting and deals with patenting animals on a case-by-case basis.

3.3 Human-Related Inventions

This field of biotechnology clearly ranks as one of the most controversial in the U.S. as well as in Europe. Unlike the patent laws in Europe¹⁵¹, the U.S. Patent Act does not provide any statutory regulation concerning human-related inventions.

a) The Legal Situation in the U.S.

In 1987, after *Ex parte Allen*, the PTO announced that the PTO "...now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101."¹⁵² The PTO expressly excluded human beings from patent eligibility since a property right in a human being is not compatible with the Thirteenth Amendment of the U.S. Constitution, which sets forth that "[n]either slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction" and bans property rights on human beings, but the PTO did not define the concept of human being itself, thus leaving some ambiguity.¹⁵³

¹⁵⁰ Flammer, *supra* note 13, at 153.

¹⁵¹ See Directive 98/44/EC Article 5 and 6; *see also* EPC 53(a) (2000); *see also* Implementing Regulations Rule 20 (2000)

¹⁵² 1077 Official Gazette Pat. Office 24 (Apr. 21, 1987)

¹⁵³ See Magnani, *supra* note 54, at 448.

As explained before, *Ex parte Allen* paved the way to patenting transgenic animals such as the “Harvard Onco-mouse,” which was the first animal manipulated by the insertion of a human gene to be patented.¹⁵⁴ After that, many patents were issued for transgenic animals with human genes, also for larger animals such as sheep or pigs.¹⁵⁵

Patents on human cell lines or transfected cells including human DNA sequences are also widely accepted.¹⁵⁶ Cell lines are fully human cells which contain the entire human genome.¹⁵⁷ In the beginning, these patents were subject to criticism since they were seen as merely discovered but not invented.¹⁵⁸ The PTO countered that even if the genetic material itself has not been invented, its discovery can form the basis for obtaining a patent on a gene that is isolated by human intervention from its natural state by purifying the gene and separating it from other molecules naturally associated with it as long as the application “discloses a specific, substantial, and credible utility”¹⁵⁹. This resembles the approach set forth in Article 5 (2) and (3) of Directive 98/44/EC which declares that isolated sequences or a partial sequence of a gene can constitute patentable subject matter if the industrial application of such is disclosed in the patent application. Like the EPO, the PTO does not show any ethical concerns regarding the patenting of human DNA.

Finally, in 1998 Stuart Newman and Jeremy Rifkin filed a patent application with the PTO for a technique for combining human and animal embryonic cells to form an animal-human chimera.¹⁶⁰ A chimera is defined as a single organism consisting of a mixture of two or more genetically distinct organisms of the same or different species.¹⁶¹ The term goes back to Greek mythology where a Chimera was a fire-breathing monster having a lion's head, a goat's body

¹⁵⁴ Jagels, supra note 16, at 132.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ Hagen, supra note 15, at 44.

¹⁵⁹ *Id.*

¹⁶⁰ Jagels, supra note 16, at 133.

¹⁶¹ Munzer, supra note 47, at 124.

and a serpent's tail.¹⁶² Compared with a hybrid, which is a genetic cross between a female of one species and a male of another and whose entire cells are mixtures of these different species, a chimera consists of some cells from one species and some from the other, so that each cell can be classified as being from one of these species.¹⁶³

On the scientific front, chimeras could be useful for serving as testing models for future therapies or to produce human organs and tissues which could then be transplanted into human beings.¹⁶⁴

The primary objective of this patent application was not to obtain a patent for their invention but to spur public debate on the ethical concerns regarding patenting life forms.¹⁶⁵ Newman and Rifkin hoped that the patent application would get rejected on moral grounds, and calculated that in the event that they obtained a patent for their invention, they would still be able to prevent scientists from creating chimeras for at least twenty years.¹⁶⁶ They obviously achieved their goal since the PTO issued a media advisory in response to the extensive public interest roused by the patent application. The PTO declared "*inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement*"¹⁶⁷. The PTO rejected the patent application, not for failing to meet the utility requirement but, among other reasons, for failing to meet the requirement of establishing statutory subject matter. According to the PTO, Congress did not intend to include human beings under Section 101 U.S. Patent Act.¹⁶⁸ This interpretation of 35 U.S.C. §101 is clearly contradictory to the decision in *Diamond v. Chakrabarty*, which stated that the decisive question in the patentability of an invention is whether the invention is man-

¹⁶² *Id.*

¹⁶³ Magnani, *supra* note 54, at 445.

