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Cover Page Footnote

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The Patentability of Transgenic Animals in the United States of America and the European Union: A Proposal for Harmonization

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INTRODUCTION

From the moment they emerged, humans have attempted to influence their surroundings. A chief example is human use of plants and animals for food and medicinal purposes. Human insight into the physical characteristics of plants and animals has led to continuous efforts to strengthen preferred characteristics and to eliminate disfavored ones. By crossing and selection of animals and plants, humans have been able to accumulate preferred characteristics of parent animals in their offspring.

Human capability to alter the biological constitution of animals and plants has always been limited. Human influence has extended only to the conditions under which autonomous biological processes, such as natural reproduction, took place and even that influence was relatively small. This limited influence

was due in part to scientists' inability to interbreed animals belonging to different species due to physiological differences.[1] Other limitations stemmed from the long reproduction process, the uncertainty of outcomes, and the possibility that parents' negative characteristics would be expressed in their offspring.

Advances in genetics have broadened human capability to alter plants and animals. Understanding the distinctive hereditary characteristics of organisms and the reasons for their expression has spurred a revolutionary change in the biological discipline. The knowledge acquired by scientists in the past 150 years has made manipulation of the biochemical compounds and processes that determine the formation of hereditary characteristics possible. Biotechnology enables organic alteration of biological material, such as animals.

The development of biotechnology has removed the initial barrier between biology and technology. To a certain extent, life has a technical character that can be subjected to human-based technologies resulting in a kind of evolution on command. Accordingly, biology has changed from a merely descriptive science into one with concrete applications. This change has enabled biotechnology to become subject matter protected under patent law.

Patent law has been the natural source of protection for biotechnology. It gives an inventor the right to exclude others from using his patented invention for a certain period of time. Traditionally, "life" was not covered under patent law. Although this exclusion started to change in the nineteenth century because of advances in microbiology, multicellular organisms such as plants and animals remained outside of the scope of patent law until far into the twentieth century.[2] Patent law adapted in scope to

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[1] *See* HENDERSON'S DICTIONARY OF BIOLOGICAL TERMS 507 (12th ed. 2000) (defining species as a group of interbreeding individuals not normally able to interbreed with other such groups and subdivided into subspecies, geographic races and varieties). A geographic race is a group of individuals within a species which forms a permanent and genetically distinguishable variety. *Id.* at 204. A variety is a taxonomic group below the species level. *Id.* at 578. Varieties are variances; deviations from the mean. *Id.*

[2] *See infra* Part II.C–D (discussing the expansion of patent law doctrine to accommodate biotechnology).

include protection for multicellular organisms. These organisms have led to key biotechnological inventions in the past fifty years.

The genetic transformation of agricultural and other animals has had widespread effects. Transformation of animals led to the production of new and better medicines and improved nutrition. The "creation" of animals in which "human" genetic diseases, such as certain cancers develop in vivo,[3] has facilitated research of cancer prevention, detection, and treatment. Moreover, genetic modification has enabled animals to thrive in environments in which originally they could not survive and thereby has had great strides in the battle against hunger. Biotechnology has also led to the development of enzymes that destroy pollutants and modified organisms that benefit security and defense by breaking down dangerous gases.

The universal and far-reaching consequences of biotechnology have stimulated research and development. The number of patent applications filed globally for biotechnological inventions increases every year, while many patents for modified animals already exist. The development of animal biotechnological inventions is particularly important for the realization of biotechnological promise.

The conditions under which biotechnological inventions are patentable influence the pace of such realization. The scope of patentability has a profound impact on the incentive to invest in biotechnology. Biotechnological research and development depends mostly on private market actors. These actors are companies that focus on biotechnological development, creation, and marketing of products therefrom. The differing patentability standards that exist in different countries may create an uneven playing field. Because genetic modification of animals may have great and far-reaching consequences on evolution, it is important to address the extent of human participation in this process. From the human perspective, the scope of patentability plays a critical role. The standards for patentability of animal biotechnological inventions must be determined responsibly and evaluated

[3] *See* STEDMAN'S MEDICAL DICTIONARY 1951 (26th ed. 1995) (defining in vivo as in "the living body, referring to a process or reaction occurring therein").

accurately. The presumed universal reach of biotechnology and the primarily international focus of the actors involved in its development and application demands harmonization of the major patent regimes involved.

Harmonization of patent law is necessary to reduce regional trade barriers that derive from differing standards of patentability. Moreover, harmonization is critical to infuse "responsible" limitations into standards of patentability. For patenting modified animals, the important regimes are the United States (U.S.), the European Union (EU), and Japan. Harmonization means that compromises must be made. Certain approaches will be adapted and adopted, while others will be abolished entirely.

This Article focuses on the patentability of animals under the patent regimes of the U.S. and EU. Differences and similarities will be described along with preferences relevant to particular inventions. The applicable law and scholarly opinions will be reviewed. Relevant biotechnological and ethical realities will be considered.[4]

The Article is divided into five Parts. Part I will describe the disciplines involved, introducing the reader to the fields of genetics, biotechnology, and patent law. Part II will describe the legal basis of U.S. patent law, its requirements and exclusions. Additionally, it will concentrate on animal patents in the U.S., in light of applicable statutes, case law, and guidelines promulgated by the U.S. Patent and Trademark Office (USPTO). Part III will discuss the legal basis of EU patent law, its requirements and

[4] This work covers a broad and interdisciplinary field. Given the limited scope of this article and the number of complex issues that arise when comparing specific rules of law in different cultures, an analysis of the Japanese regime is not included. The legal perspective will be the starting point of analysis, whereas other perspectives will be considered to the extent that they are useful. In view of the breadth of this field, and the numerous issues and questions that arise in its exploration, this work cannot be exhaustive. Furthermore, legal regimes and positions will be reviewed that operate in different legal traditions, such as the U.S. common law and continental EU civil law. While many possible solutions are similar, the approach taken may differ. For example, the common law tradition addresses legal problems on a case-by-case basis, whereas in the civil law tradition, legislatures anticipate potential problems and attempt to preemptively tackle them by enacting statutes and regulations. Although these general differences will arise in the course of this article, it is difficult to offer a comprehensive analysis given the limited scope of this article.

exclusions, and EU patentability standards. Part IV will offer a comparison of the patentability of animals in the EU and the U.S. It will focus on the differences in standards, exclusions, and scopes of patentability in both countries. Part V will focus on the need to bridge the animal biotechnological gaps between the U.S. and EU and a way to harmonize their differences. A brief proposal for harmonization of the substantive provisions affecting the manner in which transgenic animals are patented under both regimes is included.

I. GENETICS, BIOTECHNOLOGY, AND PATENT LAW

A. Genetics

The term "genetics"[5] originates from the Greek words "genesis" (origin) and "genetès" (originator) and the Latin terms "genus" (nature), "generalis" (specific), and "generatio" (origination). The term "genetics" is much newer than the terms from which it derives. Indeed, the roots of the science of heredity lie in the nineteenth century.

Scholars commonly regard the Austrian monk Gregor Mendel as the founding father of the science of heredity and, therefore, of modern genetics.[6] Mendel experimented with the hybridization of split peas and discovered a pattern in which two plants passed distinctive characteristics onto their offspring.[7] Mendel discovered that certain biological compounds play a role in the hereditary process. He published his discoveries in 1866.[8]

At the beginning of the twentieth century, the Dutch botanist de Vries and the English biologist Bateson repeated Mendel's

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[5] *See* STEDMAN'S MEDICAL DICTIONARY, *supra* note 3, at 713 (defining genetics as the branch of science concerned with the means and consequences of transmission and generation of the components of biological inheritance).

[6] *See generally* ELDON JOHN GARDNER ET. AL., PRINCIPLES OF GENETICS 15 (8th ed. 1991).

[7] *See generally* JAMES DARNELL ET AL., MOLECULAR CELL BIOLOGY 5–6 (2d ed. 1990).

[8] Gregor Mendel, *Versuche uber Pfanzenhybriden* [*Experiments with Plant Hybridization*], Natural Scientific Association of Brno, *reprinted in* MENDEL'S PRINCIPLES OF HEREDITY 335–79 (William Bateson ed., Cambridge Univ. Press, 3d ed. 1913) (1866).

experiments. Bateson and de Vries confirmed Mendel's conclusions and from then on, scientists started to search for the carriers of heredity. Even before the 20th century, cell research had emerged. In 1869, the Swiss researcher Kossel discovered that a cell nucleus contains protein and deoxyribonucleic acid (DNA).[9] He further discovered that DNA not only consists of a phosphate backbone,[10] but also of nucleic acid made up of four nucleotide bases: adenine (A), thymine (T), cytosine (C), and guanine (G), and a sugar (deoxyribose). In 1882, the German researcher, Walter Flemming, discovered that threadlike structures, known as mitotic spindles, exist in the nucleus.[11] Flemming's experiments showed that mitotic spindles multiply upon cell division and that every new cell contains one identical structure of the "mothercell."[12]

In 1952, the research of Americans Alfred Hershey and Martha Chase showed that DNA penetrated the cell walls of bacteria, while the viral proteins did not.[13] They concluded that DNA is the carrier of hereditary material.[14] The next year, the American scientist, James D. Watson, together with his English colleague, Francis H. Crick, characterized the physical structure of DNA—the double helix.[15] The strands of the double helix are complementary; the nucleotide bases A and T pair with one another, as do the bases C and G. Watson and Crick's model demonstrated that the hereditary code must be determined by the

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9 *See* Dr. Frederick A. Aldrich, *Sciencefare*, GAZETTE, Mar. 18, 1997, at 2 (stating that in "work for which he received the Nobel Prize in Medicine and Physiology in 1910, a German biochemist named Albrecht Kossel was able to isolate, by hydrolysis from Meischer's nucleic acid, a series of four nitrogen-bearing compounds or bases which he called adenine, guanine, cytosine and thymine"), *available at* http://www.mun.ca/sgs/science.march1877.html.

10 *See* STEDMAN'S MEDICAL DICTIONARY, *supra* note 3, at 1354 (defining phosphate as a salt or ester of phosphoric acid).

11 *See generally* DARNELL, *supra* note 7, at 7.

12 *Id.*

13 *Id.* at 11.

14 *Id.*

15 *Id.*; *see also* STEDMAN'S MEDICAL DICTIONARY, *supra* note 3, at 768 (defining helix as a "line in a shape of a coil . . . , each point being equidistant from a straight line that is the axis of the cylinder in which each point of the h[elix] lies"); *id.* at 769 (explaining that a double helix is the "helical structure assumed by two strands of DNA, held together throughout their length by hydrogen bombs between bases on opposite strands, referred to as Watson-Crick base pairing").

linear sequence of the four bases on the strings.[16] Watson and Crick further determined that upon cell division, the DNA is replicated. During replication, the double helix disentangles and the two strands move apart. Every strand functions as a template for the formation of a new strand, of which the bases will subsequently pair with the complementary bases. Although Watson and Crick clarified the structure and formation of DNA, it took several years to determine DNA's manner of expression and the way to decipher its code.

Scientists moved closer to deciphering DNA's code when the functioning of enzymes involved in protein synthesis was clarified and in vitro[17] translation systems were developed. As a result of these developments, it became possible to decipher the genetic code. In 1972, the first successful genetic manipulation was achieved, and recombinant-DNA[18] was produced.[19] In that same year, scientists effectuated an important biotechnological application of recombinant DNA technology, i.e., the production of human growth hormone.

B. Biotechnology

DNA is a polymer of nucleotides.[20] A nucleotide consists of three components—a five-carbon sugar, an inorganic phosphate, and a nitrogen base.[21] As previously mentioned, DNA contains the bases A, G, T, and C.[22] The way the genetic code is constituted is the same in any organism. Hence, the species restriction that exists with breeding and selection does not exist at the biochemical level. In all organisms, the structure of DNA is formed by two

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16 *See* DARNELL, *supra* note 7, at 11.

17 *See* STEDMAN'S MEDICAL DICTIONARY, *supra* note 3, at 889 (defining in vitro as a process or reaction occurring in an artificial environment, as in a test tube or culture media).

18 *See id.* at 1511 (defining recombinant-DNA [hereinafter "rec-DNA"] as "[a]ltered DNA resulting from the insertion into the chain, by chemical, enzymatic, or biological means, of a sequence (a whole or partial chain of DNA) not originally (biologically) present in that chain").

19 *See* GARDNER, *supra* note 6, at 18.

20 *See generally id*. at 92–127 (describing the constitution and functioning of DNA).

21 *See id.* at 97.

22 *See supra* notes 9–12 and accompanying text.

intertwined polynucleotides, which are held together by nitrogen bonds. The complementary bases are paired, A with T and G with C. A group of three bases is called a triplet.[23] A triplet codes for a specific amino acid. A combination of amino acids, encoded by a combination of triplets, comprises a particular protein with a particular function. All combined triplets form the entire genetic code of an organism.[24] Through processes known as transcription[25] and translation,[26] genes are expressed and the formation of particular proteins and ultimately all physiological features of an organism are determined.

The use of recombinant-DNA (hereinafter "rec-DNA") permits genetic engineering and the genetic modification of organisms.[27] This technology allows for the recombination of genetic material of more than one organism. Genes can be introduced and removed or blocked. An organism in which foreign material from an organism of a different species is introduced is called transgenic.[28] Restriction enzymes are crucial for the formation of rec-DNA because they recognize particular base sequences and cut the DNA strand at those sites.[29] The singular cut DNA strands can have sticky ends. Uneven DNA of a different source that is cut with the same restriction enzyme will have the complementary sticky ends. When DNA fragments so obtained are mixed and joined through a process known as ligation, rec-DNA is created.[30] Often, DNA is

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[23] *See generally* STEDMAN'S MEDICAL DICTIONARY, *supra* note 3, at 1856 (stating that a triplet can be used to describe a group of three bases in DNA and transfer-RNA [hereinafter "t-RNA"], to be discussed below); *id.* at 361 (stating that such a group in messenger-RNA [hereinafter "m-RNA"] is called a codon).

[24] The genetic code was deciphered in 1961, and accordingly, the world learned which combination of triplets codified which proteins. *See* J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCI. 1304 (2001) (describing how scientists around the world unravelled the human genetic code).

[25] *See generally* STEDMAN'S MEDICAL DICTIONARY, *supra* note 3, at 1836 (stating that transcription is where the message of the combination is transcribed to the m-RNA).

[26] *See generally id.* (stating that translation is where the message is translated by the t-RNA to enable protein synthesis).

[27] *See id*.

[28] *Id.* at 1030.

[29] *See* DARNELL, *supra* note 7, at 206–12 (describing the formation of rec-DNA in more detail).

[30] *See generally* STEDMAN'S MEDICAL DICTIONARY, *supra* note 3, at 1655. This is called "splicing."

recombined into certain vehicles employed to transfer DNA fragments into host cells. These vehicles, most commonly plasmids[31] and viruses,[32] are called vectors.[33] Cells containing foreign DNA are often selected on the basis of antibiotic resistance genes carried by the vector.

Other methods used for the transfer and recombination of foreign DNA fragments, in vivo[34]or in vitro,[35] are electroporation (changing the density of cell membranes though electric impulses whereby DNA can leak in); micro-injection (injecting DNA into the cell nucleus); nucleus transplantation (replacing the nucleus of a zygote with a foreign nucleus); DNA gun (bombarding cells with particles coated with foreign DNA); and cell extraction (mixing cells as such).[36] These methods may be applied in combination with other technologies, such as cloning, mutagenesis (chemical or radioactive treatment of cells whereby the DNA is altered), artificial insemination, embryo transplantation, and embryo fusion.[37] These techniques are applied to animals to serve various goals, as discussed below.

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[31] Plasmids are independent circular DNA molecules that have the capability to replicate within the organism in which they are introduced—and express their DNA. Plasmids are rapidly exchanged between cells, and transfect the cells easily, which makes them very suitable for DNA introduction in an organism.

[32] Viruses are also used to introduce foreign DNA.

[33] *See* STEDMAN'S MEDICAL DICTIONARY, *supra* note 3, at 1911 (defining a vector as "DNA such as a chromosome or plasmid that autonomously replicates in a cell to which another DNA segment may be inserted and be itself replicated as in a cloning." The Greek Charon, a known vector, was the ferryman who transferred the souls of the deceased to the next world.).

[34] *See id.* at 1951.

[35] *See id.* at 889.

[36] *See* E.S. VAN DE GRAAF, PATENT LAW AND MODERN BIOTECHNOLOGY: A COMPARATIVE STUDY ABOUT THE REQUIREMENTS AND THE SCOPE OF PROTECTION 28 (1997) (providing further explanation of these methods); Larry Gold & Joseph Alper, *Keeping Pace with Genomics Through Combinatorial Chemistry,* 15 NATURE BIOTECHNOLOGY 297 (1997) (Embryo fusion results in animals that are the sum of the parts of the parents. These animals, called chimaeras, are named after the fire-breathing chimera in Greek mythology that had the head of a lion, the body of a goat, and the tail of a serpent.).

[37] *See* DARNELL, *supra* note 7; BIEMANS ET AL., DNA—EEN BLAUWDRUK [DNA—A BLUEPRINT] 142 (1993).

C. Goals of Animal Biotechnology

1. Medical Purpose

Genetic modification of animals can serve various medical purposes. First, animal models can enable researchers to study the functions of specific genes. Integration of foreign DNA can result in the expression of new genetic information, but it can also block the expression of existing genetic information. The gene function can be identified by blocking expression and observing the changes that result. Second, genetically-modified animals enable scientists to learn the expression and workings of genetically determined hereditary human diseases. For example, a scientist trying to enhance understanding of a certain cancer may insert human oncogenes (i.e., cancer-causing genes) into animals to study their expression in an unnatural environment. Scientists may find it advantageous to study the function of oncogenes in non-human mammals. The "Harvard mouse" is an example of an animal that was created for this purpose.[38] Third, genetic modification of animals may enable scientists to develop gene treatments for humans based on genetic modification of animals.[39] For example, future treatments for humans with Albinism may stem from gene therapy of albino mice. Like humans with Albinism, albino mice have a defect in the tyrosinase enzyme.[40] Scientists have cloned the gene for the tyrosinase enzyme and inserted it into the nuclei of embryonic albino mice. The treatments succeeded in helping the embryos grow into pigmented transgenic mice. In the near future, this treatment, as well as others that have been used successfully in animals, may be applied successfully to humans.[41] Fourth,

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[38] The "Harvard mouse" enables analysis of human breast cancers. It was modified in P. Leder's lab at Harvard and subsequently patented in the U.S. and EU.

[39] While gene therapy on fertilized human egg cells has been prohibited worldwide, it has been conducted successfully on mice.

[40] *See generally* Vitali Alexeev et al., *Localized in Vivo Genotypic and Phenotypic Correction of the Albino Mutation in Skin by RNA-DNA Oligonucleotide,* 18 NATURE BIOTECHNOLOGY 43 (2000).

[41] In 1993, the first human being underwent onco-gene therapy. The treatment seenmed to have potential. In 1999, gene therapy on a human being in the U.S. failed and the patient died—realization of these therapies seems to be harder than once expected. *See* Richard A. Morgan & W. French Anderson, *Human Gene Therapy*, 62

genetically modified animals could produce important medicinal proteins.[42] The female offspring of Herman the bull, for example, secrete lactoferrin, a protein used to treat gastroenteritis and blood-poisoning.[43] A human gene introduced into Herman the bull resulted in a large production of the corresponding protein, lactoferrin.

2. Veterinary Purpose

Biotechnological alterations can also serve the interests of modified animals.[44] For example, the protein lactoferrin also protects Herman the bull's female offspring against udder infections.[45] Moreover, genetic modification of agricultural animals, like cows, pigs, and chickens, can increase their productivity. For example, scientists have genetically modified the bull "Sunny Boy" to increase its productivity. Because of bio-technological alterations, Sunny Boy's female offspring now produce extraordinary quantities of milk.[46]

ANN. REV. BIOTECHNOLOGY 191–217 (1993) (discussing the benefits of oncogene therapy but recognizing that realization of these therapies seems to be harder than once expected); Vermij, *Het Einde van een Wondertherapie* [*The End of a Miracle Therapy*], WETENSCHAP & TECHNIEK [SCI. & TECH.], Jan. 13, 2000, at 1. *See also* Trisha Gura, *After a Setback, Gene Therapy Progresses . . . Gingerly*, 291 SCI. 1692 (2001) (presenting an example of a gene therapy that appears to have great potential for the treatment of hemophilia).

42 Transgenic animals secrete particular proteins, e.g., in milk.

43 *See* GARDNER, *supra* note 6, at 642; Philippe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 3 (1997) (describing production of other medicines, such as erythropoietin (EPO), through transgenic animals).

44 *See* Lisa J. Raines, *The Mouse That Roared*, 1988 ISSUES SCI. & TECH. 64.

45 *See id.* at 67–68.

46 *See generally* Dan L. Burk, *Patenting Trangenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1635 (1993); Thomas Traian Moga, *Transgenic Animals as Intellectual Property (or the Patented Mouse That Roared)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 511, 530 (1994); Carrie F. Walter, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1033 (1998).