¹⁶⁴ Munzer, *supra* note 47, at 130.

¹⁶⁵ *See* Enerson, *supra* note 11, at 693.

¹⁶⁶ Magnani, *supra* note 54, at 443.

¹⁶⁷ U.S. Patent & Trademark Office, *Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998)*, available at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm> (last visited June 10, 2008)

¹⁶⁸ Jagels, *supra* note 16, at 134.

made. The chimera subject of the application is obviously man-made since such a creature does not exist in nature, and consequently it fulfils the requirement of patentable subject matter according to the established case law. Clearly, the PTO was trying to avoid reintroducing the moral utility doctrine by arguing this way.

The revised Manual of Patent Examining Procedure 2003 corresponds with the position of the PTO regarding the Newman/Rifkin application and sets forth that “[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter”¹⁶⁹

b) The Legal Situation in Europe

Within the EPC and at European Community level, there are several statutory regulations which have to be considered in regard to human-related inventions. Within the EPC, it is Article 53(a) as well as Rule 20 of the EPC-Regulations. As mentioned before, Article 53(a) excludes from eligibility for patenting any inventions whose commercial exploitation would be contrary to "ordre public" or morality. Article 6 (2) of Directive 98/44/EC makes these terms concrete with respect to human-related inventions and sets forth an exemplary list of activities which are considered unpatentable.¹⁷⁰ These activities, which probably represent the most sensitive fields of biotechnological inventions in regard to humans, are processes for cloning human beings¹⁷¹, processes for modifying the germ line genetic identity of human

¹⁶⁹ Manual of Patent Examining Procedure 2105 (2003)

¹⁷⁰ Directive 98/44/EC Article 6 (2): “On the basis of paragraph 1, the following, *in particular*, shall be considered unpatentable...”

¹⁷¹ Cloning is the process of creating an organism that is an exact genetic copy of another organism. One can distinguish between two main types of cloning, reproductive and therapeutic cloning, which differ as regards their purpose. Reproductive cloning is aimed at producing an organism that is genetically the same as another currently or previously existing organism. The technique by which cloning is accomplished is the so-called “somatic cell nuclear transfer” (SCNT). Within this technique, genetic material is transferred from the nucleus of a donor adult cell to an egg whose nucleus has been removed. Once the cloned embryo reaches an appropriate stage, it is implanted into the uterus of a female host where it continues to develop until birth. In contrast, therapeutic cloning does not intend to create a fully-grown organism but to produce embryos in order to harvest embryonic stem cells which are very useful in research, as discussed above. These embryonic stem cells are

beings and the use of human embryos for industrial or commercial purposes. The identical provisions can also be found in Rule 28 of the EPC-Regulations.

Article 3 (2) of Directive 98/44/EC as well as Rule 27 (a) of the EPC-Regulations state that *“biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature”*. Article 5, which is identical to Rule 20 of the EPC-Regulations, clarifies in (1) that *“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”*, in (2) that *“an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”* and in (3) that *“the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application”*.

Article 5 (1) of Directive 98/44/EC was one of the most controversial provisions.¹⁷² This provision aims to provide the broadest solution in order to leave no doubt that human beings are excluded from patentability.¹⁷³ The intention behind this exclusion consists solely of ethical grounds.¹⁷⁴ On the one hand, the human body at the various stages of its formation and development is expressly excluded; on the other hand, it can be derived from Article 6 (2) (c) that embryos are eligible for patentability if they are used for purposes other than commercial or industrial purposes. These provisions can be construed as contradictory since embryos also represent a stage of formation and development of the human body and, therefore should not be patentable at all. Following this point of view, the human fertilized egg or totipotent stem

removed from the embryo at a very early stage, this process results in the death of the embryo which raises strong ethical concerns. It is often argued that allowing therapeutic cloning is the slippery stone to reproductive cloning. (The President’s Council on Bioethics, *Cloning*, available at http://bioethics.gov/topics/cloning_faq.html (last visited June 16, 2008))

¹⁷² Flammer, supra note 13, at 138.

¹⁷³ *Id.*

¹⁷⁴ Singer ed., supra note 36, at 100.

cells should not be patentable either since they have the potential to develop into a human being.¹⁷⁵ The decisive question is when human life begins for the purposes of patenting.¹⁷⁶ Article 5 (2) Directive 98/44/EC is of eminent importance regarding the production of pharmaceuticals.¹⁷⁷ This importance arises from the provision that elements of human beings which are isolated from their natural state by purification and separated from their natural environment are eligible for patentability.¹⁷⁸ The phrase “*even if the structure of that element is identical to that of a natural element*” seems to contradict the general principle that mere discoveries are not patentable since the elements in question already existed in nature.¹⁷⁹ This contradiction dissipates when one reads Article 5 (2) in conjunction with Article 5 (1), which stipulates that a simple discovery of elements of the body is unpatentable. The decisive criterion in Article 5 (2) which renders an element of the human body a patentable invention is contained in the term “isolated.”¹⁸⁰ Consequently, it is the process of isolation which separates the element of the human body from its natural environment, thus making the discovery a patentable invention.¹⁸¹ Nevertheless, it can be argued that an element of the body remains the same no matter whether it is isolated or not.¹⁸²

Article 5 (3) is a special provision regarding sequences or partial sequences of a gene; its regulations state that it is not enough to claim a sequence or a partial sequence of a gene without declaring its concrete industrial application.¹⁸³ In order to fulfil this requirement, the applicant has to clarify which protein or partial protein is produced as well as what specific

¹⁷⁵ Hagen, *supra* note 15, at 26.

¹⁷⁶ *Id.*

¹⁷⁷ Flammer, *supra* note 13, at 140

¹⁷⁸ *See* Singer ed., *supra* note 36, at 100.

¹⁷⁹ Guiseppa Sena, *Directive on Biotechnological Inventions: Patentability of Discoveries*, 731 ICC (1999)

¹⁸⁰ Mills, *supra* note 20, at 133.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ Flammer, *supra* note 13, at 142.

function it performs.¹⁸⁴ This indicates that the requirement that the industrial application be stated is held to a higher standard with respect to gene sequences than for other inventions.¹⁸⁵

As mentioned above, finding a compromise on biotechnological inventions within the European Union Member States was a lengthy undertaking that finally resulted in the adoption of Directive 98/44/EC.

Pursuant to Article 15 of Directive 98/44/EC, the Member States of the European Union should have brought their national patent laws into compliance with the Directive by July 30, 2000, but in fact by that time only six Member States had implemented the Directive into their national legal systems, namely Denmark, Finland, Ireland, the United Kingdom, Greece and Spain.¹⁸⁶ Hence, several infraction proceedings were commenced.¹⁸⁷ Apparently, even after the adoption of Directive 98/44/EC disharmony among the Member States of the European Union continued; on October 19, 1998 the Netherlands, with the support of Italy and Norway, filed an action to annul Directive 98/44/EC.

Here I want to point to significant passages of the judgment relating to the failure of Directive 98/44/EC to adequately respect human dignity and human integrity from the viewpoint of the Netherlands with regard to Article 5 of the Directive. The European Court of Justice argued that these principles are clearly taken into account in Directive 98/44/EC insofar as Article 5(1) provides that the human body at the various stages of its formation and development cannot constitute a patentable invention. Nor are the elements of the human body patentable in themselves or their discovery eligible for patentability, “...*only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an*

¹⁸⁴ Flammer, *supra* note 13, at 142; Mills, *supra* note 20, at 133.

¹⁸⁵ Mills, *supra* note 20, at 133.