3. Socio-Economic Purpose

Agricultural animals may be genetically modified to enable their exploitation in what once were unsuitable environments. For example, certain soils can only provide nutrition for

a limited number of cows. If one can increase milk production of the cows exploited in such an area, fewer animals would be needed to produce the same amount of milk. This increase in milk production could boost socio-economic circumstances. A similar approach might be adopted in creating resistance against certain diseases, such as sleeping sickness in cows. In Zimbabwe, for example, sleeping sickness leads to inefficient milk and meat production. Animal biotechnological research could possibly eliminate sleeping sickness by creating resistance in genetically modified animals. These developments could increase life expectancy in developing countries and contribute positively to their socio-economic circumstances.[47]

4. Environmental Purpose

Genetic modification of animals may alter the functioning of certain organs in their offspring.[48] For example, one may alter the intestinal function of a particular animal so that the amount of polluting secretions and unpleasant scents decreases. Additionally,

[47] Such effects would also lower medical costs. Socioeconomic circumstances will not change drastically by the development of particular medicines only, because there are also political, ideological and similar considerations. On the other hand, gene therapy could be promising as an AIDS treatment in countries like Asia and Africa, where approximately ninety percent of AIDS patients live. Gene therapy seems to be promising for treatment of this illness. *See* Morgan, *supra* note 41; Ulrich Schatz, *Patentability of Genetic Engineering Inventions in EPO Practise*, 1 INT'L REV. INDUS. PROP. & COPYRIGHT L. 4 (1998). The HIV blocker AZT has been developed through animal biotechnological research. Distribution of medicines may be problematic, however, in view of patents held on their active ingredients or methods of treating diseases by administering claimed compounds. *See* S. Abdool Karim, *Globalization, Ethics and AIDS Vaccines*, 288 SCI. 2129 (2000); Karl Vick, *African AIDS Victims Losers of a Drug War; U.S. Policy Keeps Prices Prohibitive*, WASH. POST, Dec. 4, 1999, at A1.

[48] *See supra* note 45 and accompanying text (explaining that lactoferrin protects female offspring of Herman the Bull against udder infections).

animals may be modified so as to break down polluting substances in their direct environment, such as crude oil.[49]

D. Patent Law

Legal scholars commonly regard the Arrangement of Venice of 1474 to be the oldest civil law patent statute.[50] They consider the British Statute of Monopolies of 1623 to be the oldest common law patent statute.[51] Patent law grants an inventor the temporary right to exclude others from the use of his or her technical invention. Governments, legal scholars, and economists consider technological innovation to be the most important factor in increasing productivity. Economic progress requires a continuous stream of ideas and inventions to improve efficiency in production. Technological innovation leads to more effective use of labor, capital, and natural resources. It can thereby lead to higher levels of productivity with less investment. The subsequent economic growth, and the concomitant increase in wealth can lead to an improvement in quality of life, including improved health, educational, and social conditions.

Despite the great rewards associated with patenting inventions, they require significant investment.[52] Without patent protection,

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[49] *See* PIETER VAN DOOREN, DE GENETISCHE REVOLUTIE [THE GENETIC REVOLUTION] 66 (1994).

[50] *See generally* JAN J. BRINKHOF, *Over Octrooi en Economie* [*About Patents and Economy*] 795 (1990) (discussing the Arrangement of Venice statute); *cf.* Giuli Mandich, *Venetian Patents (1450–1550)*, 30 J. PAT. & TRADEMARK OFF. SOC'Y 166, 175–81 (1948) (describing the Venetian statute in more detail).

[51] The Statute of Monopolies, enacted in 1623, is one of a set of measures on economic matters enacted by the Tudors in the first quarter of the seventeenth century making use of proclamations of the king, whereby the statutory law grew in the English common law. Both the Statute of Monopolies and the Arrangement of Venice were intended to attract investment and know-how into the respective jurisdictions. The first reference to patents is thought to have been made by Aristotle. ARISTOTLE, POLITICS 36–39 (Stephen Everson ed., Cambridge Univ. Press 1988) (360 B.C.E.).

[52] Private ownership and enhancement, i.e., the capitalistic economic model, are necessary assumptions for this argument. *See generally* BRINKHOF, *supra* note 50, at 794; Richard R. Nelson & Sidney G. Winter, *In Search of Useful Theory of Innovation*, 6 RESEARCH POL'Y 37 (1977). Patent law, however, does not seem to be a prerequisite for technological innovation. In the nineteenth century, the Netherlands and Switzerland experienced vast technological and economic development without having patent laws. In the twentieth century, a similar development occurred in South Korea, partly without

everyone could profit from the invention and free-ride on the investment that the inventor alone had to bear. Patents address this issue by enabling the inventor to recover a profit for a period of time in which he or she retains exclusivity for this invention. The inventor can also use this time period to advance the invention.

An important aspect of patent protection is the exchange of information—the inventor must expose the know-how related to the invention. This allows others to build on the invention for experimental purposes, thereby encouraging the continuous flow of inventions. After the period of patent protection has lapsed, the previously protected information falls into the public domain so that society may freely use that information.

The informational function of patent law thereby strengthens the spread and use of technological expertise.[53] The forthcoming chapters will describe the interaction between patent law and the development of biotechnological applications within the U.S. and EU.

II. THE UNITED STATES OF AMERICA

A. Legal Basis

The Constitution gives Congress legislative authority to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their

applicable patent laws. *See* ROBERT PATRICK MERGES, PATENT LAW AND POLICY 10–11 (1982).

[53] *See generally* L. WICHERS HOETH, KORT BEGRIP VAN HET INTELLECTUELE EIGENDOMSRECHT [INTRODUCTION TO INTELLECTUAL PROPERTY LAW] 10 (1993); ROBERT M. SHERWOOD, INTELLECTUAL PROPERTY AND ECONOMIC DEVELOPMENT, 67, 191 (1990); WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO], INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE 45 (1997) (discussing further economic analysis and effect); Michael North, *The U.S. Expansion of Patentable Subject Matter: Creating a Competitive Advantage for Foreign Multinational Companies?*, 18 B.U. INT'L L.J. 111, 112–117 (2000) (providing a comprehensive and concise economic analysis of corporate behavior and competition within countries with patent regimes); C. Oppenheim, *The Information Function of the Patents*, 1979 EUROPEAN INTELL. PROP. REV. 344. *But see* Ashoka Mody, *New Environment for Intellectual Property*, World Bank Industry Series Paper No. 3 (1989) (criticizing the assumption of the stimulative effect of patent law).

respective Writings and Discoveries."[54] Congress has used this authority by enacting the U.S. Patent Act (hereinafter the "Act").[55] The PTO has the authority to examine patent applications and reject or issue patents.[56] The Act is legally operative within the international framework.[57]

B. Requirements

Section 101 of the Act states that "whoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . ."[58] Thus, a patentable invention must be a process, machine, manufacture, or composition that is a new and useful improvement upon the prior art.

Section 102 of the Act describes the novelty requirement.[59] In short, novelty means that the invention was not and could not have been known by someone other than the inventor before the inventor filed an application. The invention could have been known if it was printed in any publication—including patent applications—in any country.[60]

Novelty is determined according to the moment of invention.[61] Another requirement of section 102 is utility, which contains three separate requirements. First, the invention must be operable or capable of use (general utility). Second, it must solve the problem it is designed to solve (specific utility). Third, the invention must have a minimal social benefit and not be merely harmful or deleterious (beneficial utility).[62]

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54 U.S. CONST. art. I, § 8, cl. 8.

55 35 U.S.C. §§ 1–376 (2000).

56 *See id.* §§ 1–13.

57 *See* Graeme B. Dinwoodie, *The Integration of International and Domestic Intellectual Property Lawmaking*, 23 COLUM.-VLA J.L. & ARTS 307 (2000); *infra* Part V.

58 35 U.S.C. § 101.

59 *Id*. § 102.

60 *Id.* § 102(a), (e).

61 *See id.* § 102(a); *id.* § 102(g) (referring to "prior art").

62 *See* MERGES, *supra* note 52, at 189.

Section 103 of the Act further provides that a patent may not be granted if "the subject matter as a whole would have been obvious."[63] The subject matter must not be obvious to a person skilled in the art.[64] Nonobviousness may be a more difficult hurdle to surmount for patentability than the utility and novelty requirements because it demands that the invention comprise a technical accomplishment. The technical step, moreover, must have certain significance. It is beyond the scope of this article to go into the particular degree of significance necessary[65] especially because this test is judge-made and highly abstract. An applicant must show that the differences between the subject matter sought to be patented and the prior art are such that the subject matter would not have been obvious to a person having ordinary skill in the art. In determining nonobviousness, a court considers: a) the scope and content of the prior art; b) the differences between the prior art and the claims at issue; and c) the level of ordinary skill in the pertinent art.[66]

Pursuant to section 101 of the Act, the invention must either be a process, a machine, or a composition of matter.[67] Section 100 of the Act defines process as "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."[68] A process may be patented, even if the resulting product cannot.[69] A machine is defined as "every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or

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63 35 U.S.C. § 103.

64 *See* Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983) (providing a list of factors relevant to the determination of the level of skill in the art, including type of problems encountered in the art and prior art solutions to those problems).

65 S*ee generally* MERGES, *supra* note 62, at 479.

66 *See* Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966); *In re* O'Farrell, 853 F.2d 894, 902 (Fed. Cir. 1988); Custom Accessories Inc. v. Jeffrey-Allan Indus. Inc., 807 F.2d 955, 958 (Fed. Cir. 1986); MERGES, *supra* note 62, at 479.

67 35 U.S.C. § 100.

68 *Id.* § 100(b); s*ee generally* Cohrane v. Deener, 94 U.S. 780, 788 (1877) (describing the process as a mode of treatment of certain materials to produce a given result. The mode of treatment could be an act, or series of acts, performed upon the subject matter to be transformed to a different state or thing.).

69 Eileen Morin, *Of Mice and Men: The Ethics of Patenting Animals,* 5 HEALTH L.J. 147, 153 (1997).

result."[70] A manufacture is the production of articles from raw or non-raw materials by giving them new forms, characteristics, qualities, or combining them in a new fashion, regardless of whether it is done by hand or by machine.[71] A composition of matter includes all compositions "of two or more substances and . . . all composite articles, whether they be the result of chemical union, or mechanical mixture, or whether they be gases, fluids, powders, or solids."[72]

To be patentable, an inventor must satisfy the enablement requirement in section 112 of the Act. An invention is enabling if the specifications and drawings of the claims enable any person skilled in the art to make and use the claimed invention without undue experimentation.[73] The purpose of the enablement requirement is to facilitate the teachings of the patent so that they may be repeated easily without wasting resources. Moreover, it ensures that the inventor's contribution is stable rather than fortuitous.[74]

Section 154 describes the rights granted under an issued patent. The patentee receives the "right to exclude others from making, using, offering for sale, or selling the invention throughout the U.S. . . . and, if the invention is a process . . . the right to exclude others from using, offering for sale, or selling" products made by the patented process.

C. Exclusions

The scope of patentable subject matter is broad, but limited.[75] For example, laws of nature, principles, physical phenomena,

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[70] Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1853).

[71] *See, e.g.*, Am. Fruit Growers v. Brogdex Co., 283 U.S. 1, 11 (1931).

[72] Shell Development Co. v. Watson, 149 F. Supp. 279, 280–81 (D.D.C. 1957), *aff'd*, 252 F.2d 861 (D.C. Cir. 1958).

[73] *See* 35 U.S.C. § 112.

[74] *See generally* Scripps Clinic & Research Found. v. Genentech Inc., 927 F.2d 1565, 1571 (Fed. Cir. 1991). Timothy G. Hofmeyer, Comment, *Everybody's Got Something to Hide Except Me and My Patented Monkey: Patentability of Cloned Organisms*, 16 J. MARSHALL J. COMPUTER & INFO. L. 971, 983 (1998).

[75] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) ("Congress plainly contemplated that the patent laws would be given wide scope . . . [but t]his is not to suggest that § 101 has no limits or that it embraces every discovery.").

abstract ideas, and products of nature are not patentable.[76] Furthermore, human beings are not patentable, at least not on a statutory basis.[77] The processes and products of human cloning—thus not including human beings—may be patentable. The federal government does not fund the use of this technology, however.[78]

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[76] *See, e.g.*, *id.* at 310 (finding that laws of nature, phenomena and abstract ideas held not patentable); Gottschalk v. Benson, 409 U.S. 63, 67–68 (1972) (deciding that mathematical algorithm is akin to mental process and unpatentable); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (finding that only process that applied phenomena to new and useful end patentable); O'Reilly v. Morse, 56 U.S. 62, 127–28 (1854) (holding that electro-magnetism used for printing signs, characters or letters is not patentable); Le Roy v. Tatham, 55 U.S. 156, 175 (1853) (stating that principle in abstract is fundamental truth and unpatentable); Hotel Sec. Checking Co. v. Lorraine Co., 160 F. 467, 469 (2d Cir. 1908) (holding that business method of bookkeeping was an abstract idea and not patentable).

[77] Pat. & Trademark Off. Notice: Animals-Patentability, *reprinted in* 1077 OFFICIAL GAZETTE PAT. & TRADEMARK OFF. 24 (Apr. 21, 1987) [hereinafter PTO Notice]. *See also Patents and the Constitution: Transgenic Animals: Hearings Before the House Subcomm. on Courts, Civil Liberties and the Administration of Justice*, 100th Cong. 22 (1987) (statement of Donald Quigg, Commissioner, U.S. Pat. & Trademark Off.). Several other bills, containing provisions that would limit patentability of human-animal subject matter, were introduced but never enacted. *See* H.R. 922, 105th Cong. (1998); H.R. 923, 105th Cong. (1998); H.R. 2326, 106th Cong. (1999). Until now, human-related inventions were not statutorily excluded from patentability. *See* Mark Jagels, *Dr. Moreau Has Left the Island: Dealing with Human-Animal Patents in the 21st Century*, 23 T. JEFFERSON L. REV. 115, 141–42 (2000).

[78] In 1997, the U.S. government prohibited federal funding of the application of these technologies on human beings and human materials. *See Fact Sheet on Eight Years of Peace, Progress and Prosperity*, Pres. William J. Clinton, 2001 WL 20770, at *14 (documenting that President Clinton banned federal research on human cloning and asked the scientific community to recognize a voluntary moratorium on human cloning); 143 CONG. REC. E607 (daily ed. Apr. 9, 1997) (statement of Hon. Hamilton) (stating that President Clinton ordered a moratorium on the use of federal funds for human cloning and urging Congress to wait until a national bioethics commission reviews the legal and ethical issues surrounding cloning before it passes a bill to ban human cloning outright); NATIONAL BIOETHICS ADVISORY COMMISSION, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS COMMITTEE 13 (1997); Alexandra Hawkins, *Protecting Human Dignity and Individuality: The Need for Uniformity in International Cloning Legislation*, 14 TRANSNAT'L LAW 243, 274 (2001). The Bush Administration has reconsidered this position and allows for federal funding of stem cell research. *See, e.g.*, Pres. George W. Bush, *Stem Cell Science and the Preservation of Life,* N.Y. TIMES, Aug. 12, 2001, at D13; Jeremy Rifkin, *Will Companies Hold Control of Life Made in a Petri Dish?*, L.A. TIMES, July 23, 2001, at B11; Sheryl Stolberg, *The President's Decision: The Research; U.S. Acts Quickly to Put Stem Cell Policy in Effect*, N.Y. TIMES, Aug. 11, 2001, at A1; Editorial, *Stem Cell Impasse*, WASH. POST, July 12, 2001, at A26 (describing various views on the cloning issue before Bush made his decision). There were several cloning bills proposed in Congress but not ultimately

D. Patents for Transgenic Animals

1. Historic Development

The "products of nature doctrine" and the "pre-emption theory" (with respect to plant materials) excluded living matter from patentability. The products of nature doctrine precluded patentability of materials existing in nature, including living matter.[79] Under this doctrine, one could secure patents for fermentation processes and purified, naturally occurring chemical or biological compounds, as well as patents for microorganisms as a culture or in combination with a carrier.[80] The product claims for the microorganisms, however, were not patentable because they comprised living material—microorganisms.

The PTO approached the patentability of plant and plant materials as well as animals and animal materials in a way analogous to judicial approaches to patents claiming living matter. For example, the PTO rejected a patent application for altered

enacted. *See, e.g.*, The Human Cloning Prohibition Act, S. 1601, 105th Cong. (1998). *See also* Jennifer Cannon & Michelle Haas, *The Human Cloning Prohibition Act: Did Congress Go Too Far?*, 35 HARV. J. LEGIS. 637, 638 (1998) (critiquing S. 1601 because it "ignored important procedural safeguards, employed vague statutory language, and created a bill with significantly adverse implications"). On July 31, 2001, the House Judiciary Committee passed the Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong., H.R. REP. NO. 172, at 1 (2001) [hereinafter HCPA]. The HCPA must still pass the Senate and the President must sign it, and it does not necessarily determine PTO policy regarding patentability of biotechnological processes and products. *See* Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft, 945 F.2d 1546, 1553 (Fed. Cir. 1991) (reasoning that the PTO employs a broad definition of patentability and will issue a patent if the invention is not frivolous or "injurious to the well-being, good policy, or good morals of society"). This determination is related to the interpretation of the "beneficial utility" requirement of the invention. *See* MERGES, *supra* note 52, at 189.

[79] *See* VAN DE GRAAF, *supra* note 36, at 115 (noting that courts have interpreted the doctrine as an inquiry into "whether a naturally occurring product has been changed or altered to the extent that the claimed form d[oes] not exist in nature"); Robert A. Armitage, *The Emerging U.S. Patent Law for the Protection of Biotechnology Research Results*, 1989 EUROPEAN INTELL. PROP. REV. 47. *Cf.* David Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive,* 16 FORDHAM INT'L L.J. 990, 1028 n.176 (stating that the products of nature doctrine "denies patentability of things already existing in nature").

[80] VAN DE GRAAF, *supra* note 36, at 114. *See also* Morin, *supra* note 69, at 147. Louis Pasteur obtained a patent for a culture of yeast in 1873. U.S. Patent No. 141,072 (issued May 9, 1873).

plant material because the subject matter consisted of nothing more than a combination of several products of nature.[81] With respect to animals, it rejected the patent application for shrimps in which the head and the digestive organs were removed.[82] Alterations that were not considered sufficiently permanent were not patentable.[83] The nonpatentability of plants was also related to the "pre-emption theory" derived from the existing Plant Patent Act and the Plant Variety Protection Act.[84] The pre-emption theory precluded the patentability of plant varieties, plants, and partial plant materials—such as cells—when used to breed new plant varieties. Each act protects particular plant varieties. The Plant Patent Act covers asexually produced plants, including cultivated mutants and hybrids. The Plant Variety Protection Act covers sexually produced plants, including seed-bearing plants, but not fungi and hybrids.[85]

In *Diamond v. Chakrabarty*,[86] the U.S. Supreme Court narrowed the products of nature doctrine, thereby broadening the definition of patentable subject matter under Section 101 of the Act.[87] *Chakrabarty* involved the patentability of altered microorganisms (the bacterium from the genus Pseudemonas),

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[81] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 129–30 (1948) (rejecting an application for patent claiming mixture of bacterial strains which used to infect plant roots, thereby contributing to the plant's production of nitrogen).

[82] *See* WADDEL A. BIGGARD, PROSECUTION OF U.S. BIOTECHNOLOGICAL RELATED PATENT APPLICATIONS 17 (1985).

[83] VAN DE GRAAF, *supra* note 36, at 115.

[84] 35 U.S.C. §§ 161–164 (2000); 7 U.S.C. §§ 2321–2583 (2000).

[85] *See generally* GEERTRUI VAN OVERWALLE, PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS (1996) (discussing legal protection of plants and plant materials). MERGES, *supra* note 62, at 157–70 (reviewing the various approaches to be taken to (non)protection for plants and plant materials and noting that the preclusion of patentability of plant varieties and related materials cannot be based on referenced acts or their legislative history). Section 101 of the Act does not justify preclusion of patentability. Moreover, preclusion does not derive from the International Union for the Protection of New Varieties of Plants, Dec. 2, 1961, 815 U.N.T.S. 89 [hereinafter UPOV], because the U.S. made reservations to article 2(1) of that treaty. More importantly, the UPOV is an executive agreement that has not been ratified by the Senate. Section 101 of the Act seems to override it. The PTO however, has taken a somewhat different stance possibly contrary to the Supreme Court's determination in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). *See* MERGES, *supra* note 62, at 131.

[86] 447 U.S. 303 (1980).

[87] 35 U.S.C. § 101 (2000).

which contained two plasmids that had been genetically modified to provide a separate hydrocarbon degradative pathway. The invention provided for a bacterium capable of breaking down multiple components of crude oil.[88] The Court concluded that the bacterium was human-made instead of a products of nature and was, therefore, patentable as a manufacture or a composition of matter.[89] In reaching this decision, the Court determined that Congress intended section 101 of the Act to encompass "anything under the sun that is made by man."[90] Accordingly, the distinction under section 101 of the Act is not between living and nonliving materials, but between human-made and non-human-made (natural) materials.[91] The Court further reasoned that patent law practice may protect inventions that Congress did not foresee at the time the statute was enacted.[92]

Courts should be wary of excluding subject matter because exclusion should be left to Congress.[93] In *Ex parte Hibberd*,[94] the PTO Board of Patent Appeals and Interferences (BPAI) further expanded the definition of patentable subject matter under section 101 of the Act. *Hibberd* involved the patentability of plants and plant materials—entire plants and tissue cultures of maize plant cells with an increased content of the amino acid tryptophan. This invention produced a high level of amino acids. The BPAI relied on *Chakrabarty* to find that the Plant Patent Act and the Plant Variety Protection Act do not narrow the scope of patentable subject matter under section 101 of the Act.[95] According to the

88 *Chakrabarty*, 407 U.S. at 305.