¹⁸⁶ Gateway to the European Union, *European Commission Report of 7 October 2002 on the development and implications of patent law in the field of biotechnology and genetic engineering*, available at http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&andoc=2002&nu_doc=545 (June 10, 2008)

¹⁸⁷ Case C-448/03, *Commission v. France*, OJ C 217 of 28.08.2004, C-454/03, *Commission v. Belgium*, OJ C 262 of 23.10.2004, C-450/03, *Commission v. Luxembourg*, OJ C 262 of 23.10.2004, C-5/04, *Commission v. Germany*, OJ C 6 of 08.01.2005, C-4/04, *Commission v. Austria*, OJ C 6 of 08.01.2005, C-456/03, *Commission v. Italy* [2005] ECR I-5335, OJ C 217 of 03.09.2005

industrial application can be the subject of an application for a patent.”¹⁸⁸ Furthermore, Article 6 of the Directive provides a safety net for inventions whose commercial exploitation would be contrary to “ordre public” and morality. As a result, the European Court of Justice dismissed the application in its judgement of October 9, 2001.¹⁸⁹ The judgement held that human dignity and integrity were sufficiently taken into consideration by the provisions of Directive 98/44/EC. As of January 15, 2007, all European Union Member States had finally implemented Directive 98/44/EC in their national laws.¹⁹⁰

c) Conclusion

The problem in Europe as well as the U.S. is the application of the term “human” as a boundary for patentability. While humans are not eligible for patentability, the patentability of animals (subject to specific conditions under the EPC) is widely accepted. The well-defined human species identity has blurred as biotechnology has progressed. But what amount of human DNA will render an animal or a chimera a human being and vice versa? Without a precise concept of what constitutes a human being, these provisions will become useless.¹⁹¹

Apparently, biological criteria do not suffice to distinguish human beings from animals, hence the suggestion to replace the rule which prohibits patenting “humans” with a rule which prohibits patenting “persons”, leaving behind the notion of how to define a human being through on biological criteria and moving forward to a notion which tries to define human beings in a more sophisticated way.¹⁹² Persons as creatures which possess the ability to reason and are aware of themselves could represent a new distinction criterion.¹⁹³ This new

¹⁸⁸ Judgement of the European Court of Justice from October 9, 2001, <http://www.ipjur.com/data/011009ECJ-C-377-98.pdf> (last visited June 16, 2008)

¹⁸⁹ *Id.*

¹⁹⁰ European Commission, *State of Play of the Implementation of Directive 98/44/EC (Last revision 15-01-2007)*, available at:

http://ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf

¹⁹¹ See Hagen, supra note 15, at 33ff; see also Magnani, supra note 54, at 450.

¹⁹² Hagen, *id.*

¹⁹³ Magnani, supra note 54, at 450.

approach sounds interesting but is not fully developed yet. How can someone determine if a chimera is self-aware?¹⁹⁴ What about men and women who are mentally disabled?

The term “human being” is not even precise enough with respect to the stages of development of a human being. When does a human being start to be a human being under the meaning of patent laws? This was one of the main issues regarding the question of the patentability of human embryonic stem cells. In order to show how the stages of human development are treated under the U.S. and European patent laws, it is worth presenting a review on the question of patentability of human embryonic stem cell research.

3.3.1. Human Embryonic Stem Cells

a) Definition

Stem cells are unspecialized cells found in all multi-cellular organisms.¹⁹⁵ Human embryonic stem cells and adult stem cells represent the two main types within the human organism.¹⁹⁶ In contrast to embryonic stem cells, adult stem cells are able to differentiate into only those cells inherent to the tissue in which they reside.¹⁹⁷ Embryonic stem cells have the unique ability to develop into virtually any type of cell in the body.¹⁹⁸ Furthermore, one can distinguish between three classes of human stem cells, namely totipotent, pluripotent, and multipotent stem cells.¹⁹⁹ Totipotent cells, such as a fertilized egg cell, have the full potential to develop into all of the other cells within the human body; they can even develop into a human

¹⁹⁴ *Id.*

¹⁹⁵ Johanne Medina, *Is Stem Cell Research a One-Way Ticket to the Island of Dr. Moreau? Singapore and the United States' Differing Paths*, 21 Pac. McGeorge Global Bus. & Dev. L.J. 125 (2008)

¹⁹⁶ *Id.*

¹⁹⁷ Julia vom Wege Dovi, *Speaking Words of Wisdom: Let it be: The Reexamination of the Human Embryonic Stem Cell Patents*, 12 Marq. Intell. Prop. L. Rev. 107 (2008)