89 *Id.* at 307, 310.

90 *Id.* at 309 (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

91 *Id.* at 313.

92 *Id.* at 313. *But see id.* at 314–17 (not directly responding to the argument that Congress failed to foresee genetic technology when it enacted section 101).

93 *Id.* at 315–18 (adding that section 101 of the Act does not explicitly exclude genetically modified organisms, whereas it has explicitly excluded other inventions such as those useful only in the utilization of nuclear material).

94 227 U.S.P.Q. (BNA) 443 (BPAI 1985).

95 *Id.* at 444 (reasoning that the pre-emption of the *lex specialis* and the *lex generalis* applies only if the two are contradictory or irreconcilable); *see also id*. at 446 (determining that such was not the case here).

BPAI, the International Union for the Protection of New Varieties of Plants (UPOV) does not alter the scope of section 101, either.[96]

2. Patents Granted

In *Ex parte Allen*, the BPAI essentially accepted the patentability of animal subject matter.[97] *Allen* involved product-by-process claims to hydrostatically altered Pacific polypoid oysters, which grew larger than normal oysters.[98] The examiner rejected the application on the grounds that (a) the polypoid oysters were living organisms and thereby fell outside the patent statute's scope, and (b) the oysters were obvious because they did not sufficiently differ from those produced by other known means.[99] The BPAI reversed the examiner's determination that the oysters fell outside the scope of section 101. It relied on *Chakrabarty*'s holding that the Plant Patent Act encompasses human-made life forms and, therefore, reasoned that the polypoid oysters were nonnaturally occurring. The PTO has confirmed the *Allen* decision with respect to the patentability of the oysters and stated that:

> The Patent and Trademark Office now considers non-naturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of *35 U.S.C. 101* [sic] . . . . The Board's decision does not affect the principle and practise that products found in nature will not be considered to be patentable subject matter under *35 U.S.C. 101* and/or *102* [sic]. 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.[100]

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[96] *Id.* at 447. *See also* MERGES, *supra* note 52, at 157–70 (noting the preclusion of patentability of plant varieties and related materials cannot be based on referenced acts nor their legislative history).

[97] 2 U.S.P.Q.2d (BNA) 1425 (BPAI 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988).

[98] *Id.* at 1426–27.

[99] *Id.* at 1426.

[100] PTO Notice, *supra* note 77, at 24 (explicitly excluding human beings from patentable subject matter and stating that "[a] claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. [§] 101"). The PTO bars the issue of patents claiming human-based inventions because of its

In *Animal Legal Defense Fund v. Quigg*, animal rights groups and farmers unsuccessfully challenged the PTO's rule on both procedural and substantive grounds.[101] The plaintiffs argued that the rule should have been published in the Federal Register pursuant to section 553 of the Administrative Procedure Act (APA) and that the PTO should have invited the public for comment. Moreover, the plaintiffs asserted that the PTO had no statutory authority to define the scope of patentable subject matter. The plaintiffs sought a court declaration that animals are not patentable subject matter. The U.S. District Court for the Northern District of California rejected these assertions and held that the rule was an interpretation of prior decisional precedent and, therefore, not the result of substantive rulemaking. It was an interpretative rule not subject to APA notice and comment requirements.[102] The Federal Circuit affirmed dismissal and determined that the animal rights groups and farmers lacked standing.[103] It, therefore, did not address the substantive issue of whether transgenic animals should be patentable.[104]

After issuing its rule, the PTO placed an eight-month moratorium on further animal patents to allow Congress time to

interpretation of patent law and its reliance on the 13th Amendment of the Constitution. Scholars and judges have criticized this approach. *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (1990) (illustrating a patent on a human cell line); James P. Daniel, *Of Mice and 'Manimal': The Patent & Trademark Office's Latest Stance Against Patent Protection for Human-Based Inventions*, 7 J. INTELL. PROP. L. 99, 116–18 (1999); Jagels, *supra* note 77, at 136; Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 448 (1999).

[101] 710 F. Supp. 728 (N.D. Cal. 1989); Morin, *supra* note 69, at 156–57.

[102] *Animal Legal Def. Fund.*, 701 F. Supp. at 731–32 (deciding that a PTO rule was interpretive because it clarified prior cases such as *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1427 (BPAI 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988) and *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443 (BPAI 1985)).

[103] The case first went up to the Ninth Circuit, who determined that the court lacked jurisdiction to hear the case. *See* Animal Legal Def. Fund v. Quigg, 900 F.2d 195, 197 (9th Cir. 1990) (reasoning that "[t]he complaint squarely raises the question of whether the Patent Act allows the Commissioner to authorize the patenting of animals . . . [t]he answer to this question turns on a construction of patent law" and arises under the patent law). The case was then transferred to the Federal Circuit. Animal Legal Def. Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991).

[104] Elizabeth J. Hecht, Note*: Beyond* Animal Legal Defense Fund v. Quigg*: The Controversy Over Trangenic Animal Patents Continues,* 41 AM. U. L. REV. 1023, 1060 (1992).

debate the various issues involved in patenting animals.[105] At the end of the moratorium, the PTO issued the first patent claiming a genetically modified animal, "the Harvard mouse."[106] Insofar as relevant here, the claims read:

> 1. A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage . . . .
>
> . . . .
>
> 11. The mammal of claim 1, said mammal being a rodent.
>
> 12. The mammal of claim 11, said rodent being a mouse.[107]

The transgenic mice, intended for research, had an increased susceptibility to breast cancer. The patent covers not only the original transgenic mice, but also their progeny and any mammal bearing the inserted oncogene sequence. The patent claims include the animals containing the oncogene because the gene is expressed in the phenotype of the animal.[108] The use of this oncogene in another mammal arguably constitutes patent infringement. The scope of the patent is based partially on the reproductive capacity of animals, thus ensuring "production of the invention," one of the patentee's rights. On the other hand, its scope is also based on the assumption that this invention applies to all mammals, including human beings, which are excluded from the claim because of their non-patentability as such.[109]

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[105] 36 PAT. TRADEMARK & COPYRIGHT J. (BNA) 888, at 271–72 (1988).

[106] U.S. Patent No. 4,736,866 (issued Apr. 12, 1988) [hereinafter "Harvard mouse patent"].

[107] *Id*.

[108] The term phenotype refers to the visible or otherwise measurable physical and biochemical characteristics of an organism resulting from the interaction of genotype and environment. STEDMAN'S MEDICAL DICTIONARY 1071 (24th ed. 1982). The term genotype refers to the precise genetic constitution of an organism. *Id.* at 581.

[109] *See* J.H. STEK, OCTROOIRECHT EN TRANSGENE DIEREN [PATENT LAW AND TRANSGENIC ANIMALS] 64–65 (1991); VAN DE GRAAF, *supra* note 36, at 355; Moga, *supra* note 46, at 519; Morin, *supra* note 69, at 158–59.

Since the Harvard mouse patent, the PTO has granted numerous patents for transgenic animals.[110] Most product patents encompass only the genetically modified animals that carry the particular feature in their genotype.[111] The scope of these patents is restricted to the animals that were used by the inventor, and thus belonging to one race.[112] Other patents have a broader scope,

[110] It would fall outside the scope of this article to review all of the patents granted for transgenic animals after issuance of the Harvard mouse patent, *supra* note 106. The review is, therefore, limited.

[111] Some of the illustrated patents also encompass processes, which, due to scope, are omitted here.

[112] *See, e.g.*, U.S. Patent No. 6,156,952 (issued Dec. 5, 2000) claiming a "*transgenic rat* whose genome contains at least one copy of a human immunodeficiency virus type 1 . . . DNA . . . said rat develops at least one symptom of . . . AIDS") (emphasis added) (partial claim); U.S. Patent No. 5,981,830 (issued Nov. 9, 1999) (claiming a "*transgenic mouse*, whose genome comprises a homozygous disruption of the endogenous hepsin gene. . .said disruption results in said mouse exhibiting elevated blood serum alkaline phosphatase levels . . . .") (emphasis added) (partial claim); U.S. Patent No. 5,625,126 (issued Apr. 29, 1997) (claiming a "*transgenic mouse* containing in its genome a transgene comprising in operable linkage a plurality of human V genes . . . in response to antigenic stimulation") (emphasis added) (partial claim); U.S. Patent No. 5,602,309 (issued Feb. 11, 1997) (claiming a " *transgenic mouse* whose somatic and germ cells contain and express a gene coding for mouse nerve growth factor, said mouse exhibiting hyperinnervation when compared to a normal mouse, and said gene having been introduced into fertilized mouse embryo") (emphasis added) (partial claim); U.S. Patent No. 5,591,669 (issued Jan. 7, 1997) (claiming a " *transgenic mouse* having a phenotype characterized by a disruption of the . . . endogenous heavy chain and an absence of plasma B cells producing naturally occurring mouse antibodies") (emphasis added) (partial claim); U.S. Patent No. 5,434,340 (issued July 18, 1995) (claiming a "*transgenic mouse* having a phenotype characterized by the substantial absence of mature T-cells otherwise naturally occurring in said mouse . . . being incapable of mediating T-cell maturation in said transgenic mouse") (emphasis added) (partial claim); U.S. Patent No. 5,387,742 (issued Feb. 7, 1995) (claiming a "*transgenic mouse* whose cells contain a DNA sequence, comprising . . . [a] nerve tissue specific promotor; and a DNA sequence . . . wherein the promotor and DNA sequence. . . are operatively linked . . . and integrated in the genome of the mouse and expressed") (emphasis added) (partial claim); U.S. Patent No. 5,183,949 (issued Feb. 2, 1993) (claiming an animal produced by "the injection of human T-cells infected in vitro with HIV-1" leading to *rabbit model* for testing anti-AIDS therapeutic agents, vaccines, and HIV-1 infection) (emphasis added) (partial claim); U.S. Patent No. 5,175,385 (issued Dec. 29, 1992) (claiming *a virus resistant mouse*, prepared by introduction of a gene encoding a human interferon having a antiviral activity into a host mouse); U.S. Patent No. 5,175,385 (issued Dec. 29, 1992) (claiming *a virus resistant mouse*, prepared by introduction of a gene encoding a human interferon having a antiviral activity into a host mouse); U.S. Patent No. 5,175,383 (issued Dec. 29, 1992) (defining an animal containing a recombinant gene that is capable of promoting as "benign prostatic hyperplasia or hypertrophy in *said transgenic mouse*")

however, encompassing not only the animals wherein the genetic modification occurred, but also the animals' offspring and/or animals of different races and/or higher taxonomical units, such as species. Broad patents were, among others, granted for:

- *transgenic mouse offspring* produced *by the mating* of a first transgenic mouse carrying a transresponder transgene whose expression is regulated by a viral gene product of HbV-1 and a second transgenic mouse carrying a transactivator transgene;[113]
- [*a t*]*ransgenic mouse* or the *progeny thereof* whose somatic and germline cells contain a stably integrated DNA sequence selected from the . . . rat AGP gene which is expressed in the mouse to produce rat alpha-1-acid glycoprotein;[114]
- [*a*] *transgenic non-human mammal* whose genome comprises DNA construct comprising. . .a rabbit WAP promotor. . .said mammal expresses said DNA sequence such that a recoverable amount of. . .protein is produced in the milk of said mammal;[115]
- *a non-human mammal, a mouse in particular* . . . wherein the . . . Kir6.2 gene . . . essential for insulin secretion . . .is lost . . . ;[116] [and]
- *a transgenic rodent*, comprising amyloid plaques in its brain tissue . . . said rodent has at least 50% increase in the number of amyloid plaques compared to . . . a control rodent . . . .[117]

(emphasis added); U.S. Patent No. 5,175,384 (issued Dec. 29, 1992) (describing *an immune-deficient mouse* "characterized by the substantial absence of mature T-cells otherwise naturally occurring in said mouse) (emphasis added); Kluth, *The Evolution of Patents on Life: Transgenic Animals, Clones and Stem Cells*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 830, 833 (2001) (discussing the claims in the '383 and '384 patents).

113 U.S. Patent No. 5,221,778 (issued June 22, 1993) (emphasis added) (partial claim).

114 U.S. Patent No. 5,648,597 (issued July 15, 1997) (emphasis added) (partial claim).

115 U.S. Patent No. 5,965,788 (issued Oct. 12, 1999) (emphasis added) (partial claim).

116 U.S. Patent No. 6,194,634 (issued Feb. 27, 2001) (emphasis added) (partial claim).

117 U.S. Patent No. 6,172,277 (issued Jan. 9, 2001) (emphasis added) (partial claim).

Most of the patents granted after 1988, however, have a more limited scope than the patent granted in Harvard mouse.[118] As described, claim 1 of the Harvard mouse patent extends to all non-human mammals having the particular genetic feature—thereby comprising the entire zoological class mammalia, except human beings.[119] Claims 11 and 12 of the patent encompass rodents (order Rodentia) and mice (race).[120] In general, one could conclude that patents granted after 1988 chiefly encompass particular animals (a variety of a particular race), and no longer embrace entire (sub)classes or orders.[121] Only a few patents extend, or appear to extend, to higher taxonomical units such as

[118] *See*, *e.g.*, U.S. Patent No. 6,191,342 (issued Feb. 20, 2001); U.S. Patent No. 6,187,993 (issued Feb. 13, 2001); U.S. Patent No. 6,166,289 (issued Dec. 26, 2000); U.S. Patent No. 6,136,040 (issued Oct. 24, 2000); U.S. Patent No. 5,859,312 (issued Jan. 12, 1999); U.S. Patent No. 5,631,407 (issued May 20, 1997); U.S. Patent No. 5,663,482 (issued Sept. 2, 1997); U.S. Patent No. 5,661,016 (issued Aug. 26, 1997); U.S. Patent No. 5,550,316 (issued Aug. 27, 1996); U.S. Patent No. 5,530,179 (issued June 25, 1996); *supra* note 112.

[119] *See* HENDERSON'S DICTIONARY OF BIOLOGICAL TERMS 580 (9th ed. 1982); LYNN MARGULIS & KARLENE V. SCHWARTZ, FIVE KINGDOMS: AN ILLUSTRATED GUIDE TO THE PHYLA OF LIFE ON EARTH (1st ed. 1982). That insertion and expression of an oncogene is a particular variety of mice has succeeded does not necessarily mean that this will also be possible in other mammals. Whereas this process may be performed on the animals of one race (mice) or the animals of a same species (rodents), such is likely not to be performed, without further and possibly significant adaptation of the process, on animals of other taxonomic (sub)orders. These animals differ largely in genotype. The manner of expression of strange genetic material in an animal, and the extent to which it will thereby contribute to development of certain characteristics—in case of the Harvard mouse patent, development of certain cancers—depends on the entire biochemical context of the animal concerned. The complete or incomplete transcription and translation of a gene depends on its location on the chromosome and the manner in which the functions of the codons are performed within the cells. Genes could, therefore, operate in a variety of ways in different genetic contexts, e.g., in similar but genetically differing animals. In view hereof, one should not lightly assume that the inventions concerned can be performed in all animals of different zoological subclasses and orders. Such may be problematic in view of the enablement requirement of section 112 of the Act. *See* VAN DE GRAAF, *supra* note 36, at 345–48; Hofmeyer, *supra* note 74, at 984.

[120] U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

[121] *See supra* note 112.

classes or orders.[122] Some patents have been granted for the modified animals themselves, as well as their natural offspring.[123]

This bears significance because, although the offspring will reveal the particular genetic feature created by the invention, the offspring does not derive alone from technology. In fact, the offspring's existence apparently results from a natural process and is excluded from patentability under the "laws of nature" and/or "products of nature" doctrines.[124]

Notwithstanding this broad construction of patent scope, there has been a general narrowing in the scope of patentable subject matter. This may stem from the increased level of skill of the patent examiners. At the time the Harvard mouse patent was issued, PTO examiners had relatively little skill in reviewing applications for patents claiming animal biotechnological inventions. Examiners relied heavily on information the applicants provided, but they had an incentive to acquire the broadest patent possible. The present examiners have more experience and, therefore, better insight into the specifications, limitations, and realistic applications of the inventions concerned.[125]

3. Issues Reviewed

a) Novelty and Nonobviousness

The patentability of genetically altered animals may be problematic in view of the novelty and nonobviousness requirements of sections 101, 102, and 103 of the Act. While most of the referenced patented animals underwent minor changes and, for the most part, pre-existed naturally, the patents granted for them extended to the entire animal. In principle, this broad scope derived from the characteristics of the inventions involved and the

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[122] *See supra* notes 115–117 and accompanying text (including "nonhuman mammals" and "rodents").

[123] *See supra* notes 113–114 and accompanying text (including "transgenic mouse offspring produced by the mating" and "their progeny"). The '597 patent, *supra* note 114, does not specify whether also naturally produced progeny is encompassed. However, this may be suggested for the broad description of the particular claim.

[124] *See supra* Part II.C.

[125] Moga, *supra* note 46, at 521.

environments in which they operated. Inventions such as insertion and expression of genes cannot be separated from their entire influence on the geno- and phenotype of the animal. After *Allen* and the Harvard mouse patent, the PTO considered the entire genome of the modified animals concerned different enough to be "novel." From a comparative standpoint, however, the genomes of non-modified mice may not differ substantially from the genomes of the transgenic one.[126]

The nonobviousness requirement may also impose a burden on the patentability of transgenic animals. In 1995, Congress amended this requirement to accommodate biotechnological developments.[127] As amended, section 103(b) provides that, under

[126] *See* Hofmeyer, *supra* note 73, at 989–90. On this ground, the Trial Division of the Canadian Federal Court denied the patent application for the "Harvard mouse" (Patent App. No. 484,723, denied August 4, 1995). The Commissioner ruled that claims covering a transgenic non-human mammal were not patentable subject matter under Canadian Patent Act, R.S.C. 1985, ch. P-4, § 2 (2001) (Can.), but approved the issue of patents covering the method and use claims. This decision is not published. *See* Morin, *supra* note 69, at 147 n.3.

The Canadian Federal Court also denied the application insofar as it covered the transgenic mice as such in President and Fellows of Harvard College v. Canada (Commissioner of Patents), [1998] 3 F.C. 510, 525, *rev'd*, [2000] 4 F.C. 528 (Can.). *See id.* paras. 23–24 ("A mouse is a complex life form and thus there are many features of the mice which are not under the control of the inventors. They have created a method to inject eggs with a myc gene but they have not invented the mouse. It is not necessary for the inventor to directly control all aspects of the natural process leading to the creation of the end product. . . . However, the ultimate product which will result from the process is completely unknown and unknowable. . . . On even the broadest interpretation I cannot find that a mouse is 'raw material' which was given new qualities from the inventor. Certainly the presence of the myc gene is new, but the mouse is not new . . . . [T]here is no way to separate the transgene from the rest of the mouse once it is introduced and everything else about the mouse is present completely independently of human intervention."). Whereas the inseparability of the transgene and the animals may be regarded a reason in the U.S. to grant patents, it is a reason not to grant them in Canada. Clearly, the balance is struck differently in the U.S. and Canada. *See* Morin, *supra* note 69, at 197 (arguing that the Canadian Intellectual Property Office should follow the more liberal U.S. approach). The review of the same application before the European Patent Office (EPO) is discussed in Chapter III.

[127] *See* 35 U.S.C. § 103(b) (2000).

> (1) [A] biotechnological process using or resulting in *a composition of matter that is novel* under section 102 . . . and nonobvious under section (a) of this section shall be considered nonobvious if—

certain formalistic requirements: 1) a process may be classified as nonobvious if the resulting or used composition of matter is novel and nonobvious and 2) a composition of matter used in or produced by a patented biotechnological process shall also be covered by such patent. The first requirement fails to indicate the nonobviousness of a process or shed any light on the standard for novelty and nonobviousness of transgenic animals. The second requirement specifies the general approach to product-by-processes for biotechnological composition of matter.[128] Furthermore, it allows for the patenting of genes used in the application of patented biotechnological processes.[129]

The amendment of section 103 of the Act eases the patentability of biotechnological inventions, whether they are processes or products. Amended section 103, however, does not

> (A) claims to the process and *composition of matter* are contained in either the same application for patent or in separate applications having the same effective filing date; and
>
> (B) *the composition of matter*, and the process at the time it was invented, were owned by the same person . . . .
>
> (2) A patent issued on a process under paragraph (1)—
>
> (A) shall also contain the claims to *the composition of matter* used in or made by that process . . . .
>
> (3) For purposes of paragraph (1), the term "biotechnological process" means-
>
> (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—
>
> (i) express an exogenous nucleotide sequence,
>
> (ii) inhibit . . . or alter expression of an endogenous nucleotide sequence, or
>
> (iii) express a specific physiological characteristic not naturally associated with said organism;
>
> (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
>
> (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

Id. (emphasis added). *See also* VAN DE GRAAF, *supra* note 36, at 272–304; Walter, *supra* note 46, at 1039–40.