¹⁹⁸ Medina, *supra* note 196

¹⁹⁹ National Institutes of Health, *Stem Cell Information: Frequently Asked Questions*, available at <http://stemcells.nih.gov/info/faqs.asp> (last visited Apr. 22, 2007) [hereinafter NIH FAQs]; Caroline P. Torrisi, *Embryonic vs. Adult: The History and Future of the Stem Cell Debate*, 3 J. Health & Biomed. L. 143 (2007)

being.²⁰⁰ Totipotent cells are created at fertilization and are present for four days after conception, and then they become pluripotent cells.²⁰¹ Pluripotent cells can develop into any type of cell in the body except for the cells necessary for fetal development.²⁰² Multipotent cells can only develop into cells with the same tissue of origin, e.g., blood cells can develop into other types of blood cells but not into skin cells.²⁰³

While human embryonic stem cell research could lead to cures for millions of people afflicted with life-threatening diseases such as cancer, diabetes, Alzheimer's, Parkinson's, and HIV/AIDS, it raises strong moral and ethical concerns because it requires the destruction of human embryos.²⁰⁴

b) Legal Situation in Europe

Regarding human embryos, Directive 98/44/EC prohibits their use for industrial or commercial purposes.²⁰⁵ From this it follows that other uses are permitted, for example uses for therapeutic and diagnostic purposes.²⁰⁶ Directive 98/44/EC has failed to deliver precise legal provisions on the patentability of human embryonic stem cells.²⁰⁷ Consequently, the national patent offices of the EU Member States have developed their own diverse principles.²⁰⁸ The Commission's European Group on Ethics in Science and New Technologies (hereinafter EGE) released a report on "The Ethical Aspects of Patenting Inventions Involving Human Stem Cells" in 2002 in response to a request by the European Commission.²⁰⁹ As the

²⁰⁰ NIH FAQs

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ Medina, *supra* note 196; Dillon Beardsley, *A Two-Front Assault on the Stem Cell Patents*, 6 J. Marshall Rev. Intell. Prop. L. 501 (2007)

²⁰⁵ Directive 98/44/EC Article 6(2)(c)

²⁰⁶ *See, e.g.* Flammer, *supra* note 13, at 151.

²⁰⁷ Aurora Plomer, *Stem Cell Patents : European Patent Law and Ethics Report* 23 (2006)

²⁰⁸ *See, id.* at 30f

²⁰⁹ European Group on Ethics in Science and New Technology (hereinafter EGE), *Ethical aspects of patenting inventions involving human stem cell*, available at http://ec.europa.eu/european_group_ethics/publications/docs/avis16_complet_en.pdf (last visited on June 10, 2008)

investigation unfolded, the EGE came to the conclusion that only modified human embryonic cell lines fulfil the legal requirements of patentability.²¹⁰

This opinion faced harsh criticism and even the EPO did not follow its recommendations.²¹¹

European patent No. EP 0695351, entitled “Isolation, selection and propagation of transgenic stem cells,” which is commonly known as the “Edinburgh patent” was the first case where the

EPO had to deal with the patenting of stem cells. The corresponding patent application was

filed in 1994 and granted in 1999.²¹² The claimed invention encompasses a method of

genetically modifying animal stem cells to give them a survival advantage over unwanted

differentiated cells.²¹³ The method enables the culturing and isolation of desired stem cells.²¹⁴

According to the opinion of the EGE, this patent fulfils the legal requirements of patentability

since it represents modified stem cell lines.²¹⁵ The granting of this patent by the EPO initiated

a major public debate and dramatic protests.²¹⁶ The controversial part of the patent concerned

the method for preparing a transgenic animal.²¹⁷ The EPO failed to insist on limiting the term

"animal," therefore the method could also be applied to humans.²¹⁸ Besides other critical

points, the Opposition Division of the EPO noted that “*not only the industrial or commercial use of human embryos but also the human [embryonic stem] cells retrieved therefrom by*

destruction of human embryos” shall be considered unpatentable. Further, it held that all