[128] Eight years before the amendment, in *Allen*, the BPAI held that if the product in a product-by-process claim is the same as a product in the prior art, or is obvious in view thereof, it could not be patented, even if the process was novel and nonobvious. *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1427 (BPAI 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988); *see also* VAN DE GRAAF, *supra* note 36, at 305 (noting that the amendment removes a restriction to patentability of said products).

[129] *In re* Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

directly focus on the patentability of transgenic animals as such.[130] In view of the PTO's relatively low standard for novelty and nonobviousness, as illustrated by the referenced animal patents, the PTO will likely consider many similar processes to be nonobvious. The product-by-process animals derived from these techniques subsequently enable patentability of animals and other products.[131] Because of these formalistic requirements, however, section 103's overall impact is quite modest.[132]

b) Products of Nature

The "products of nature" doctrine has a very restrictive application, under which "anything under the sun that is made by man" is considered patentable subject matter.[133] Anything that does not occur naturally without the interference of man, whether almost insignificant or more influential, is considered to be "made by man" according to the PTO and some courts.[134] Even with this restrictive interpretation of what constitutes a natural product, however, one may doubt whether the broad scope of some of the patents granted by the PTO for transgenic animals, which in certain instances covers the offspring, is defensible.[135] The offspring cannot be considered to be products-by-process in the

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[130] *See* MERGES, *supra* note 62, at 602.

[131] Many identical technologies (methods and processes) are used by biotechnologists in an identical manner but on different subjects and biological materials. *See* Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 735–36 (1990). One may doubt whether the animal may be regarded as the product-by-process. Clearly, the entire animal (or most of it and its features) does not exist because of the isolated application of the process—the insertion of the transgene. *Cf.* Joshua V. Funder, *Rethinking Patents for Plant Innovation*, 21 EUROPEAN INTELL. PROP. REV. 551, 568 (1999) ("[A]s yet no human is able to re-create a living organism from its constituent components . . . . [O]ur inability to reproduce life suggests that claiming the whole organism . . . on the basis of altering several biological processes may not yet be justified.").

[132] MERGES, *supra* note 62, at 602. For example, the product and process need to be developed by the same firm or group.

[133] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[134] *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426 (BPAI 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988).

[135] *See* Funder, *supra* note 131, at 567–68; U.S. Patent No. 5,648,597 (issued July 15, 1997) ("progeny"); U.S. Patent No. 5,221,778 (issued June 22, 1993) ("offspring . . . by mating"); U.S. Patent No. 4,736,866 (issued Apr. 12, 1988) ("ancestor"); Hofmeyer, *supra* note 74, at 986.

sense that the initial process, the insertion and expression of the gene in the "original" animal, was not carried out on them by the inventor. The offspring may be products-by-process if they have been cloned. As the products of natural reproduction, most of the offspring referred to in referenced animal patents cannot be products-by-process, since the natural process of mating is excluded from patentability under the "laws of nature" doctrine. Consequently, the products of such a process can only be patentable if they are novel and nonobvious manufactures or compositions of matter that do not occur in nature absent active human intervention. In view of the restrictive application of the "products of nature" doctrine, one may also argue, however, that if there was at least some human intervention in the natural process (e.g., if that process occurred in vitro) a broad patent scope may be justified.

c) Utility

Pursuant to section 101 of the Act, an invention must satisfy a three-pronged test of utility. First, it must have general utility (capable of use); second, specific utility (solve problem it was made for); and, third, beneficial utility (not only harmful for society).[136] The general utility prong will usually not create any problems for the biotechnological inventions concerned. Transgenic animals are generally considered useful by medical researchers, and most have some practical utility, thereby satisfying the requisite level of general utility.[137] Moreover, the utility requirement does not require proof of the invention's usefulness; a general proposed use, which the inventors seemingly always have in mind, suffices.[138]

Biotechnological inventions may not satisfy the second prong of the test, however, due to their lack of specific utility. If the PTO applied the utility requirement in a strict manner, many potential biotechnological inventions may never be patented. For example, the expression of an inserted gene is unpredictable and there is a

[136] MERGES, *supra* note 62, at 189.

[137] *See* Hofmeyer, *supra* note 74, at 987; Moga, *supra* note 46, at 525–42; Walter, *supra* note 46, at 1038.

[138] Walter, *supra* note 46, at 1038.

substantial likelihood that it will not succeed. A skilled person in the art may not be willing to accept certain in vivo tests as predictive models of utility against development of particular features.[139] The same applies to the specific utility of transgenic animals to be used as research models, i.e., to analyze the development of a certain illness or to experiment with a medicinal or other treatment, as was the purported utility of the Harvard mouse.[140] Strict interpretation of this prong of the utility requirement may especially hamper smaller biotechnological companies or less wealthy inventors who lack the financial means to provide excessive clinical data to prove the specific utility of the invention. Furthermore, because the invention is not yet patented, these small companies cannot raise the funds necessary for more extensive testing.[141] Recently, however, the PTO and courts have moved away from the traditional strict approach. Currently, the PTO initially assumes that an invention, for which a patent application is filed, has specific utility. The PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure.[142] Only when the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the patent applicant to provide additional evidence.[143] In 1995, the PTO issued special examiner guidelines for biotechnology applications.[144] These guidelines have undergone certain changes and the PTO issued the most recent guidelines in January 2001.[145] The guidelines state that if an applicant has asserted that an

[139] *See, e.g.*, *Ex parte* Aggerwal, 23 U.S.P.Q.2d (BNA) 1334, 1338 (BPAI 1992) ("[T]here is considerable doubt that those skilled in the art would be willing to accept appellants' in vitro tests and in vivo tests as established models predictive of utility against tumors in humans.").

[140] *See supra* note 38.

[141] VAN DE GRAAF, *supra* note 36, at 338.

[142] *In re* Marzocchi, 439 F.2d 220, 224 (C.C.P.A. 1971).

[143] *In re* Bundy, 642 F.2d 430, 433 (C.C.P.A. 1981).

[144] 60 Fed. Reg. 36,263 (July 14, 1995) (partially following the decisions in *Marzocchi* and *Bundy*).

[145] 66 Fed. Reg. 4 (Jan. 5, 2001) (amending 64 Fed. Reg. 71,440 (Dec. 21, 1999), corrected at 65 Fed. Reg. 3,425 (Jan. 21, 2000)). *See also* Julian David Forman, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 654–57 (2002) (finding the guidelines of Jan. 5, 2001 more stringent than the previous guidelines).

invention is useful for any particular purpose, and if this assertion would be considered to be credible by the skilled person, the examiner should not reject the patent because of lack of utility (thereby combining the two prongs of general and specific utility). The examiner assesses credibility from the perspective of one of ordinary skill in the art in view of any evidence of record that is relevant to the assertions. The PTO considers evidence of experts, prior art, test results, and publications of all sorts. Data derived from in vitro testing may support an applicant's assertions towards in vivo application.[146] In view of the applicable utility examination guideline, one may conclude that the special utility prong of the utility requirement of section 101 of the Act will not be a substantial hurdle for an applicant seeking a patent covering a transgenic animal.

The third prong of the utility requirement of section 101 of the Act, the beneficial utility requirement, may have a particular meaning when discussing animal biotechnological inventions. Courts have invoked this prong to deny patentability for immoral subject matter, e.g., with respect to gambling devices.[147] Beneficial utility has also barred patentability of inventions that were only useful for immoral purposes.[148] This utility requirement may bar two types of inventions: inventions that are used to deceive or commit fraud and those that are frowned upon by society at large. In principle, biotechnological inventions are not

[146] *See supra* note 144; *In re* Brana, 51 F.3d 1560, 1567 (Fed. Cir. 1995).

[147] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (holding that an invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society; an invention that is mischievous or immoral, such as one to poison people or to facilitate private assassination, is not useful).

[148] *See, e.g.*, Chi. Patent Corp. v. Genco, 124 F.2d 725, 728 (7th Cir. 1941) (granting patent but distinguishing between game of pinball and gambling product whose sole use is as gambling apparatus); Rickard v. Du Bon, 103 F. 868, 873 (2d Cir. 1900) (invalidating a patent for invention that produced artificial spots on domestic tobacco because it was deceptive and lacked utility); Meyer v. Buckley Mfg. Co., 15 F. Supp. 640, 641 (N.D. Ill. 1936) (denying patent for vending machine that was a game of chance); Nat'l Automatic Device Corp. v. Lloyd, 40 F. 89, 90 (C.C.N.D. Ill. 1889) (denying a patent for a toy horse course because product could be used as a gambling device); Schultze v. Holtz, 82 F. 448 (C.C.N.D. Cal. 1897) (denying a patent for return device for coins for machines that were operated with coins because product could be used as a gambling device).

used to commit fraud or to deceive.[149] Society may, however, frown upon them.[150]

The present status of the third prong of the utility test, beneficial utility, is not unequivocal. In 1977, the BPAI ended the nonpatentability of gambling devices, and de facto prohibition, based on lack of beneficial utility.[151] The PTO and courts have not unequivocally rejected the application of the beneficial utility requirement as such. A U.S. District Court explicitly rejected the doctrine in *Whistler Corp. v. Autotronics Inc*.[152] The *Whistler* court held that Congress should amend the patent law if it preferred to bar patentability of radar detectors to evade speed limit enforcement.[153] Alternatively, the Federal Circuit's decision in *Tol-o-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft* may provide a basis for more frequent invocation of the doctrine by the PTO and courts.[154] It embraced the beneficial utility doctrine, although it did not find it applicable to the case at hand.[155] If the PTO and courts were willing to apply the beneficial utility requirement on a case-by-case basis, they could do so by balancing the immoral uses of the inventions with the moral ones.[156] With respect to chimaeras, the PTO has announced that

[149] However, in a stretch of the mind, one could imagine that genetic modifications could lead to deceit on descent of animals and animal materials, e.g., for commercial agricultural purposes.

[150] Magnani, *supra* note 100, at 453–54.

[151] *Ex parte* Murphy, 200 U.S.P.Q. (BNA) 801 (BPAI 1977).

[152] 14 U.S.P.Q.2d (BNA) 1885 (N.D. Tex. 1988).

[153] *Id.* at 1886.

[154] 945 F.2d 1546 (Fed. Cir. 1991) (discussing the applicable standard of utility and repeatedly referring to *Lowell v. Lewis*, 15 F. Cas. at 1018).

[155] *Compare Tol-o-Matic*, 945 F.2d at 1548 (finding a patent on a rodless pistol cylinder not invalid for lack of beneficial utility), *with* Markman v. Westview Instruments Inc., 52 F.3d 967 (Fed. Cir. 1995) (not invoking beneficial utility). *But see* Magnani, *supra* note 100, at 453 (suggesting that the extensive reference to the doctrine shows that the Federal Circuit is laying groundwork for future invocation of the doctrine).

[156] *E.g.*, *In re* Nelson, 280 F.2d 172, 178 (C.C.P.A. 1960). *See also* Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies,* 47 MD. L. REV. 1051, 1066 (1988) (suggesting that courts may be willing to balance these features of a particular invention in determining utility). This approach aligns with the "deontological theory" of ethics that provides for ethical rules to determine under which circumstances certain actions may be taken. The deontological approach provides for a balancing inquiry. Other theories are the "virtue theory" that relies on absolute normative principles, and the "consequentalist theory" that focuses on

inventions directed to human/non-human chimaeras may not be patentable where they fail to meet the public policy and morality aspects of the utility requirement.[157] The PTO's position supports the invocation of the beneficial utility requirement with respect to transgenic animals that contain human material. The basis for the distinction between human/animal chimaeras and animal/animal chimaeras is however, unclear.[158] The definition of what constitutes a "human" versus an "animal" is also unclear.[159] Due to the lack of clarity between what constitutes a human and an animal and the generally restrictive application of the doctrine in recent cases, one may doubt whether a rejection of a patent application for lack of beneficial utility will stand on appeal.[160]

Legal scholars widely reject application of the beneficial utility doctrine when discussing the patentability of transgenic animals.[161]

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the consequences of acts and their (un)ethical nature. *See* VAN DE GRAAF, *supra* note 36, at 70–72; Morin, *supra* note 69, at 168; Schrecker, *Different Philosophies on the Ethics of Patenting Higher Life Forms*, 17:4 POL'Y OPTIONS 18, 19 (1996). Another theoretical division is offered by Dr. Verhoogh in his research for The Institute of Theoretical Biology of the University of Leiden, the Netherlands. *See* LINSKENS VERHOOGH, HET MAAKBARE DIER EN TRANSGENE DIEREN [THE FABRICATED ANIMAL AND TRANSGENIC ANIMALS] (1990). Verhoogh identifies four theories: (1) preference-ulitarism (all living creatures are in principle of equal value, but fundamental interests of one should be protected if this will only result in damage to non-fundamental interests of the other); (2) two-factor egalitarianism (creatures with a higher and more complex psychological capacity are of more value); (3) theory of law (all creatures are of equal value, but the interests of one group may be sacrificed for the interests of another group); and (4) theory of respect for nature (biocentrism, all creatures are of equal value). Clearly, the PTO and Congress follow the two-factor egalitarianism theory. *See generally* W.J.M. Heijs & C.J.H. Midden, *Biotechnology, Attitudes and Influencing Factors: Summary Report* 1 (1996) (reviewing the various ethical principles and approaches).

[157] D.J. Quigg, Media Advisory Statement by Commissioner of Patents and Trademarks, *Patent and Trademark Office Issues, Statement on Patenting of Partial Human Life Forms*, 6 J. PROPRIETARY RTS. 17 (1988). *But see* Jasmine Chambers, *Patent Eligibility of Biotechnological Inventions in the U.S., Europe and Japan: How Much Patent Policy is Public Policy*, 34 GEO. WASH. INT'L L. REV. 223, 242 (2002) (indicating that it would be hard to refuse protection for human/animal chimaeras based on the PTO's policy).

[158] Daniel, *supra* note 100, at 119.

[159] *See* Philippe Ducor, *The Legal Status of Human Materials*, 44 DRAKE L. REV. 195, 201 (1996); Rachel E. Fishman, *Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?*, 15 AM. J.L. & MED. 461, 477–80 (1989).

[160] *See* Magnani, *supra* note 100, at 454–55.

[161] *See, e.g.*, Daniel, *supra* note 100, at 125 (arguing that the PTO is not suited to make such determinations and that, if a "moral bar" should be raised, it must be done by Congress); Hecht, *supra* note 104, at 1057 (arguing that the patent system is neutral and

It appears as if the patentability of transgenic animals will not be restricted significantly by the beneficial utility requirement. The large number of patents issued by the PTO in recent years for transgenic animals, including ones that carried one or more human transgenes, supports this conclusion.[162] Thus, one may conclude that patentability of transgenic animals in the U.S. is based on principles of the virtue theory.[163] The absolute principles applied encompass, for example, the principle that human beings are distinct from animals, the principle that human beings are more valuable than animals, and the principle that the rights of animals are subordinate to the rights of humans.

d) Definitions of Species

As discussed above, the distinction between what constitutes an animal and what constitutes a human being is unclear. This distinction is critical because humans are not patentable subject matter.[164] The PTO's recent statement that human/nonhuman chimaeras may lack beneficial utility under section 101 of the Act makes it clear that one must identify what is human and what is not.[165] Absent clear zoological classification, legal scholars have

is not suited to regulate the application of patented inventions; Congress could prohibit explicitly, but has decided not do so, and the risks of transgenic research are speculative and not direct and proven); Merges, *supra* note 156, at 1062–68 (noting that moral norms change over time and have no clear limits, while recognizing the role of patent law as a technological—not moral—stimulator); Walter, *supra* note 46, at 1045–46 (arguing that it is inappropriate for the PTO to make far-reaching ethical decisions and that the possible ethical problems relate to biotechnology and not to the patenting of such and its products). *But see* VAN DE GRAAF, *supra* note 36 (arguing that the patentee should have certainty about the possibility of exploitation of the invention); Peter Drahos, *Biotechnology Patents, Markets and Morality*, 21 EUROPEAN INTELL. PROP. REV. 441, 448 (1999) (arguing that the important societal consequences of certain inventions call for a moral evaluation by patent offices of the inventions for which patents are sought).

[162] *See supra* notes 111, 115–120; U.S. Patent No. 5,859,312 (issued Jan. 12, 1999) (transgenic animal having human transgenes); U.S. Patent No. 5,814,318 (issued Sept. 29, 1998) (transgenic animal producing human antibodies); U.S. Patent No. 5,770,429 (issued June 23, 1998) (transgenic animal producing human antibodies); U.S. Patent No. 5, 625, 126 (issued Apr. 29, 1997) (transgenic animal producing human antibodies).

[163] *See* VAN DE GRAAF, *supra* note 36, at 70–72; Morin, *supra* note 69, at 168; Schrecker, *supra* note 156, at 19, and accompanying text.

[164] *See supra* note 77.

[165] *See* Quigg, *supra* note 157. The need to phrase a concise definition is revealed by the filing of a test patent application for "the product of the combination of human and

suggested that species may be distinguished by their ability to reason.[166] The drawback to this approach, however, is it is difficult to quantify reasoning ability.[167]

e) Enablement

Pursuant to section 112 of the Act, the patent applicant must disclose his invention sufficiently to enable one skilled in the art to make and use the invention without undue experimentation. If the invention cannot adequately be disclosed in the specifications (section 112) and/or drawing (section 113), it can be deposited (section 114). Written and drawn disclosure can be problematic with inventions of genetic modification because the magnitude of an entire genomic region complicates one's ability to describe the effects of a genetically modified animal.[168] For transgenic animals, however, even deposit does not solve this problem.[169]

f) Third Party Interests

Various third parties may be affected by patents claiming transgenic animals. First, agricultural farmers may be affected.

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animal embryo cells to produce a single human/nonhuman chimera," allegedly on approximately a "50/50" basis. *See* Daniel, *supra* note 100, at 100–01; Jagels, *supra* note 77, at 116–17; Magnani, *supra* note 100, at 446.

166 *See, e.g.*, Magnani, *supra* note 157, at 450.

167 *See* Fishman, *supra* note 159, at 478–80 (proposing a multi-prong test, based on certain geno- and phenotypical characteristics and/or the origin of species without regard to whether it was in vitro or in vivo); Ducor, *supra* note 159.

168 *See* Akim F. Czmus, *Biotechnology Protection in Japan, the European Community and the U.S.*, 8 TEMP. INT'L & COMP. L.J. 435, 440 (1994); Hofmeyer, *supra* note 74, at 991.

169 The PTO permits patentees to deposit their inventions in places called depositaries. While deposit may often be sufficient to meet enablement requirements, it may be inappropriate for transgenic animals because deposit of an animal does not reveal the operable invention in the genome. *See* Hofmeyer, *supra* note 74, at 993. Only deposit of particular material of the animal could sufficiently disclose the invention, but may not show the entire invention (both in geno- and phenotype). Joseph Straus, *Ethische, rechtliche und wirtschaftliche Probleme des Patent und Sortenschutzes für die biotechnologische Tierzüchtung und Tierproduktion* [*The Ethical, Legal and Economic Problems of Patent and Species Protection for Biotechnological Animal Breeding and Animal Production*] 39 GEWERBLICHER RECHTSSCHUTZ UND URHEBERRECHT, INTERNATIONALER TEIL [GRUR INT'L] 913 (1990). *See also* VAN DE GRAAF, *supra* note 36, at 339–45 (describing the enablement requirement in the context of animal material deposit).

The "first sale doctrine" implies that patents cannot restrict post-sale activities. The patentee's right to limit sales ends when the patented product is sold. It prevents purchasers down the distribution chain from being charged with infringement that grows out of a transaction further up the chain.[170] The first sale doctrine is not generally applicable to a patented transgenic animal. Due to reproductive capacities, animals reproduce without interference of the licensor or purchaser. Patents for these animals may encompass animals of a certain race that have the particular feature or explicitly encompasses all direct progeny.[171] Transgenic animals are especially attractive to farmers, due to their disease resistant qualities or greater productive capacities.[172] Farmers with limited financial resources, however, may be disadvantaged by the present scope of transgenic animal patents. Reproduction and use of the acquired transgenic animal by such farmers will constitute infringement. Compensation to the patentee may take the form of damages after infringement has occurred or be added to the initial acquisition price. Proposed legislation that would provide for a so-called farmer's exemption has not been enacted by Congress.[173] A farmer's exemption may not, however, be necessary.[174] Note that U.S. patent law does not provide for compulsory licenses.[175]

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[170] *See* Intel Corp. v. U.L.S.I. Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993).

[171] *See supra* notes 112–113.

[172] *See infra* Part C.1–3.

[173] In 1989, two bills were introduced that considered the position of farmers. H.R. 1556, 101st Cong. (1989); H.R. 1557, 101st Cong. (1989). These bills were similar to earlier attempts to create farmers' exemptions. H.R. 4970, 100th Cong. (1988); H.R. 4971, 100th Cong. (1988) (permitting farmers to reproduce patented animals during professional farming activities and allowing them to sell their offspring but prohibiting them from alienating germ cells, sperm, or embryos). *See* Hecht, *supra* note 104, at 1063–67; Morin, *supra* note 69, at 191–92.

[174] *See* Hecht, *supra* note 104, at 1073 (suggesting that patentees will not find it economically necessary to enforce their rights to the full extent and collect royalties); Walter, *supra* note 46, at 1041–42 (1998) (suggesting that the benefits of the transgenic animals will lower costs for farmers drastically, even if the higher acquisition prices and royalties are included and that inventors would, without patent protection, license out their animals more selectively. This is based on the assumption that alternative legal instruments, like the general law of contracts, will not provide enough protection to the inventor. This assumption is reviewed and confirmed. CHRISTINE ENZING, OCTROOIERING VAN GENETISCH GEMODIFICEERDE DIEREN: FEITEN EN MENINGEN [PATENTABILITY OF GENETICALLY MODIFIED ANIMALS: FACTS AND OPINIONS] 21 (1991)). *See also* Eckehart Von Pechmann, *Ist der Ausschluss von Tierzüchtungen und Tierbehandlungsverfahren*

Second, the Federal Circuit's denial of standing to animal rights groups and farmers in *Animal Defense* may drastically limit the possibilities for subjects, other than patentees, to negate the scope and contents of an issued patent.[176] It appears as if the validity of a patent on a transgenic animal can be challenged by patentees only, who are not likely to challenge their own patents.[177] While anyone may request re-examination of a patent, he or she can do so only on the basis of lack of novelty or nonobviousness.[178]

Standards of patentability for transgenic animals may not be affected directly by third party interests such as farmers and animal rights groups. The present regime provides strong protection for societal interest in innovation and the rights of patentees. Moreover, opponents appear to have limited opportunities to challenge that regime, at least procedurally.

III. EUROPEAN UNION

A. Legal Basis

The European patent system relies on the Convention on the Grant of European Patents.[179] The EPC aims to harmonise patent law among member states of the EU. Inventors can file patent applications in one state cognisable in all member states at the European Patent Office (EPO). The EPO is authorized to examine a patent application, reject it, or issue it. The patentee receives a bundle of national rights. The EPC outlines procedural law while

vom Patentschutz Gerechtfertigt? [*Is the Exclusion from Patentability of Animal Products and Animal Therapeutic Methods Justified?*] 36 GRUR INT'L 344 (1987); Straus, *supra* note 169, at 929.

175 *See* MERGES, *supra* note 52, at 189.

176 *See* Animal Legal Def. Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991).

177 Hecht, *supra* note 104, at 1059–60 (including challenges on grounds other than "inequitable conduct" (fraud) or "double patenting"). *See also* MERGES, *supra* note 62, at 751–95.

178 35 U.S.C. § 302 (2000). This does not serve the interests of stakeholders, other than patentees, either.

179 Convention on the Grant of European Patents, October 5, 1973, 1065 U.N.T.S. 199 [hereinafter EPC].

national law determines the substance and scope of patents granted. The EPC also includes important substantive provisions that determine the contents and scope of the patents acquired to a significant degree. Post-acquisition procedures are conducted in the member states, but enforcement may vary considerably from country to country. Before the conclusion of the EPC, various member states had ratified the Treaty of Strasbourg.

The Treaty of Strasbourg attempted to unify substantial patent law.[180] This treaty had a profound influence on the formation of the EPC,[181] but because of the EPC, the Treaty of Strasbourg has lost its relevance.[182] Furthermore, the Union Patent Treaty has been concluded, although it is not yet in force.[183] The Dutch Patent Act of 1995[184] is particularly relevant because the EPC provides for a collection of national patents, and national patent law is thus important for the content and scope of a particular patent. Directive 98/44 on the legal protection of biotechnological inventions (hereinafter the "Directive") has a profound influence on both the EPC and the national patent laws of the member states.[185] The Directive states that biotechnological inventions must be protected by patent law and sets forth the conditions for protection. Member states were supposed to amend their patent

[180] Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions, Nov. 27, 1963, Europ. T.S. No. 47 [hereinafter Unification Convention].

[181] It may be considered to be part of its legislative history and, therefore, important for its interpretation.

[182] WICHERS HOETH, *supra* note 53, at 9 (1993).

[183] This treaty will be replaced by the Agreement on Union Patents (1989) as soon as such is ratified by twelve member states. *Id.* at 9–10; Czmus, *supra* note 168, at 443–44.

[184] Rijksoctrooiwet houdende regels met betrekking tot octrooien [ROW 1995] [Patent Act Containing Rules With Respect To Patents 1995], Dec. 15, 1994, Stb. 1995, 51 (amended by statute on Dec. 14, 1995, Stb. 1995, 668) [hereinafter Dutch Patent Act]. Because of the scope of this article only a limited review of patent law of member states is appropriate. The conflicting views between the Dutch legislature and the European Commission on, e.g., the patentability of transgenic animals, is illustrative for the unclear situation in which patentees may find themselves when they have obtained a national patent under the EPC. For example, the Netherlands has tried to have European patent regulations declared void by the European Court of Justice. *See* Jan J. Brinkhof, *Patent Litigation in Europe: Two Sides of the Picture*, 9 FED. CIR. B.J. 467 (2000) (discussing the complexities of patent litigation in the EU). Another reason for the references to particularly Dutch patent law is the Dutch legal education of the author of this article.

[185] Council Directive 98/44/EC, 1998 O.J. (L 213) 13–21 [hereinafter Directive 98/44].

laws accordingly by July 30, 2000.[186] The Directive has been incorporated into the EPC.[187] The EPO has been examining patent applications for biotechnological inventions in accordance with the provisions of the Directive.

B. Requirements

EPC article 52(1) states that "[E]uropean patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."[188] Thus, an invention must be novel, industrially applicable and comprise an inventive step.

An invention changes what exists. An invention that embraces a solution must be sufficiently novel and inventive. An invention is novel if it is, in view of the prior art, not known to a person skilled in the art.[189] The state of the art does not include applications that are filed later than the one involved, for the EPC applies the first-to-file standard.[190] It includes, however, everything already public before the day of application. This includes European and foreign patents and pending applications, literature, and even oral communications.[191] The Technical Board

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[186] *Id.* at 20–21. The patent acts of most member states are brought into compliance with Directive 98/44. In the Netherlands, however, the proposed legislation is still processed in the Houses of Parliament. On April 3, 2002, the Dutch Tweede Kamer der Staten General (House of Representatives of the States General) voted against full implementation of Directive 98/44. Handelingen Eerste en Tweede Kamer, *at* www.overheid.nl.

[187] *See* Implementing Regulations to the EPC, June 16, 2000, 1997/7 O.J. 437 (incorporating Directive 98/44) [hereinafter Implementing Regulations]. This will further enhance harmonization of patent law in the EU and will increase the consistency of national interpretation of national patents granted pursuant to the EPC with the interpretations given thereto by the EPO. This incorporation occurred after the case law discussed below was formed and will therefore not be included in the review thereof. In view of the timing of the incorporation of Directive 98/44 in the EPC, its provisions will be discussed separately.

[188] *See* EPC*, supra* note 179, art. 52(1), 1065 U.N.T.S. at 271.

[189] *See id.* art. 56,. at 273; Hoge Raad der Nederlanden [Dutch Supreme Court] [DSC], Jan. 18, 1940, Nederlandse Jurisprudentie [NJ] 1940 (Hoge Raad der Nederlanden [HR] [highest court]).

[190] *See id.* arts. 54(2)–(3), at 272.

[191] *See* Case T 939/92, Agrevo/Triazole sulphonamides, 1996 E.P.O.R. 171, 178–79 (TBA 1996) (reasoning that state of the art "could reside solely in the relevant common general knowledge, which again, may or may not be in writing, that is, in textbooks or the

of Appeal of the EPO (TBA) applies a "problem and solution approach" for measuring the inventive step and nonobviousness requirement. The TBA identifies the closest prior art, assesses the technical results of the invention in view of the prior art, defines the technical problem that is to be solved by the invention, and determines whether a person skilled in the art would have suggested the claimed technical features for the solution provided.[192] Thus, it assumes that the person skilled in the art is knowledgeable about publications and other common knowledge around the world.[193]

The invention must have a technical character.[194] The technical character of an invention is different from its industrial applicability. Subject matter that may be industrially applicable, such as computer software, is excluded.[195] The technical contribution to the art may derive from the underlying problem and the claimed invention as such, or in the means providing for the solution of the underlying problem or the effects achieved thereby.[196] The industrial application of an invention relates to its practical applicability. An invention must offer a concrete solution for an existing problem.[197]

like, or be simply a part of the unwritten 'mental furniture' of the notional 'person skilled in the art'"); Case T 654/92, Sony/Interessengemeinschaft für Rundfunkschutzrechte E.V., 1994 O.J. 1 (TBA 1994); Case T 534/88, BM/Ion etching, 1991 E.P.O.R. 18, 21 (TBA 1990) (including lecture in state of the art).

[192] *See, e.g*., Case T 208/84, Computer related invention v. Vicom, 1987 O.J. 14 (TBA 1986) (requiring technical features to have a practical technical effect).

[193] Case T 020/81, Shell, 1982 O.J. 217 (TBA 1982); *see also* Hague District Court [DC] 41 BUREAU VOOR DE INDUSTRIËLE EIGENDOM [BIE] [NETHERLANDS INDUS. PROP. OFF.] 176 (1991).

[194] Relaxin/Howard Florey institute, 1995 O.J. E.P.O. 388 (Opp. Div. 1994); Rule 27 (1)(a) Implementing Regulations to the EPC. *See also supra* note 149.

[195] *See* EPC, *supra* note 179, arts. 52(2), 53(b).

[196] Case T 833/91, IBM/External interface simulation, 1998 E.P.O.R. 431, 437 (TBA 1993).

[197] *Cf.* Case T 939/92, Agrevo/Triazole sulphonamides, 1996 E.P.O.R. 171, 180 (TBA 1995) (reasoning that "the notional 'person skilled in the art' is not assumed to seek to perform a particular act without some concrete technical reason: he must, rather, be assumed to act not out of idle curiosity but with some specific technical purpose in mind"). *See also* Octrooi Raad [OR] [Dutch Patent Council], 188 BIE 21 (Sept. 30, 1987).

The invention may be a product or a process.[198] EPC article 64(2) states that a patented process encompasses products that were directly acquired by application of the process. EPC article 83 prescribes enablement requirements. The invention must be described in a manner such that an expert can take all the required steps and repeat the invention. It is insufficient that it is likely that the process, described in the specification to the claim, will lead to the result described.[199] Thus, EU patentability requirements are generally similar to those in the U.S.[200]

C. Exclusions

1. Classification

The EPC contains specific classes of exclusions from patentability. First, article 52(2) says that discoveries, scientific and mathematical theories, aesthetic designs, business methods, computer programs, and presentations of data are not inventions. In view of article 51(1), they are not patentable.[201] Second, article 53 states:

> Patents shall not be granted in respect of:
>
> (a) inventions whereof the publication or exploitation would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

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[198] *See* Dutch Patent Act, Dec. 15, 1994, Stb. 1995, 51 (amended by statute on Dec. 14, 1995, Stb. 1995, 668); Directive 98/44, *supra* note 185; VAN DE GRAAF, *supra* note 36, at 60.

[199] *See, e.g.*, Case T 226/85, Stable Bleaches/Unilever, 1988 O.J. E.P.O. 336 (TBA 1987); VAN DE GRAAF, *supra* note 36, at 325.

[200] *See* VAN DE GRAAF, *supra* note 36, at 427–41; Czmus, *supra* note 168, at 439 (discussing the novelty requirement); Darrell Dotson, Note, *The European Controversy Over Genetic-Engineering Patents*, 19 HOUS. J. INT'L L. 919, 925 (1997) (noting all requirements of patentability).

[201] The technical isolation of a gene, as such, without further modification, could be regarded as a discovery. The EPO considers the isolated gene to be an invention. *See* Directive 98/44, *supra* note 185, art. 3(1), (2); Case T 292/85, Genentech I, 1989 O.J. E.P.O. 275 (TBA 1988).

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

2. Article 53(a): *Ordre Public* and Morality

The EPO strictly excludes patentability of inventions that are contrary to "*ordre public*" or morality.[202] In *Plant cells/Plant Genetic Systems*, the *ordre public* exclusion was analyzed extensively by the TBA.[203] In holding that "patent offices are at the crossroads between science and public policy," the TBA rejected the suggestion that patent law is not suited for moral considerations.[204] It held that morality is concerned with the difference between right and wrong. The totality of acceptable norms, deeply rooted in European culture, is the basis for such belief.[205] Inventions must conform to that belief.[206] The concept of *ordre public* focuses on the protection of the physical integrity of individuals as part of society, public security, and the environment.[207]

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[202] Case 320/87, Lubrizol, 1990 O.J. 71 (TBA 1988). *See also* STEK, *supra* note 109, at 47; Straus, *supra* note 169, at 260.

[203] Case T 356/93, Plant cells/Plant genetic systems, 1995 O.J. 545 (TBA 1995) (discussing genetically transformed plant cells and plants). The exclusion of EPC art. 53(a) has also been discussed in detail with respect to transgenic animals, to be discussed below. Plant Genetic Systems is one of the many cases that may be discussed while reviewing EPC, *supra* note 179, art. 53(a). For the purpose of this article, such discussion is limited.

[204] *See* STEK, *supra* note 109, at 46; Schatz, *supra* note 47, at 2 (suggesting that patent law is not aimed at moral considerations).

[205] Various ethical theories determine what is "wrong" or "right." *See* VAN DE GRAAF, *supra* note 36, at 70–72; VERHOOGH, *supra* note 156 and accompanying text. Since Europe is presently far from being one in a cultural sense, it may be doubted whether one set of deeply rooted European norms exists, and if so, how to acknowledge them.

[206] *See Plant Genetic Systems*, 1995 O.J. at 545 (Plant biotechnology is no more "wrong" than traditional selective breeding. The inventions at hand were not excluded from patentability on this ground.).

[207] *See id.* (The inventions at hand were not posing a serious threat to the environment. Appellants had submitted evidence that genetic engineering of plants as such could threaten the environment. It was, however, not extraordinarily likely that the inventions at hand would pose such a threat.).

The EPO may consider public perception when deciding on whether a particular invention violates article 53(a).[208] In *Greenpeace v. Plant Genetic Systems*, the EPO's Opposition Division stated that public perception is particularly important under EPC article 53(a) when determining whether there is a general consensus that exploitation of a certain invention is immoral.[209] The last sentence of article 53(a) states that an invention will not be considered contrary to *ordre public* or morality simply because it is prohibited by national laws and regulations of the member states. These laws and regulations could, however, impose conditions on biotechnological research and development.[210] Article 53(a) gives a private right of action to the citizens of member states.[211]

3. Article 53(b): Plant or Animal Varieties, or Essentially Biological Processes, but Not Microbiological Processes or the Products Thereof

a) Plant or Animal Varieties

The exclusion of plant and animal varieties derives from article 2 of the Treaty of Strasbourg, [212] which allowed member states to ban patents on plant and animal varieties. With respect to the plant varieties, many countries did not want to contravene[213] the International Union for the Protection of New Varieties of Plants

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[208] Greenpeace v. Plant Genetic Systems, 1993 IIC 24 (Opp. Div. 1992).

[209] VAN DE GRAAF, *supra* note 36, at 66. It may, however, be complicated to determine accurately whether such consensus exists. The subject-matter of inventions may be too complex for many citizens in EU member states to comprehend. Also, the consensus must not be within one member state, but within the entire EU. Finally, the manner of reception of such consensus is unclear, e.g., by referenda, surveys, in the course of the opposition procedure of the EPC, *supra* note 179, article 99, etc.

[210] *See, e.g.*, Gezonheids en Welzijnswet voor Dieren [Health and Welfare Law for Animals], incorporated in the Dutch Patent Act, Dec. 15, 1994, Stb. 1995, 51 (amended by statute on Dec. 14, 1995, Stb. 1995, 668), art. 3b; Besluit Genetisch Gemodificeerde Organismen [Decree Genetically Modified Organisms], Stb. 53 (1990).

[211] *See* Dotson, *supra* note 200, at 926.

[212] *See supra* notes 179–182 and accompanying text.

[213] *See* Rudolph Teschemacher, *The Practice of the European Patent Office Regarding the Grant of Patents for Biotechnological Inventions*, 19 IIC 18 (1988).

(UPOV),[214] which was signed less than two years earlier. Originally, UPOV article 2(1) prohibited double protection of plant varieties; consequently, many countries devised sui generis protection.[215] The UPOV ban on double protection was lifted via an amendment on March 19, 1991. In EPC article 53(b), however, the exclusion of plant varieties has survived several revisions.[216] The EPO has interpreted the exclusion restrictively in cases dealing with plant varieties, excluding plants only in the genetically specified form of a particular variety.[217]

The reason for excluding animal races from patentability is related to the controversy that arose during the preparatory discussions for the Treaty of Strasbourg.[218] The participating countries fiercely debated the ethical implications, resulting in the concerned signatories excluding animal races.[219] Another reason animal races were excluded was the dominating view at the time that assumed that patent law was neither suited for, nor appropriately directed at, animal races. The rationale included the presupposed difficulties in disclosing the invention, the self-replicating capabilities of animals that complicate determining the content and scope of patents, and the lack of expertise on the part of various patent offices and courts.[220]

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214 *See supra* note 85 and accompanying text.

215 In the Netherlands, sui generis protection for plant varieties was arranged in the form of the Zaai en Plantgoed Wet [Sowing Seeds and Plants Statute], Stb. 455 (1966).

216 *See also* Directive 98/44, *supra* note 185, art. 4(1)(a).

217 *See* Case T 49/83, Propagating material/Ciba-Geigy, 1984 O.J. E.P.O. 112 A (TBA 1983); Case T 320/87, Hybrid plants/Lubrizol, 1990 O.J. E.P.O. 71 (TBA 1988); Case T 1054/96, Transgenic plant/Novartis, 1998 O.J. E.P.O. 511 (TBA 1997) [hereinafter *Novartis I*], *referred*, Case G 1/98, Transgenic plant/Novartis, 2000 O.J. E.P.O. 111, para. 3.10 (Enlarged Bd. of App. 1999) [hereinafter *Novartis II*]. For the TBA's motivation regarding the referral, see 1998 EUROPEAN INTELL. PROP. REV. 193. As long as plant varieties are encompassed by the claim, they are barred. *See* Case T 356/93, Plant cells/Plant genetic systems, 1995 O.J. E.P.O. 545 (TBA 1995). The TBA affirmed this substantive approach in *Novartis*. The Enlarged Board of Appeal in *Novartis II* overruled, finally. The meaning of the exclusion of animal varieties, and its impact on the patentability of transgenic animals, is discussed below.

218 *See* TESCHEMACHER, *supra* note 213, at 303–04.

219 *See* 1998 EUROPEAN INTELL. PROP. REV. 194; Straus, *supra* note 169, at 913; Von Pechmann, *supra* note 174, at 344; Volker Vossius, *Patentschutz für Tiere;* Krebsmaus/Harvard [*Patent Protection for Animals;* Onco-mouse/Harvard], 92 GRUR INT'L 333 (1990).

220 *See* Straus, *supra* note 169.

b) "Essentially Biological" Processes

Like the exclusion of plant and animal varieties, article 53(b) exclusion of essentially biological processes from patentability originates from article 2 of the Treaty of Strasbourg.[221] At the time of the Strasbourg Convention, essentially biological processes referred only to the normal, or traditional, breeding activities of plants and animals.[222] It had been recognized that traditional, natural processes are not worthy of patent protection. Further, they could not meet the enablement requirement of EPC article 83 (i.e., it was hard to repeat the result and lacked technical character.)[223] Biotechnological advancement has changed this situation. Now, distinguishing an "essentially biological" process is more difficult because of rec-DNA technology. Humans are able to change the genetic material of plants and animals by manipulating the natural, or essentially biological, processes.[224]

In view of these advances, the EPO has determined what processes are essentially biological. In *Hybrid plants/Lubrizol*, [225] the TBA held that whether a nonmicrobiological process is to be considered essentially biological depends on the extent of human intervention, the result achieved thereby, and the essence of the invention.[226] To render the process not essentially biological, human intervention is not enough per se; such intervention has to be more than trivial.[227]

In *Plant cells/Plant Genetic Systems*,[228] the TBA held a process for producing plants, combined with a process for genetically modifying them, to be essentially biological and, as such,

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[221] *See supra* notes 179–182, 210 and accompanying text. The exclusion of essentially biological processes is reviewed here because of its indirect impact on the issues that are at the heart of this article.

[222] *See* VAN DE GRAAF, *supra* note 36, at 103; Schatz, *supra* note 47, at 7; Straus, *supra* note 169, at 922.

[223] *See* WICHERS HOETH, *supra* note 53, at 30 (1993); Schatz, *supra* note 47, at 7.

[224] *See* VAN DE GRAAF, *supra* note 36, at 103; Volgens van Nispen, *Octrooirecht en Biotechnologie* [*Patent Law and Biotechnology*], 1990 AGRARISCH RECHT [AGRARIAN LAW] 165, 169.

[225] Case T 320/87, 1990 O.J. E.P.O. 71 (TBA 1988).