²¹⁰ See *id.*, EGE-opinion: “Isolated stem cells which have not been modified do not, as product, fulfil the legal requirements, especially with regards to industrial applications, to be seen as patentable. In addition, such isolated cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body. When unmodified stem cell lines are established, they can hardly be considered as a patentable product. Such unmodified stem cell lines do not have indeed a specific use but a very large range of potential undescribed uses. Therefore, to patent such unmodified stem cell lines would also lead to too broad patents. Therefore only stem cell lines which have been modified by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial application, fulfil the legal requirements for patentability. As to the patentability of processes involving human stem cells, whatever their source, there is no specific ethical obstacle, in so far as they fulfil the requirements of patentability (novelty, inventive step and industrial application).”

²¹¹ Rimmer, *supra* note 144, at 266.

²¹² *Id.*

²¹³ European Patent Organization, *Background Information on the "Edinburgh" Patent*, available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/9F9D1E12002AF456C125723D00586376/\\$File/background_edinburgh_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/9F9D1E12002AF456C125723D00586376/$File/background_edinburgh_en.pdf) (last visited June 10, 2008)

²¹⁴ *Id.*

²¹⁵ See Hagen, *supra* note 15, at 76.

²¹⁶ Rimmer, *supra* note 144, at 266.

²¹⁷ *Id.*

²¹⁸ European Patent Organization, *Background Information on the "Edinburgh" Patent*, *supra* note 214

kinds of human embryonic stem cells (totipotent, pluripotent, multipotent) are excluded from patentability, thereby disregarding the opinion of the EGE.²¹⁹ The Opposition Division construed Article 6 (2) (c) of the Directive, which is identical to Rule 28 of the EPC-Regulations, in a broad fashion,²²⁰ and reasoned that Rule 20 of the EPC-Regulations, which clarifies that the human body, at the various stages of its formation and development, cannot be eligible for patentability, would otherwise be redundant.²²¹ As a result, the Opposition Division of the EPO decided to maintain the patent in an amended form that excluded human and animal embryonic stem cells.²²² This decision was approved by the Examining Division in the so-called Wisconsin Alumni Research Foundation ("WARF"), where it was argued that a process for isolating stem cells which includes the destruction of a human embryo cannot be considered patentable at all in light of Article 53 (a) and Rule 23(d) (c) [now Rule 28] of the EPC-Regulations.²²³ On appeal, the Technical Board of Appeal of the EPO tried to determine the scope of Rule 28 of the EPC-Regulations, recognized that legal practice across Europe is controversial (e.g. the German and United Kingdom Patent Offices grant patents on methods involving pluripotent human embryonic stem cells, in contrast to the majority of the EU Member States²²⁴) and finally decided to refer several questions to the Enlarged Board of Appeals.²²⁵ The Enlarged Board of Appeals determined, among other things, whether Rule 23(d) (c) [now Rule 28] of the EPC-Regulations "*forbid[s] the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application — at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived...*"²²⁶ and came to the conclusion that under the EPC it is not possible to grant a patent for an invention which

²¹⁹ Rimmer, supra note 144, at 268.

²²⁰ Plomer, supra note 208, at 31.

²²¹ Hagen, supra note 15, at 76.

²²² *Id.*

²²³ *Id.* at 77.

²²⁴ Plomer, supra note 208, at 30.

²²⁵ Rimmer, supra note 144, at 270.

²²⁶ *Id.*

necessarily involves the use and destruction of human embryos at any time.²²⁷ However, the Enlarged Board of Appeals also stressed that its decision does not concern the general question of human stem cell patentability.²²⁸

In summary, to date the EPO opposes patenting human embryonic stem cells and primarily relies on two arguments: first, human embryonic stem cells are seen as a stage of development of the human body and the various stages of the formation and development of the human body are expressly prohibited by statute as subject matter for a patent;²²⁹ second, human embryonic stem cells can only be derived from the destruction of human embryos and are therefore prohibited on grounds of morality. Nevertheless, there are some states in Europe which hold a different view at national level and where patent protection for human embryonic stem cells can be obtained subject to certain requirements.²³⁰

c) Legal Situation in the U.S.