[226] *Id.* para. V(6).

[227] *Id.*

[228] Case T 356/93, Plant cells/Plant genetic systems, 1995 O.J. E.P.O. 545 (TBA 1995).

unpatentable pursuant to EPC article 53(b).[229] The TBA concluded that the transformative step was essentially technical, with a decisive impact on the final result.[230] The performance of this step, and achievement of the result, was not possible without human intervention.[231] Thus, essentially biological processes are those that occur entirely without human intervention. Also considered essentially biological are processes that are influenced by human interferences in a trivial manner.[232]

c) Microbiological Processes and Products

The last sentence of article 53(b) indicates that microbiological processes and their direct products are distinguishable from essentially biological products.[233] This exemption derives from article 2 of the Treaty of Strasbourg.[234] The editing of this provision was in line with the distinction that was made at the time between macro- and microbiology. At the time, the macrobiological processes and products were not in anyway considered to be technological, and thus were not within the reaches of patent law. This was in contrast to microbiological processes and their direct products, for which several patents had been granted in the nineteenth century.[235]

The term "microorganism" does not have a taxonomic meaning, but instead refers to the size of the organisms. For example, pathogens were traditionally considered microorganisms. "Microbiology" deals with the biology of microscopic forms of life,[236] or microorganisms. At present, biotechnologies and microbiological methods are combined for the genetic engineering

229 *Id*. para. XI(40.1).
230 *Id*.
231 *Id*.
232 *See* Walter Moser, *Exceptions to Patentability Under Article 53(b) European Patents Convention*, 28 IIC 848, 851 (1997).
233 *See* EPC, *supra* note 179, art. 53(b).
234 *See supra* notes 179–182 and accompanying text.
235 *See* Schatz, *supra* note 47, at 5; Joseph Straus, *Biotechnologische Erfindungen—ihr Schutz und seine Grenzen* [*Biotechnological Inventions—Their Protection and Its Limitations*], GRUR INT'L 256 (1992).
236 MERRIAM WEBSTER'S DICTIONARY 326 (Home & Office ed. 1995).

of plants and animals.[237] This raises the question whether a process that is applied on both cellular and genetic levels can still be regarded as "microbiological," and, moreover, whether the direct product thereof can also be considered to be "microbiological" when it is an animal or plant.[238]

The TBA has determined that the term "microorganism" also encompasses multicellular material, such as plants, animals, plasmids, and viruses.[239] Also, the term "microbiological process" only refers to processes that are "typically" microbiological. Products that are created or manipulated with the help of microorganisms, by a process that is entirely microbiological, are the products that "derive directly therefrom." Hence, they are patentable under EPC article 53(b).[240]

D. Patents for Transgenic Animals

1. Historic Development

Around 1900, German cattle breeders attempted to acquire protection for the products they produced—the animals they bred.[241] Of course, their production methods comprised processes of an essentially biological nature.[242] In 1969, the first patent for a bred animal was granted.[243] The *Bundesgerichtshof* (German Court of Appeals) ruled that a pigeon with red feathers could be patented under the *Patentgesetz* (German Patent Act).[244] Noting that the breeders methodically controlled natural forces to achieve a perceivable and causal result, the *Bundesgerichtshof* determined

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[237] *See* TESCHEMACHER, *supra* note 213, at 307; Moser, *supra* note 232, at 851.

[238] *See* VAN DE GRAAF, *supra* note 36, at 106.

[239] Case T 356/93, Plant cells/Plant genetic systems, 1995 O.J. E.P.O. 545, para. 29 (TBA 1995).

[240] *See id*.; VAN DE GRAAF, *supra* note 36, at 107; Moser, *supra* note 232, at 849.

[241] *See* JOSEF KOHLER, HANDBUCH DES DEUTSCHEN PATENTRECHTS [HANDBOOK OF GERMAN PATENT LAW] (reprint ed. 1984).

[242] *See id*. It is obvious that essentially essentially biological processes created these animals; they derived from veterinary selection and *breeding* as it has been performed for thousands of years.

[243] *See* Rote Taube [Red Pigeon], Entscheidungen des Bundesgerichtshofes in Zivilsachen [BGHZ] [Supreme Court] 52, 74 (75) (F.R.G.).

[244] *See id*.

that their method had a technical character. The invention, however, was not repeatable and, therefore, not patentable.[245] Later, the Treaty of Strasbourg and the EPC explicitly prohibited patents on inventions like the red pigeon. In 1983, however, the TBA held that there is no general prohibition on patenting modified living subject matter, while explicitly referring to EPC articles 52(1) and 53(b).[246] This decision was confirmed in *Hybrid plants/Lubrizol*.[247]

2. Patents Granted

In 1990, the EPO granted the first patent on a transgenic animal under the EPC, the Onco-mouse.[248] The initial application contained the following claims:

> 1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neo-plasmas, said method comprising introducing an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage . . . .
>
> . . . .
>
> 17. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than the 8-cell stage.
>
> 18. An animal as claimed in claim 17, which is a rodent.[249]

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[245] *See id*. at 76.

[246] *See* Case T 49/83, Propagating material/CIBA-GEIGY, 1984 O.J. E.P.O. 112 A, para. III (TBA 1983).

[247] Case T 320/87, Hybrid plants/Lubrizol, 1990 O.J. E.P.O. 71, para. IV(a) (TBA 1988).

[248] Case T 19/90, Onco-mouse/Harvard, 1990 O.J. E.P.O. 476 (TBA 1990) [hereinafter *Onco-mouse/Harvard II*], (commenting on European patent application 85.304.490.7). The TBA considered the impact of this patent within the European Union and took the unusual step of publishing the reasons for its decision. The application and procedure are reviewed extensively here. *Onco-mouse/Harvard II* is the only *fully* litigated transgenic animal patent under the EPC, and reveals its policy on patentability of transgenic animals.

a) The Examining Division in the First Instance

The Examining Division determined whether the applicant's invention might be considered novel and inventive within the meaning of EPC articles 52(1) and 56.[250] In light of the exclusion of animal varieties of EPC article 53(b), the Examining Division had to interpret the meaning of the term "animal variety."[251] It rejected[252] the TBA's narrow interpretation of the term "plant variety."[253] Animals can never be technical.[254] The Examining Division suggested that this determination is supported by the different terms that are used in the applicable texts of the EPC.[255] According to the Examining Division, the meaning of the terms *Tierarten,* "animal varieties," and *races animales* partially overlap, and this justifies a broad interpretation.[256] This broad definition leads to the exclusion of all animals, since all animals belong to a race and all races to a species.[257] Furthermore, the Examining Division stressed that animals could never be direct products of microbiological processes—this would enable evasion of the exclusion of animal varieties and is unacceptable.[258] Thus, claims 17 and 18 were denied (with respect to non-human mammalian animals and rodents) completely. The Examining Division also denied the claim with respect to the "ancestors" noting that they

[249] European Patent Application No. 85.304.490.7, *reprinted in Onco-Mouse/Harvard II,*1990 O.J. E.P.O. 476 para. I.

[250] *See* Case V 4/89, Onco-mouse/Harvard, 1989 O.J. E.P.O. 451 (Examining Div. 1989) [hereinafter *Onco-mouse/Harvard I*], *rev'd*, *Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. at 476. This discussion follows the exact order of the various procedural stages and the EPO groups' analysis and contents.

[251] *Onco-mouse/Harvard I*, 1989 O.J. E.P.O. para. 7.1.

[252] *Id*. para. 7.1.4. The restrictive interpretation was adopted in view of the existing sui generis protection for plant varieties, and the UPOV prohibition of double protection. *See supra* Part III.C.3(a).

[253] Case T 320/87, Hybrid plants/Lubrizol, 1990 O.J. E.P.O. 71, para. IV(e) (TBA 1988).

[254] *See Onco-mouse/Harvard I*, 1989 O.J. E.P.O. para. 7.1.4.

[255] *See id.* Pursuant to EPC article 177, the convention is published in three equally valid and applicable languages: German, French, and English (the official languages of the EU).

[256] *Onco-mouse/Harvard I*, 1989 O.J. E.P.O. para.7.1.4.

[257] *Id.* para. 7.1.6.

[258] *Id*.

would result from natural reproduction, which is an essentially biological process.[259]

The Examining Division did not consider the process to be microbiological.[260] It also did not deem it to be essentially biological, for it involved micro-injection of genetic material into the nucleus of the embryos.[261] The process was, however, considered unpatentable because of the enablement requirement of EPC article 83.[262] The Examining Division thought that the genetic differences among all sorts of mammalians are too large to have a reasonable expectation that the process can be repeated on all of these.[263] Thus, the process claims were also denied[264]—the application was denied entirely.

Furthermore, the Examining Division determined that, in itself, the claimed invention was not violating *ordre public* or "morality."[265] It conducted a marginal review: inventions were to be excluded from patentability only if they would lead to uproar, disturbance of the public order, or criminal behavior.[266] It simply concluded that such is not the case with the invention at hand.[267] The invention was considered to be beneficial to mankind.[268] The Examining Division justified its restrictive test of EPC article 53(a) for precluding patentability on the ground that it did not consider patent law the appropriate instrument for solving the problems that may derive from genetic engineering.[269]

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[259] The Examining Division ignored the fact that the claims did not refer to reproductive means. Thus, the descendants could also result from technological processes, such as cloning..

[260] The Examining Division's reasons for this conclusion do not appear in the decision.

[261] *Onco-mouse/Harvard I*, 1989 O.J. E.P.O. para. 7.2.1.

[262] *Id*. para. 11.

[263] *Id*. para. 11.2.

[264] *Id*. para. 7.2.4.

[265] *Id*. para. 10.1.

[266] *Id*.

[267] *Id*. para. 10.2

[268] *Id*.

[269] *Id*.

b) The TBA in the Second Instance

On appeal, the TBA first considered the repeatability[270] of the invention.[271] It determined that a specification to a claim does not have to set forth the application of the process entirely if it concentrates on a new field of technology.[272] Only if the repeatability is seriously doubted does EPC article 83 bar patentability.[273] It concluded that the specification enables a person skilled in the art to repeat the processes involved in micro-injection of genetic material and expression thereof.[274] Harvard, the patent applicant, asserted that the invention could be applied to other mammals than mice, by the inclusion of the term "non-human mammalians" in the specification.[275] The TBA did not have any opposing evidence.[276]

The TBA considered the article 53(b) preclusion of animal variety patents an exception to the general requirements criteria in article 52(1).[277] Therefore, it had to be interpreted restrictively.[278] The legislative history of the Treaty of Strasbourg and the EPC does not support the broad interpretation of the Examining Division. According to the TBA, the inclusion of the terms *Tierarten*, "animal varieties," and *races animales* in the text of the EPC supported a restrictive interpretation.[279] The second exclusion contained in EPC article 53(b) embraces animals as such.[280] The respective terms used in the different translations, i.e., *Tiere*, "animals," and *animaux*, have the same meaning. If they did not have a different rationale and meaning, the drafters would not have used different terminology for the exclusions.

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[270] *See* EPC, *supra* note 179, art. 83.

[271] *Onco-Mouse Harvard II*, Case T 19/90, 1990 O.J. E.P.O. 476, para. 3 (TBA 1990).

[272] *Id*. para. 3.3.

[273] *Id*.

[274] *Id*.

[275] *Id*.

[276] *Id*.

[277] *Id*. para. 4.

[278] *Id*. para. 4.5. This is in compliance with Case T 320/87, Hybrid plants/Lubrizol, 1990 O.J. E.P.O. 71, para. V(5)–(6) (TBA 1988).

[279] *Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. para. 4.6.

[280] *Id*. para. 4.1 (excluding "essentially biological processes for the production of . . . animals").

The TBA held that the EPO has to find a compromise between an inventor's need to receive appropriate protection for his invention and the public's interest that certain categories of animals be excluded from patentability.[281] Before such a compromise can be found, one first needed to ascertain the exact meanings of the terms *Tierarten*, "animals," and *animaux*.[282] If the mice did not fall within the scope of these terms, their patentability was not barred by article 53(b).[283] If the mice did fall within the scope of one of these terms, the correctness of such term was to be reviewed through comparison with the other two terms.[284]

The TBA agreed with the Examining Division with respect to the non-essentially biological nature of the process of micro-injection,[285] but it did not agree that the "ancestors" produced through natural reproduction were excluded from patentability.[286] It concluded that this exclusion for processes had been applied incorrectly to the Onco-mouse.[287] Claim 17 applied to products-by-process, the ancestors, that remain products for the purpose of patentability.[288] Also, it found that if the parents were not excluded from patentability—to be determined under article 53(b)—then the ancestors were also not to be excluded, for they were genetically identical.[289]

The final sentence of EPC article 53(b) contains an exception to the exclusion from patentability of that provision.[290] The general requirements for patentability are fully applicable to microbiological processes and their direct products, contrary to the decision of the Examining Division in this regard.[291] The direct products of microbiological processes were held to be patentable, even if they were animals.[292] Thus, it was necessary to determine

281 *Id*. para. 4.5.
282 *Id*. para. 4.6.
283 *Id*. para. 4.8.
284 *Id*.
285 *Id*. para. 4.9.1.
286 *Id*. para. 4.9.2.
287 *Id*.
288 *Id*.
289 *Id*.
290 *Id*. para. 5.
291 *Id*.
292 *Id*.

whether the process at hand was a microbiological one, and if so, whether the animals derived directly from it.

The TBA held that a full test to the article 53(a) exclusion of patentability was necessary, especially for applications that embrace genetic engineering inventions.[293] Genetically modifying animals by inserting oncogenes may be problematic in view of the *ordre public*.[294] First, it may cause animal suffering.[295] Second, eventual release of the animals would have unlimited and irreparable consequences.[296] In determining a patent application, the EPO needed to balance the interests in preventing animal suffering, environmental protection, and humankind's need for curing genetic diseases.[297] Consequently, the TBA remanded the case to the Examining Division.[298]

c) The Examining Division in the Third Instance

On remand, the Examining Division concluded that the meaning of EPC article 53(b) is unclear in light of the different terms its translations contain (*Tierarten*, "animal varieties," and *races animaux*).[299] Claims 17 and 18 of the application focused on non-human mammals, such as rodents, and particularly mice. The Examining Division subsequently defined "animal variety" as:

> [R]odents or even mammals constitute a taxonomic unit much higher than species. An "animal variety" or "race animale" is a sub-unit of species and therefore of even lower ranking than a species. Accordingly, the subject

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[293] *Id*.

[294] *Id*.

[295] *Id*.

[296] *Id*. These considerations relate to oppositions that were conducted pursuant to EPC, *supra* note 179, article 99. Some of the filed oppositions are discussed in Morin, *supra* note 69, at 159–60.

[297] *Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. para. 5.

[298] *Id*. Pursuant to EPC, *supra* note 179, article 111(1), the TBA could have decided the case itself or, as it did, remand to the Examining Division. It remanded because the review in this case was important, deserving two instances.

[299] Case V 6/92, Onco-mouse/Harvard, 1992 O.J. E.P.O. 589 para. 2 (Examining Div. 1992) [hereinafter *Onco-mouse/Harvard III*].

> matter of the claims to animals per se is considered not to be covered by the . . . terms of article 53(b) EPC.[300]

Hence, with respect to the animals, the application was not rejected under EPC article 53(b).[301]

Furthermore, the Examining Division held that genetic engineering inventions as such do not violate *ordre public* or morality, and, therefore, do not need to be excluded from patentability per se pursuant to EPC article 53(a).[302] It determined that:

> (i) A patent does not give the patentee a right to exploitation, but the right to exclude others from exploiting the invention for a certain period of time;[303]
>
> (ii) [t]he principle is patentability; exclusions therefrom need to be interpreted restrictively;[304]
>
> (iii) [n]ew technologies always bring new risks; the risks need to be reviewed in view of the benefits those technologies; after such review the determination about patentability can be made;[305]
>
> (iv) [i]f inventions concern higher forms of life, the possible sufferance of these forms because of the invention needs to be considered in aforementioned review;[306] [and]
>
> (v) [t]his review needs to be made with respect to every invention, on a case-by-case basis.[307]

Subsequently, the Examining Division balanced the interests mentioned by the TBA.[308] It concluded that the invention at hand

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[300] *Id*. Thus, the claims do not focus on *Tierarten*, "animal varieties," and *races animaux*. In fact, the Examining Division conducted a zoological classification. To be able to do so, however, it must have had defined them.

[301] *Id*. para. 4(v).

[302] *Id*.

[303] *Id*. para. 3.

[304] *Id*.

[305] *Id*.

[306] *Id*.

[307] *Id*.

[308] *Id*. para. 4.

did not violate the *ordre public* or morality[309] for the following reasons:

> (i) The invention is beneficial to human beings; cancer is a disease that has numerous victims, and every new means in the battle against this disease should be welcomed;[310]
>
> (ii) [a]nimal suffering will decrease because of this invention; a smaller number of animal models will be needed than in conventional research;[311]
>
> (iii) [t]here are no alternatives to animal models for cancer research;[312]
>
> (iv) [i]n view of the need for environmental protection, the purpose and use of the invention needs to be considered; the animal models that are produced by the invention are to be used in laboratories by skilled personnel; the chance that the animals may end up in free nature is small, and would only increase by a mistake—and the risk of a mistake cannot in itself support denial of the application at hand;[313] [and]
>
> (v) [t]he fact that a certain technology may create risks does not render it a violation of *ordre public* or morality; the exploitation of such technologies must be regulated by governmental bodies other than the EPO.[314]

As a result, it granted the patent.[315]

3. The European Case Law Reviewed

Clearly, transgenic animals can fulfill the requirements of EPC articles 52(1) and 56. They can be novel, inventive, and have industrial application.[316] Genetically modified animals can have a

309 *Id*.
310 *Id*. para. 4(i).
311 *Id*. para. 4(ii).
312 *Id*. para. 4(iii).
313 *Id*. para. 4(iv).
314 *Id*. para. 4(v).
315 *Id*.
316 *See generally id*.

technical character, so long as they do not derive from essentially biological processes.[317] *Plant cells/Plant Genetic Systems* shows that as long as the same result could not have been achieved without human intervention, and the difference from the result without such intervention is not trivial, they are not so produced.[318] In case the applied method of genetic modification can be considered to be microbiological, the animals that directly derive therefrom are patentable.[319] This is so, regardless of whether the animal would be a *Tierart*, "animal variety" or *race animaux*.[320]

In view of *Plant cells/Plant Genetic Systems*, it may be doubted whether the process of genetically modifying an animal (such as micro-injection in the case of the Onco-mouse) can be regarded as microbiological. In *Plant cells/Plant Genetic Systems,* the TBA held that only processes that are typically microbiological would be included.[321] It may be argued that the biotechnological process is of decisive importance to the final result—the transgenic animal with the particular feature. Furthermore, and contrary to the determination of the TBA in *Onco-mouse/Harvard*, it has been held that entire multicellular organisms cannot derive from microbiological processes.[322]

The zoological classification that the Examination Division made in *Onco-mouse/Harvard III* is not entirely correct. The

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[317] *See* Case T 320/87, Hybrid plants/Lubrizol, 1990 O.J. E.P.O. 71, paras. 4–6 (TBA 1988); Case T 356/93, Plant cells/Plant genetic systems, 1995 O.J. E.P.O. 545 (TBA 1995).

[318] *Plant genetic systems*, 1995 O.J. E.P.O. para. 18.7.

[319] *Onco-Mouse/Harvard II*, Case T 19/90, 1990 O.J. E.P.O. 476, para. 4.9.2 (TBA 1990).

[320] The EPO uses both the terms *races animaux* and "races animals." Its terminology is followed where the applicable holdings are relevant. The correct term is *races animales*.

[321] *Plant genetc systems*, 1995 O.J. E.P.O. para. 17.1–13.

[322] *See id*. The TBA held that the modified cells could directly derive from the microbiological process, not the entire plant. *But see Novartis*, Case T 1054/96, 1998 O.J. E.P.O. 511, paras. 48–50 (TBA 1997) (requiring a conceptual approach—the question is whether the modified organism is still related to the microbiological process, or comes closer to a "variety"). Arguably, this approach cannot stand. Article 53(b) is clear on the inclusion of products that derive directly from microbiological processes: they are patentable. A conceptual approach does not seem reconcilable with this provision whereas a technical approach, *see, e.g.*, *Plant Genetic Systems*, 1995 O.J. E.P.O. para. 17.1–13, seems to be. *Novartis II*, 2000 O.J. E.P.O. para. 4, seems to confirm this with respect to EPC articles 53(b) and 64(2).

Examination Division considers *Tierarten* (species) to be of a higher taxonomical unit than the "animal varieties" and *races animaux*, whereas the latter are considered as of the same taxonomical unit.[323]

"Varieties" and "races," however, do not have to be of the same taxonomical unit.[324] Depending upon the particular circumstances, the term "variety" may relate to a higher or lower taxonomical unit than "races."[325] The term "variety" means "deviation from type or species".[326] Thus, "varieties" could be deviations from a species, from a race, or from a specific variety within the same species or race.[327] In line with the holding of the TBA, it should be determined whether an invention falls within the scope of any of the terms used in the respective texts of EPC article 53(b). Thus, the invention may resemble a "race," a "variety" of a "race," an *Arte*, a "variety" of an *Arte* and, obviously, a "variety" of a "variety" of a "race" or *Arte*. If any of the terms apply, it should be determined whether they have the correct meaning.[328] In the case of transgenic animals, the invention will mostly be a "variety" of a particular race—it concerns minor genetic changes that will not easily result in a new "race."[329] Within the near future, however, biotechnologists may create new races. Certain chimaeras may be genetically distinguishable from the races that have provided their genetic parts—they may not be classifiable in one or the other racial category.[330]

Onco-mouse/Harvard permits the issuance of broad patents. The application must focus on taxonomical units higher than *Tierarten*, whereas the specification only has to instruct the successive steps to be performed in modifying one type of animal

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323 *Onco-mouse/Harvard III*, Case V 6/92, 1992 O.J. E.P.O. 589 para. 2 (Examining Div. 1992).

324 *Id*.

325 *Id*.

326 HENDERSON'S DICTIONARY OF BIOLOGICAL TERMS, *supra* note 1, at 578.

327 On the zoological classification of animals (including human beings), see MARGULIS & SCHWARTZ, *supra* note 119.

328 *Onco-mouse/Harvard II*, Case T 19/90, 1990 O.J. E.P.O. 476, para. 4.8 (TBA 1990).

329 *See* Schatz, *supra* note 47, at 10.

330 *See* Vossius, *supra* note 219, at 334.

of one race.[331] To protect the patentability of his other invention from being barred by article 53(b) exclusion, the inventor just has to avoid addressing his or her claim to a particular animal (of a particular race). The EPO will only reject *if* there is serious doubt about the applicant's assertions in the specification. The TBA seems to assume that all processes of genetic modification will, in principle, be performable with all animals, and that such performance will be successful as well.[332] The enablement requirement of EPC article 83 is hereby weakened. Thus, in view of *Onco-mouse/Harvard*, inventors can quite easily obtain broad patents for minimal description (and perhaps minimal invention) with respect to transgenic animals under the EPC.[333]

In view of EPC article 53(a), it is clear that the EPO applies ethical principles to the patentability of transgenic animals according to the deontological and consequentialist theories.[334] The TBA has provided for a balancing test between the purposes and consequences of the invention.[335] The EPO needs to review the purposes of the invention in light of their benefits and their consequences, such as animal suffering and the effects on the environment.[336] Applicants may, however, have to pass difficult hurdles before their claims are awarded, in view of the opposition procedure that is provided in EPC article 99. The TBA has taken opposition seriously and considers it in its deliberations.[337]

4. Directive 98/44[338]

Directive 98/44 article 1 requires that member states of the EU protect biotechnological inventions through their patent laws. This

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[331] *Onco-mouse/Harvard III*, Case V 6/92, 1992 O.J. E.P.O. 589 para. 2 (Examining Div. 1992); Case G 1/98, *Novartis II*, 2000 O.J. E.P.O. 111 para. III (Enlarged Bd. of App. 1999).

[332] *Onco-mouse/Harvard II*, 1990 O.J. E.P.O. para. 3.3, .8.

[333] *See* Dotson, *supra* note 200, at 933; Funder, *supra* note 131, at 557.

[334] *See supra* note 156 and accompanying text.

[335] *Onco-mouse/Harvard II*, 1990 O.J. E.P.O. para. 5 (applied by the Examining Division in *Onco-mouse/Harvard III*, 1992 O.J. E.P.O. at 589).

[336] *Onco-mouse/Harvard II*, 1990 O.J. E.P.O. para. 5; VAN DE GRAAF, *supra* note 36, at 70–72.

[337] *See Onco-mouse/Harvard II*, 1990 O.J. E.P.O. para. 4.9.2; Dotson, *supra* note 200, at 926.

[338] *See supra* note 185.

follows the case law of the EPO.[339] Directive 98/44 article 2 defines the terms "biological material" and "microbiological process." Article 2(1)(a) states that "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. This definition clearly encompasses animals. Article (2)(1)(b) states that a microbiological process is any process involving, or performed upon, or resulting in microbiological material. Article 2(2) states that a process for the production of plants and animals is essentially biological if it consists entirely of natural phenomena, such as crossing and selection. Article 2(3) states that an effective EC Regulation defines the term "plant variety."[340] "Animal variety" is not defined. Article 3(1) determines that inventions that fulfill the general requirements of patent law are patentable, even if they concern biological material. Article 3(2) states that biological material which is isolated from its natural environment or produced through a technical process can be the subject of an invention, even if it occurred previously in nature. This provision permits the patenting of not only genes that are isolated from the genome, but also of plasmids, viruses, and entire animals—if they can be produced through a technical process.[341]

Article 4 provides that:

1. The following shall not be patentable:

   (a) plant and animal varieties;

   (b) essentially biological processes for the production of plants or animals.

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[339] *See, e.g.*, Case G 1/98, *Novartis II*, 2000 O.J. E.P.O. 111 paras. 48–50 (Enlarged Bd. of App. 1999); Case T 356/93, Plant cells/Plant genetic systems, 1995 O.J. E.P.O. 545 (TBA 1995); *Onco-Mouse Harvard II*, 1990 O.J. E.P.O. para. 4.9.2 (TBA 1990); Case T 320/87, Hybrid plants/Lubrizol, 1990 O.J. E.P.O. 71 (TBA 1988).

[340] Directive 98/44, *supra* note 185, art. 2(3).

[341] In *Plant genetic systems*, 1995 O.J. E.P.O. at 545, the TBA doubted whether this could be achieved though a biotechnological process as such. Regarding the first part of the provision, an animal that has been isolated from its natural surrounding (caught by a technical catching technique containing an added biotechnological element) can be patented, arguably, as a product-by-process.

> 2. Inventions, which concern plants or animals, shall be patentable if the technical feasibility of invention is not confined to a particular plant or animal variety
>
> 3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological process or other technical process or product obtained by means of such process.[342]

Article 4(1)(a) and (b) follow EPC article 53(b) and the pre-existing case law.[343] It should be noted, however, that the term "essential biological processes" has a more restrictive meaning under Directive 98/44 than it had under the pre-existing case law. Directive 98/44 article 2(2) provides that they are processes that are comprised entirely of natural phenomena, such as crossing and selection. The case law shows that essentially biological processes are those that occur without a "decisive" human intervention.[344] Directive 98/44 deviates therefrom in the sense that all processes that are not entirely biological are not essentially biological. The EPO may consider animals produced by sexual reproduction, but with slight human interference, to be derived from other processes—and as such patentable.

Article 4(2) also follows the case law of the EPO, and makes clear that varieties as such are excluded from patentability.[345] The terms in the effective text of Directive 98/44 are *Tierrassen*, *races animals*, and "animal varieties."[346] Applications for inventions

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[342] Directive 98/44, *supra* note 185, art. 3(2).

[343] *See Novartis II*, 2000 O.J. E.P.O. paras. 48–50; *Plant genetic systems*, 1995 O.J. E.P.O. at 545; *Onco-mouse/Harvard II*, 1990 O.J. E.P.O. at 476.

[344] *Plant genetic systems*, 1995 O.J. E.P.O. para. 17.1.

[345] *See Novartis II*, 2000 O.J. E.P.O. paras. 48–50; *Plant genetic systems*, 1995 O.J. E.P.O. at 545; *Onco-mouse/Harvard II*, 1990 O.J. E.P.O. at 476.

[346] *See* Von Pechmann, *supra* note 174, at 347 (arguing that most applications will focus on a lower taxonomical level than species, and, therefore, the exclusion would function only if it was directed at those lower levels and that this would serve consistency). Vossius, *supra* note 219, at 337, argued, conversely, that the terms "animal varieties" and *races animaux* should be replaced by the terms "animal species" and *espèces animales* (arguing that since inventions are not likely to encompass species, the exclusion should be directed to it). The English equivalent of the terms *races animales* and *Tierrassen* would have been "animal races." Because of inclusion of the term "animal variety," varieties as such cannot be patented, and also confusion may remain on the particular meaning of the exclusion in a particular case.

that are directed at taxonomical units higher than those of races and (racial) varieties will not be barred by the exclusion that is provided for by article 4(1)(a), its implementation in national patent law, or EPC article 53(b). Since Directive 98/44 does not refer to enablement requirements, such as are included in EPC article 83, it is likely that the light standard of the TBA will be applied by the EPO, and that inventors can acquire broad animal patents with less description.[347]

Article 4(3) follows the case law with respect to the products-by-process patents for animals, akin to the ones that are provided for in the last sentence of EPC articles 53(b) and in EPC article 64(2).[348] It seems to broaden, however, the scope of the products that are derived by the processes. The term "direct," as it appears in EPC articles 53(b) and 64(2), is omitted; the products may be produced "by means" of a microbiological or other technical process. Furthermore, and in view of the definition of microbiological processes in article 2(1)(b), it is likely that the EPO considers methods of genetic modification to be microbiological.[349] The reasoning of the Examining Division in *Onco-mouse/Harvard* shows that these products can be produced "by means" of such processes.[350]

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[347] *See Onco-mouse/Harvard II*, 1990 O.J. E.P.O. at 476. Note that national courts are competent under national law with respect to the enforcement of the patent, including validity procedures, etc. Absent any reference to the enablement requirement in Directive 98/44, *supra* note 185, the national courts will set their own standards, not necessarily the same as that of the TBA. For example, in the Netherlands, the enablement requirement of the Dutch Patent Act, Dec. 15, 1994, Stb. 1995, 51 (amended by statute on Dec. 14, 1995, Stb. 1995, 668), article 25 is applied rather strictly. *See* WICHERS HOETH, *supra* note 53, at 28.

[348] *See Novartis II*, 2000 O.J. E.P.O. at 111; *Onco-mouse/Harvard II*, 1990 O.J. E.P.O. at 476. As described, it may not be difficult to directly produce an animal through a process that is not an essentially biological one. *See* Directive 98/44, *supra* note 185, art. 2(2).

[349] *See* Directive 98/44, *supra* note 185, art. 2(1)(b). The clause states that microbiological processes are processes that *involve*, or are *performed upon*, or *result in* microbiological material. Pursuant to this definition, methods of genetic modification, such as were used in *Onco-mouse/Harvard*, will be considered microbiological.

[350] Consequently, the decision in *Plant cells/Plant genetic systems*, Case T 356/93, 1995 O.J. E.P.O. 545 (TBA 1995), that entire animals can never derive *directly* from a microbiological process: only the genetically modified cells, looses its importance. The animals do not need to derive directly from the process, but must be produced *by means* thereof.

Directive 98/44 article 5(1) dictates that the human body, at the various stages of its development, and the discovery of one of its elements, including the sequence of a gene, are not patentable. An element isolated from a human body or otherwise produced by technical means may constitute a patentable invention pursuant to clause 2 of this provision. Further, article 6 states that:

> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed so contrary merely because it is prohibited by law or regulation.
>
> 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
>
> (a) processes for cloning human beings;
>
> (b) processes for modifying the germ line identity of human beings;
>
> (c) uses of human embryos for industrial or commercial purposes;
>
> (d) processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.[351]

Article 6(1) deviates from EPC article 53(a); it is narrower. Only *commercial* exploitation can be contrary to *ordre public* or morality. EPC article 53(a) provides for inventions of which the publication or exploitation is contrary to *ordre public* or morality. The patentability of human beings, their parts, and material is excluded in a broad manner. The exclusion of processes for genetic modification of animals, and the animals resulting therefrom, by article 6(2)(d) is in line with the balancing test as outlined in *Onco-mouse/Harvard*.[352]

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[351] Directive 98/44, *supra* note 185, art. 6.

[352] Directive 98/44, *supra* note 185, article 6(2)(d) provides for a combination of the deontological and consequentialist theories. However, in view of considerations 40–43 and article 6(2)(a)–(c), it is noted that Directive 98/44 makes a hard distinction between

Article 7 provides that the European Group on Ethics in Science and New Technologies (Group) evaluates all aspects of biotechnology. This provision reveals the European inclination to actively focus on ethical considerations with respect to the patentability of transgenic animals. Since the Group will function outside of the patenting process, its reports are likely to have interpretative value for national courts and the EPO. It is likely, therefore, that the Group will play a role in future proceedings under EPC article 99 (the opposition procedure).[353]

Directive 98/44 articles 8 to 11 state the content and scope of patents granted for biotechnological inventions. Article 8(1) sets forth that the protection conferred by a patent on biological material possessing certain characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. Clause 2 of this provision states that patents granted for processes of genetic modification extend to the products directly obtained thereby, and to material obtained through propagation or multiplication derived from these products. These provisions confirm the determination of the TBA toward patentability of the descendants of the genetically modified mice.[354] They also confirm the case law with respect to the scope of patents for microbiological and other processes, as defined by EPC articles 53(b) and 64(2).[355] They also significantly broaden the scope of patents for transgenic animals by stating that the patent's scope extends to all material that derives from the patented product, whether in the same or *divergent* form, if it possesses the

animals and human beings. Human beings can never be patented, whereas animals can be patented. An absolute principle is thus applied: human beings are not animals. The legal reflection of this principle shows that the framers of Directive 98/44, unlike the EPO, applied the virtue theory as well.

353 *See* VAN DE GRAAF, *supra* note 36, at 69; Drahos, *supra* note 161, at 448.

354 *Onco-mouse/Harvard II*, Case T 19/90, 1990 O.J. E.P.O. 476, para. 4.9.2 (TBA 1990).

355 *Id.*, para. 4.8; *see also* Case G 1/98, *Novartis II*, 2000 O.J. E.P.O. 111 para. 4 (Enlarged Bd. of App. 1999).

same characteristics. This will allow for a "chain patent," whose scope will expand continuously.[356]

Directive 98/44 article 9 provides that the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material in which the product is incorporated and in which the genetic information is held and performs its function—except where it involves human beings. As a result of this provision, the questions about patentability of transgenic animals and animal varieties under the EPC become, to a large extent, irrelevant. A patent granted on a gene, or gene construction, extends to the animals in which such a gene is inserted and expressed. Acquisition of a patent on a gene will suffice to obtain a de facto patent on all animals that possess and express that gene.[357] The exclusion of patentability of animal varieties by EPC article 53(b) and by article 4(1)(a), will therefore only be effective with respect to inventions that result in new animal varieties (races).

Directive 98/44 articles 10 and 11 provide exceptions to the scope provided for by articles 8 and 9. Article 10 contains a restrictive first-sale-rule (exhaustion of patent) within the EU if the biological material was obtained with the consent of the patentee and is used for the purpose for which it was acquired. Subsequent propagation or multiplication will, however, lead to patent infringement. Pursuant to article 10, a breeder can mate the acquired transgenic animals, as well as use acquired semen for reproduction, if he or she has acquired these products with the consent of the patentee within the EU and the reproduction serves the purpose for which the products were acquired. Subsequent animals may, however, not be used for reproduction. Article 10 thus provides for a breeders' exemption.

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[356] This *may* lead to conflicting patents if, for example, two patented animals are crossed to produce a third animal. Neither Directive 98/44, *supra* note 185, nor the EPC, *supra* note 179, provides for a resolution to eventual conflicts. Most national patent laws of the member states of the EU do not have "conflict provisions," either. *See, e.g.*, Dutch Patent Act, Dec. 15, 1994, Stb. 1995, 51 (amended by statute on Dec. 14, 1995, Stb. 1995, 668).

[357] *See* Robin Nott, "*You Did It!": The European Biotechnology Directive at Last*, 20 EUROPEAN INTELL. PROP. REV. 347, 348 (1998). This may lead to unsolvable conflicts between patents. The patents on the gene, the process, and the animal may be in different hands.

Article 11(2) provides for a farmers' exemption. The sale or any other form of commercialization of breeding stock or other animal reproductive material to a farmer by the holder of a patent or with his consent implies authorization for the farmer to use the protected life stock for an agricultural purpose. This includes making the animal or the reproductive material available for the purpose of pursuing his or her agricultural activity but not for sale within the framework or purpose of a commercial reproduction activity. Article 11(2) gives a farmer who, for example, produces milk or cheese, the right to use the acquired transgenic animals or semen for reproduction if this serves his agricultural goals. These goals cannot include commercial breeding. It is likely that the initial prices of transgenic animals and their materials will rise because of the exemptions in articles 10 and 11. Thus, it may be doubted whether these exemptions will serve the economic needs of breeders and farmers.

Directive 98/44 article 12 provides for a compulsory license for users of plant varieties and associated materials that fall within the scope of a patent. Such licenses are not provided for users of animal varieties and associated materials. Directive 98/44 article 13 allows for description of the invention for the purpose of enablement as required by EPC article 83 and Dutch Patent Act article 25 by deposit. It may be doubted, however, whether deposit of transgenic animals can serve as description for enablement.[358]

5. Issues Reviewed

a) Novelty and Inventive Step

Patentability of transgenic animals, as provided for by the reviewed case law and Directive 98/44, may not correspond with the general requirements for patentability as defined by EPC article 52(a) and the patent laws of member states.[359] As the Canadian

[358] *See supra* note 168; *infra* text accompanying note 366.

[359] *See, e.g.*, Dutch Patent Act, art. 2; Directive 98/44, *supra* note 185, arts. 1, 2(1)(a), 4(2) (allowing animals to be patented as products; *id.* art. 9 (allowing animals to be patented as material in which a patented product is inserted and expressed); *id.* arts. 2(1)(b), 4(3) (allowing animals to be patented as products by microbiological process); *id*. arts. 4(1)(b), 2(2), 4(3), 8(2) (allowing animals to be patented as products by other

Federal Court has noted with respect to the Harvard mouse: "the presence of the myc gene is new, but the mouse is not new."[360] Thus, the patentability of entire animals may, strictly considered, violate clear case law of the EPO and the EPC.[361] Particularly, the patentability of entire transgenic animals that have undergone only minor genetic modifications may be problematic in view of the usual assessment of the inventive step—the technical result of the invention in view of the matter that was pre-existing.[362]

b) Enablement

The TBA has loosely applied the enablement requirement as incorporated in EPC article 83.[363] This may lead to patents that do not cover their contents, because inventors need to describe their invention as not comprising an animal of a particular race, otherwise, it would be excluded from patentability.[364] Because of TBA's loose application of EPC article 83, however, the inventors can describe their invention in broad terms, i.e., comprising various species, whereas the invention is only applied (and thus

processes); *Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. at 476. The absence of any technical addition may be shown most clearly in the case of a gene, which is isolated from its environment and inserted and expressed in an animal without further modification. The processes of isolation and insertion may be technical according to the traditional view. However, under Directive 98/44, *supra* note 185, articles 3(2) and 8(1)–(2), patents will be granted not only to the processes, but also the gene, and all the animals that carry such gene (whether produced via technical insertion of the gene or by propagation).

[360] Harvard College v. Canada, [1998] 3 F.C. 510, *rev'd*, [2000] 4 F.C. 528 (Can.).

[361] *See* EPC, *supra* note 179, arts. 27(1)(a), 52(a), 54; Case V 8/94, Relaxin/Howard Florey institute, 1995 O.J. E.P.O. 388 para. 6 (Opposition Div. 1994).

[362] *See supra* note 131 and accompanying text.

[363] *Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. para. 19(a). *See also* Spindler, *Current Patent Protection Granted For Genetically Modified Organisms Under The EPC and the Scandal of EP 0695351,* 18 SANTA CLARA COMPUTER & HIGH TECH. L.J. 95*,* 112–15 (2001). After opposition procedures on July 22–24, 2002, the Edinburgh Patent, EP 0695351, was limited, so as to not include human or animal embryonic stem cells, but still covers non-embryonic stem cells that are modified. *See* Press Release, EPO, "Edinburgh" Patent Limited After European Patent Office Opposition Hearing (July 24, 2002), *at* http://www.european-patent-office.org/news/pressrel/2002_07_24_e.htm (last visited Nov. 26, 2002). This meets Spindler's criticism.

[364] *See* Directive 98/44, *supra* note 185, art. 4(1)(a), (2); Case G 1/98, *Novartis II*, 2000 O.J. E.P.O. 111 (Enlarged Bd. of App. 1999); *Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. para. 19(a).

enabled and disclosed) on one variety or race of one species.[365] In the long run, these patents do not serve the underlying goals of patent law—stimulation of technological innovation.[366] Patent applicants may disclose the invention by deposit of the material concerned: the animals.[367] Deposit, however, may not lead to full disclosure because the presence and expression of a gene in a modified animal is not always externally perceivable.

Practical problems may arise by the deposit of entire animals at the EPO.[368] Furthermore, problems may arise because EPC article 54(3) provides that patent applications are part of the "prior art," and EPC article 92 provides for publication of the application. One may doubt whether a third party can accurately acquire the prior art from the publication of the application. Pursuant to EPC article 13(2), third parties can acquire a sample of the deposited material. One also may be skeptical about the enforcement of this provision, in case a transgenic animal is deposited; or, to put it differently, how many animals must be deposited to serve the goal of this provision?

c) Exclusion of Animal Varieties

In view of the required broad description of the invention in the patent application,[369] the low standard applied to enablement and repetition,[370] the animals that are considered to be produced by microbiological processes,[371] the animals that are produced by

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[365] *See* Sven Bostyn, *DNA—Octrooien, mag het een beetje meer zijn?* [*DNA—Patents, Could It Be A Little More?*], 2002 NEDERLANDS JURISTENBLAD 258, 258–59 (particular to EU situation); Rochelle K Seide, Janet M. MacLeod & Carmella L. Stephens, *Drafting Claims for Biotechnology Inventions in* 11TH ANNUAL PATENT PROSECUTION WORKSHOP: ADVANCED CLAIM DRAFTING & AMENDMENT WRITING at 294 (PLI Pats., Copyrights, Trademarks, & Literary Prop. Course, Handbook Series No. G0-00PK, 2001) (discussing enablement difficulties in general).