In the U.S., human embryonic stem cell research was severely restricted; in 2001, the former President George W. Bush promulgated a ban on the use of federal funds for human embryonic stem cell research because of moral concerns regarding the destruction of human embryos.²³¹ This policy did not prohibit privately funded research.²³² The U.S. Congress passed two bills which would have allowed federal funding subject to specific conditions, but the first was vetoed by President George W. Bush in 2006 and the second one did not reach the two-thirds majority which would have been required to override the Presidential veto.²³³ Consequently, there was no federal law on stem cell research.²³⁴ Just a few states enacted laws providing state funding for stem cell research, for example California, which is in this respect

²²⁷ European Patent Office, *No European Patent for WARF/Thomson stem cell application* (November 27, 2008), available at <http://www.epo.org/topics/news/2008/20081127.html> (last visited March 16, 2009)

²²⁸ *Id.*

²²⁹ Directive 98/44/EC Article 5; EPC Implementing Regulations Rule 20 (2000)

²³⁰ Plomer, *supra* note 208, at 30.

²³¹ Medina, *supra* note 196

²³² *Id.*

²³³ *Id.*

²³⁴ *Id.*

one of the most progressive states.²³⁵ On March 9, 2009 President Obama lifted the ban on the use of federal funds for human embryonic stem cell research.²³⁶ President Obama acknowledged the controversy surrounding the scientific research that both involves the destruction of human embryos and is opposed by many who also oppose abortion, but in his mind the potential benefits to be gained, such as treatments that could reduce human suffering, outweighed such concerns.²³⁷ It is expected that the lifting of this ban will lead to increasing progress in this field of science.

In 1999, the former Commissioner of the PTO announced that purified and isolated stem cell lines are patentable subject matter.²³⁸ The scope of this announcement is wide and it appears to encompass totipotent human embryonic stem cells which can develop into full-grown human beings in the right environment.²³⁹ This seems to be in conflict with the general policy of the PTO, which prohibits the patenting of human beings as well as human embryos.²⁴⁰ Recent case law²⁴¹ confirms the wide scope of this statement and clarifies that totipotent human embryonic stem cells are also patentable.²⁴²

Thus, with respect to human embryonic stem cells, the U.S. tries to keep patent laws separate from moral concerns and made the issue a matter of “half-hearted” general policy under the regime of President Bush.

²³⁵ Yi-Chen Su & Albert Wai-Kit Chan, *Mary Doe's Destiny: How the United States has Banned Human Embryonic Stem Cell Research in the Absence of a Direct Prohibition*, 14 Rich. J.L. & Tech. 12 (2008)

²³⁶ The New York Times, *Obama Lifts Bush's Strict Limits on Stem Cell Research* (March 9, 2009) available at <http://www.nytimes.com/2009/03/10/us/politics/10stem.html?ref=us> (last visited March 16, 2009)

²³⁷ Los Angeles Times, *Obama OKs embryonic stem cell research* (March 9, 2009), available at <http://www.latimes.com/news/nationworld/nation/la-na-obama-stem-cells10-2009mar10,0,533514.story> (last visited March 16, 2009)

²³⁸ Rimmer, *supra* note 144, at 258

²³⁹ Hagen, *supra* note 15, at 56.

²⁴⁰ Rimmer, *supra* note 144, at 257.

²⁴¹ U.S. Patent No. 6,200,806 (filed June 26, 1998); U.S. Patent No. 6,800,480 (filed August 29, 2000); *but see* Kevin Noonan, *WARF Stem Cell Patent Rejected in Re-Examination* (April 3, 2007), available at http://patentdocs.typepad.com/patent_docs/2007/04/warf_stem_cell_.html (last visited June 3, 2008)

²⁴² Hagen, *supra* note 15, at 57.

4. Conclusion

While the U.S. patent system sits on the fence regarding ethical issues, in Europe there is a legal moral requirement concerning patentability. However, an inherent moral standard within a patent system may represent a problem with respect to the need for a reliable patent law. This is especially important for the biotechnology industry, which has to recoup the high costs associated with the lengthy research processes. Morality is a vague and culture-dependent term, and therefore moral-based variables do not offer the reliability that is expected from a modern patent system. Specific examples that illustrate how moral attitudes can change over time and with culture have been presented in this script.

To cite one final example, consider birth control devices.²⁴³ In past times these devices were considered immoral and even illegal, whereas today they are well-recognized means to curb a population explosion.²⁴⁴ The former Commissioner of the PTO pointed out that “*every attempt to stop science has been characterized by darkness.*”²⁴⁵ The morality doctrine which was introduced into the U.S. patent laws by Justice Story in 1817 seem to have disappeared in the last decades in order to make room for the new American perspective that patent laws and moral concerns should be separated from each other. This approach has been applied to micro-organisms, plants and animals where moral concerns were not considered at all before the PTO. It is not clear if the moral questions re-emerged when it came to the Newman/Rifkin patent application for an animal-human chimera since the application was finally rejected on the grounds that human beings do not constitute statutory subject matter under 35 U.S.C. § 101, instead of on grounds of morality. This line of argument was a break with the established case law concerning living matter. Since the decision in *Diamond v. Chakrabarty*, the significant distinction is whether the invention is man-made. This requirement is obviously

²⁴³ Merges, supra note 2, at 1064.

²⁴⁴ *Id.*, at 1065.

²⁴⁵ Sean M. Coughlin, *The Newman Application and the Uspto's Unnecessary Response: Patentability of Humans and Human Embryos*, 5 Chi.-Kent J. Intell. Prop. 90 (2006)

fulfilled by the chimera since such a creature would not exist in nature without human intervention. The argument that a chimera does not constitute statutory subject matter seems somewhat far-fetched.

Another point of debate was that a patent on a human being would be contradictory to the Thirteenth Amendment of the U.S. Constitution, which prohibits slavery. This argument is actually also based on morality concerns since one of the tasks of a constitution is to stipulate the basic values prevailing in a society. These basic values in turn represent nothing less than the moral attitude of a society. As a result, the attempt to keep ethical concerns out of the U.S. patent laws stands on very shaky ground.

In contrast, the EPC as well as Directive 98/44/EC at European Community level expressly state that human beings cannot be considered patentable at all,²⁴⁶ whereas animals are eligible for patentability when they pass the balancing test. The balancing test weighs animal suffering against the medical benefits to mankind.²⁴⁷

It was frequently pointed out that the PTO is by no means the appropriate forum for discussing ethical concerns. The nature of a patent is to give the inventor an exclusive right to make, use, or sell his invention for a limited period of time, but it is not an appropriate medium to prohibit research into ethically questionable areas. Nevertheless, a patent represents a right issued by the state. Along with the granting of a patent, the state authorizes the patent holder to use his invention and hence, gives it a certain seal of approval.

The attempt in the U.S. to make ethical concerns subject to general policy to alleviate the case load of the PTO leads to another problem. A patent office will always be the first point of contact regarding new technologies and therefore has to deal first of all with possible upcoming ethical concerns. Laws which prohibit research because of ethical concerns will

²⁴⁶ Directive 98/44/EC Article 6; EPC Implementing Regulations Rule 28 (2000)

²⁴⁷ Directive 98/44/EC Article 5; EPC Implementing Regulations Rule 20 (2000)

always lag behind. Law-makers cannot be expected to be visionaries. This illustrates the problem with designating ethical concerns a matter of general politics.

Patent systems in both Europe and the U.S., rely on the term “human” as a boundary regarding patentability, but neither of them actually define the term “human;” this leads to ambiguities since biotechnology has blurred the line between human or animal.²⁴⁸ How much human DNA makes a creature a human being?²⁴⁹ Is an animal/human chimera still an animal or has it crossed the line to becoming a human being? An interesting approach has emerged, suggesting that the notion of defining a human being by its biological criteria be abandoned and instead the intellectual capabilities should be considered.²⁵⁰ However, this approach is still in its infancy. Only time will tell whether it will stand up to general scrutiny from society across both continents, prove an objective definition, and finally create hope of unifying views on this very controversial subject.

²⁴⁸ Hagen, *supra* note 15, at 23.

²⁴⁹ *Id.*, at 25.

²⁵⁰ *Id.*, at 33ff; Magnani, *supra* note 54, at 450.

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