[366] *See supra* Part I.C; Funder, *supra* note 131, at 552.

[367] *See* Directive 98/44, *supra* note 185, art. 13.

[368] *See infra* text accompanying notes 415–16.

[369] *See* Directive 98/44, *supra* note 185, art. 4(1)(a), (2); *Novartis II*, 2000 O.J. E.P.O. at 111; *Onco-mouse/Harvard II*, Case T 19/90, 1990 O.J. E.P.O. 476, para. 4.9.2 (TBA 1990).

[370] *See Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. at 476.

[371] *See* Directive 98/44, *supra* note 185, arts. 2(1)(b), 4(3); *Novartis II*, 2000 O.J. E.P.O. at 111; *Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. at 476.

processes of sexual reproduction not being essentially biological,[372] the animals falling within the scope of the patents granted on the gene they carry and express,[373] and the animals propagated from animals patented in one of these manners,[374] one can conclude that the exclusion of animal varieties does not have much meaning left in the European Union at this time.

d) *Ordre Public* and Morality

The EPO will surely apply the exclusion from patentability of inventions that are considered to be contrary to *ordre public* or morality, particularly when an application embraces transgenic animals.[375] *Onco-mouse/Harvard* illustrates the manner in which this exclusion will be applied by the EPO—via of balancing the interests involved. As a result of Directive 98/44 article 6(1), which provides that only inventions whose commercial application violates *ordre public* or morality are unpatentable, it seems that all inventions with other purposes may be patented. Note, however, that one of the main goals of patent law is to allow the patentee to exploit his/her invention commercially while excluding others from doing the same. It is unlikely that inventors will apply for patents without wanting to use them for such exploitation.[376]

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[372] Directive 98/44, *supra* note 185, arts. 2(2), 4(1)(b).

[373] *Id*. art. 9.

[374] Directive 98 /44, *supra* note 185, art. 8(1), (2). *See* Spindler, *supra* note 363 (discussing EP 0 695 351).

[375] *See* Directive 98/44, *supra* note 185, arts. (2)(d), 6(1); EPC, *supra* note 179, art. 53(a); *Onco-Mouse/Harvard II*, 1990 O.J. E.P.O. at 476; EPO President Ingo Kober, Address at the EPO Annual Press Conference (June 27, 2000) (excerpt available at http://www.european-patent-office.org/news/pressrel/2000_06_27_e.htm).

> [O]ur patent examiners are keenly aware of the ethical problems attending such applications . . . . There is . . . a staff notice . . . calling attention to the specific items in the list of ethical prohibitions in the Directive. There is an early warning system for ethically sensitive applications, and there are arrangements of quality monitoring . . . .

Id.

[376] *See, e.g.*, the exclusive rights of a patentee under Dutch Patent Act, Dec. 15, 1994, Stb. 1995, 51 (amended by statute on Dec. 14, 1995, Stb. 1995, 668), art. 53(1)(a), (b) (granting the patentee the exclusive right to "sell the patented product professionally" and to "apply the patented process professionally"). Dutch Patent Act article 53(3) excludes research and preparation of medicine in a pharmacy for an inventor's private purposes from the scope of the patent. Hence, at least in the Netherlands, the "commercial restriction" of Directive 98/44, *supra* note 185, article 6(1) does not seem to make sense.

Furthermore, Directive 98/44 does not provide a definition of the term "commercially." This creates uncertainty. In view of the balancing test that is provided for in Directive 98/44 article 6(2)(d), definitions need to be formed. It is unclear what standards should be applied, while balancing the "suffering" of animals with the "substantial benefit" to humankind. The meaning of these terms is unclear.

e) Definitions of Species

Directive 98/44 articles 5 and 6(1), (2)(a)–(c) provide that human bodies, certain human materials, certain processes for genetic modification of human beings, and human cloning are unpatentable. Neither the EPC nor Directive 98/44 defines terms such as "human body," "human identity," "human origin," "human being," or what constitutes an animal, however.[377] This seems odd, especially because "plant variety" is given a particular definition.[378] The lack of a well set out and clear definitions may cause problems when biotechnology advances and new inventions are made which demand determination of their zoological nature.[379]

f) Third Party Interests

In view of the approach of the EPO to EPC article 53(a), and its detailed consideration of oppositions filed pursuant to EPC article 99 in *Onco-mouse/Harvard*, it is likely that third parties, such as animal rights groups, will increasingly be in a position to express their opinions on the patenting of particular transgenic animals (and other biotechnological inventions). Since under the EPC opponents can file an opposition to a patent application, or to an EPO patent until nine months after the issuance,[380] the legal certainty of patentees and their licensees may be diminished. In view of Directive 98/44 article 7 and the advisory and evaluative role of the European Group on Science and New Technologies (the

[377] *See* Directive 98/44, *supra* note 185, arts. 5, 6, and considerations 9, 16–17, 20–21, 26–27, 29, 38, 40–42, 44–45 (noting the terms applied).

[378] Directive 98/44, *supra* note 185, considerations 30–32.

[379] *See supra* Part II.D.3(d) for suggestions on definitions.

[380] *See* EPC, *supra* note 179, art. 99(1).

New Technologies Group), the non-technological aspects of patenting transgenic animals (and other biotechnological inventions) will be considered on a permanent basis. The New Technologies Group will most likely attend to the interests of third parties, such as animal rights groups and farmers, and will influence further developments in European patent law.

Directive 98/44 articles 10 and 11 provide for exemptions to the scope of patents for breeders and farmers. Article 12 does not include a compulsory licensing scheme for these groups. Unless the national legislatures regulate the patentees' and licensees' rights,[381] it is likely that the exemptions of referenced articles will not suit the economic needs of breeders and farmers. Patentees will most likely raise prices of their products at initial acquisition to include royalties that would, without the exemptions, be collected afterwards.

IV. THE PATENTABILITY OF ANIMALS: A COMPARATIVE PERSPECTIVE

A. Transgenic Animals as Subject Matter

Both in the U.S. and the EU, transgenic animals as such (products) can fulfill the requirements for patentability.[382] In the U.S., the decisions in *Chakrabarty*[383] and *Ex parte Allen*[384] and the Harvard mouse patent[385] show that animals that do not occur in nature could be patented.[386] In the EU, *Onco-mouse/Harvard* and Directive 98/44 articles 1, 2(1)(a), and 4(2) show that animals can fulfill the requirements for patentability.[387] Both in the U.S. and the EU, the patent offices grant patents for the entire animals

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381 *See* Directive 98/44, *supra* note 185, consideration 51.

382 *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980); *Onco-mouse/Harvard III*, Case V 6/92, 1992 O.J. E.P.O. 589 para. 4.8, .10 (Examining Div. 1992).

383 447 U.S. at 304. *See also* Quigg v. Animal Legal Def. Fund, 900 F.2d 195 (9th Cir. 1990); Quigg, *supra* note 157.

384 2 U.S.P.Q.2d (BNA) 1425, 1426–27 (S.D. Tex. 1987).

385 *See* Harvard mouse patent, *supra* note 106.

386 *See supra* note 108 and accompanying text.

387 *See Onco-mouse/Harvard I*, Case V 4/89, 1989 O.J. E.P.O. 451 (Examining Div. 1989), *rev'd*, *Onco-mouse/Harvard II*, Case T 19/90, 1990 O.J. E.P.O. 476 (TBA 1990).

concerned, but the actual invention may be the insertion of one gene and expression thereof, to alter directly only a minor portion of the genome of the animals.[388] Clearly, both in the U.S. and the EU, the patent offices uphold a low standard for novelty and nonobviousness (in the EU, inventive step).[389]

Both in the U.S. and the EU, transgenic animals can be patented as products-by-process. In the U.S., section 103(b) of the Act provides that the products of biotechnological processes fall within the scope of the patent on the process. In the EU, EPC articles 53(b) (last sentence) and 64(2), Directive 98/44 article 2(1)(b), in conjunction with article 4(3) and articles 4(1)(b), 2(2), 4(3), and 8(2), and the decisions in *Onco-mouse/Harvard* and *Novartis II* make it clear that animals fall within the scope of the patents on the processes from which they derive.[390]

In the EU, animals are also protected by the patents on the genes that are inserted into and expressed in them.[391] This patent protection is not available in the U.S. In this regard, the EU offers more possibilities for animal patents. Both in the U.S. and in the EU, genes as such are patentable.[392] In the U.S., however, the patent on the gene will not, by operation of law, extend to the animals in which it is inserted and expressed. The animal concerned has to be patented as a manufacture or composition of matter or the process whereby it was modified.[393] Only then will the animal be within the scope of the patent. In the EU, the inventor and patentee of a gene has the certainty that all animals in which it is incorporated will be within the scope of his/her

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[388] *See Onco-mouse/Harvard III*, 1992 O.J. E.P.O. 589; Harvard mouse patent, *supra* note 106. For other U.S. patents, see *supra* notes 111–116.

[389] *See* 35 U.S.C. §§ 101–103 (2000); EPC, *supra* note 178, art. 52(1), 56; Directive 98/44, *supra* note 185, arts. 1, 2(1)(a), 3(1). For a different approach, see *Harvard College v. Canada*, [1998] 3 F.C. 510, *rev'd*, [2000] 4 F.C. 528 (Can.); *In re* Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995).

[390] Together with a loose application of the enablement requirement and crafty drafting of (broad) claims, this latitude leads to the controversial scope of patent EP 0 695 351. *See* Spindler *supra* note 361.

[391] *See* Directive 98/44, *supra* note 185, art. 9.

[392] *Compare In re Deuel*, 51 F.3d at 1558, *with* Directive 98/44, *supra* note 185, art. 3(2).

[393] *See Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426 (BPAI 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988).

patent.[394] Conversely, in the U.S., inventors can apply openly for patents on transgenic animals as such.[395] Thus, they can attempt to acquire a patent on one modified animal, a group of animals, a variety, and—in case such will prove to be possible in the future—a race that has been created through biotechnology. In the EU, an application cannot directly focus on one animal or animals belonging to one race.[396]

B. Restrictions on Patentability

In the U.S., laws and products of nature are not patentable.[397] In principle, animals produced by propagation are produced through a process that is subjected entirely to the laws of nature, and are themselves products of nature.[398] However, the PTO and courts apply the doctrines of laws of nature and products of nature restrictively.[399] This is also revealed by some of the patents that the PTO has granted for transgenic animals produced by sexual reproduction; some claims explicitly include such animals within their scope.[400] Other patents implicitly include such sexually produced offspring.[401]

In the EU, essentially biological processes and their products are not patentable,[402] but an essentially biological process has to consist *entirely* of natural phenomena such as crossing or selection.[403] Thus, processes of sexual reproduction that are carried out with a slight human intervention may be subject to

394 *See supra* note 391 and accompanying text.
395 *See supra* notes 75, 100, 106, 383, 384.
396 *See* EPC, *supra* note 179, art. 53(b).
397 *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).
398 *See id.* at 310.
399 *See id.* at 309; *Allen*, 2 U.S.P.Q.2d (BNA) at 1426.
400 *See* U.S. Patent No. 5,221,779 (issued 1993, withdrawn) (The claim includes " . . . transgenic mouse offspring produced by the mating . . . .").
401 *See* Harvard mouse patent, *supra* note 106, (claiming a "transgenic non-human mammal . . . or an ancestor"); U.S. Patent No. 5,648,597 (issued July 15, 1997), (claiming a "transgenic mouse or the progeny thereof").
402 EPC, *supra* note 179, art. 53(b); *see also* Directive 98/44, *supra* note 185, art. 4(1)(b).
403 Directive 98/44, *supra* note 185, art. 2(2).

patent law, as may the products (animals) thereof.[404] Therefore, the patent offices and courts of the U.S. and EU restrictively apply the doctrines that deal with products that occur naturally.

In the U.S., an invention must be useful pursuant to article 101 of the Act.[405] Utility is, in principle, also related to the benefits that derive from an invention to society.[406] The PTO and county apply this doctrine very restrictively with respect to inventions consisting of transgenic animals.[407] The PTO's only moral restriction on patentability of living subject matter deals with human/animal chimeras,[408] but the distinction between what is "human" and what is "animal" is unclear.[409] The various patents granted for animals containing human genes seem to suggest that the PTO will not consider an invention a human/animal chimera as long as its genome consists mostly of naturally occurring, non-human genes. Although at least one federal court decision seems to suggest that the doctrine of beneficial utility may be invoked more often with respect to biotechnological inventions—such as transgenic animals—this is not very likely.[410] In the EU, EPC article 53(a) and Directive 98/44 article 6 provide for exclusions from patentability of inventions that are contrary to *ordre public* and morality. These grounds for exclusion are similar to the grounds that would govern if the PTO applied a broad doctrine of beneficial utility.[411] *Onco-mouse/Harvard* shows that these exclusions are fully effective under the EPC and that inventions are

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[404] See the patent granted in *Onco-mouse/Harvard III*, Case V 6/92, 1992 O.J. E.P.O. 589 (Examining Div. 1992) (Claim 17 encompasses a "transgenic non-human mammalian . . . or an ancestor of said animal . . . .").

[405] 35 U.S.C. § 101 (2000).

[406] *See* Magnani, *supra* note 100, at 452.

[407] *See supra* notes 160–161.

[408] *See* Quigg, *supra* note 157.

[409] *See supra* note 161. Because of the lack of an unequivocal distinction between what is "human" and what is not, it will not be easy to apply moral restrictions. Practical application will certainly be controversial. For a socio-political, philosophical, and, here and there, legal perspective on the matter, see FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE, CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION, part 3 (2002).

[410] *See* Tol-o-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft, 945 F.2d 1546, 1553 (Fed. Cir. 1991); *supra* note 155.

[411] *Compare* EPC, *supra* note 179, art. 53(a), *and* Directive 98/44, *supra* note 185, art. 6(1), *with Tol-o-Matic*, 945 F.2d at 1553, *In re* Nelson, 280 F.2d 172, 178–81 (C.C.P.A. 1960), *and* Lowell v. Lewis, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8,568).

indeed reviewed with regard to their purposes and consequences. *Onco-mouse/Harvard* and article 6(2)(d) provide for a balancing test between, on one hand, the benefits to humanity deriving from the invention and, on the other hand, the animal suffering caused.

The President of the EPO recently confirmed this approach in a public statement.[412] The constitution of the European Group on Science and New Technologies, as stated in Directive 98/44 article 7, also states that these exclusions will remain active in European patent law—perhaps more active then ever before. Thus, when patent applications are received in the EU, the EPO and national patent offices will consider non-technological concerns, such as those related to the well-being of animals, the overall ethical consequences of a certain invention, and environmental protection. These considerations are not included in the review of a patent application by the PTO and U.S. courts.

Both in the U.S. and the EU, human-related inventions are more or less excluded from patentability.[413] In the U.S., human/animal chimeras are not statutorily excluded from patentability, but the PTO has announced that it will not issue patents for human/animal chimaeras.[414] The basis for this exclusion is unclear.[415] Also, neither the PTO nor courts have determined what constitutes a "human" and what constitutes an "animal."[416] In the EU, the exclusion of human-related materials from patentability has a statutory basis—in the EPC pursuant to the incorporation of Directive 98/44 in its Implementing Rules, and

412 *See* Kober, *supra* note 375.

413 *See* Directive 98/44, *supra* note 185; *Tol-o-Matic*, 945 F.2d at 1553; *Nelson*, 280 F.2d at 178–81; *Lowell*, 15 F. Cas. at 1019.

414 *Compare* EPC, *supra* note 179, art. 53(a), *and* Directive 98/44, *supra* note 185, art. 6(1), *with Tol-o-Matic*, 945 F.2d at 1553, *Nelson*, 280 F.2d at 178–81, *and Lowell*, 15 F. Cas. at 1019.

415 It has been suggested that this exclusion derives from the U.S. Constitution's prohibition on slavery, U.S. CONST. amend. XIII. *See* Fishman, *supra* note 159, at 472–80; Walter, *supra* note 46, at 1047. Both authors reject this ground for the exclusion, as the Thirteenth Amendment prohibits human servitude, not a temporary right to combine human and animal genes.

416 *See supra* note 111.

within the near future in the member states after full implementation in their patent acts.[417]

Directive 98/44 article 5(1) determines that the human body, in its various stages of development, cannot be patentable. Clauses 2 and 3 of this provision state conditions under which human genes may be patented. Directive 98/44 article 6(2) (a)–(c) states that processes for human cloning, processes for modifying the germ line identity of human beings, and uses of embryos for industrial or commercial application are unpatentable. Arguably, the products deriving from these processes may be patentable. Although the unpatentable inventions that relate to human beings have been specified more in European patent law than in the U.S., the definitions of these materials also remain unclear in the EU. Neither the EPC nor Directive 98/44 gives a definition for what constitutes a "human being" and what constitutes an "animal." Thus, both the patent regimes of the U.S. and the EU contain a critical uncertainty in their terminology. In view of the rapidly advancing biotechnology, there is a pressing need for formation and inclusion of clear definitions.[418]

C. Enablement

Both U.S. and European patent law provide for the deposit of biological material in order to fulfill the enablement requirements under the respective regimes.[419] Under both regimes, however, deposit as such will most likely not lead to de facto full disclosure.

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[417] *See, e.g.*, Case C-377/98, Netherlands v. European Parliament and Council of the European Union, 2001 O.J. (C 331) 231, 231–45 (2002) (rejecting the Netherlands requests for invalidation of Directive 98/44). The Netherlands is obliged to implement Directive 98/44 immediately in the Dutch Patent Act, Dec. 15, 1994, Stb. 1995, 51 (amended by statute on Dec. 14, 1995, Stb. 1995, 668). Resistance in the Netherlands continues, however, and therefore the controversy is likely to be prolonged. *See* Sven Bostyn, *Het Sprookje is uit. De beslissing van het Europese Hof inzake de Nederlandse vodering tegen richtlijn 94/44/EG* [*The Fairy Tale is Over. The European Court's Decision in Regard to the Dutch Claim Against Directive 94/44/EC*], 11 BIE 392 (2001); Andrew Scott, *The Dutch Challenge to the Bio-Patenting Directive*, 1999 EUROPEAN INTELL. PROP. REV. 212.

[418] *See* Ducor, *supra* note 158, at 259; Fishman, *supra* note 159, at 478–80; Jagels, *supra* note 77, at 146.

[419] *Compare* 35 U.S.C. §§ 112, 114 (2000), *with* EPC, *supra* note 179, art. 83, *and* Directive 98/44, *supra* note 185, art. 13.

This is because the expression of genes within animals may not be observable externally. Also, practical problems may arise, such as the storage and maintenance of the animals. In Europe, patent applications become part of the prior art.[420] In view hereof, EPC article 92 provides for immediate publication when applications are filed. This is because under European patent law the EPO issues patents to the first one to file the application (first-to-file system). Directive 98/44 article 13(2) provides, therefore, for the issuance of samples of the material immediately after its deposit to interested parties. In the case of the deposit of transgenic animals, one may doubt how this would be arranged—without demanding that the applicant deposit numerous animals. In the U.S., pursuant to section 122(a) of the Act, patent applications at the PTO were confidential until the law was changed in November 1999 to require publication 18 months after the earliest filing date.[421] This is because under U.S. patent law the PTO issues patents to the first one to invent (first-to-invent system). After a patent has been granted by the PTO, samples may be obtained by interested parties as well; the same questions about how this should be done with entire animals arise as in the EU. Thus, both under the patent regimes of the U.S. and the EU, there are problems with respect to disclosure and enablement of inventions consisting of transgenic animals. These problems lead to a lack of internal (towards the patent offices) and external (towards third parties) disclosure.[422]

In view of the substantial review of the repeatability of the invention, pursuant to the enablement requirement, it is likely that the PTO will have a more traditional and strict test than the EPC. Under U.S. patent law, single transgenic animals and groups of animals belonging to or forming the same race can be patented. This will allow inventors to construct their claims, and to provide descriptions, in an accurate manner—and the PTO will review

420 EPC, *supra* note 179, art. 54(3).

421 *See* Pub. L. No. 106-13, 113 Stat. 1501a-563 (1999) (codified at 35 U.S.C. § 122).

422 *See* Czmus, *supra* note 168, at 440–41. Czmus also mentions problems that relate to the discrepancies that exist between the U.S. and the EU on the release criteria for samples and the existing disparity between the deposit deadlines.

these accordingly.[423] Under EU law, applicants are forced to construct their claims and provide descriptions in a broad manner, comprising not only one animal or a group of animals belonging to the same race, but also other animal races (or even higher taxonomical units). It is clear that the EPO will not review repeatability too strictly, for if it were to do so it is likely that many patents could not be granted.[424] This may lead to patents that are too broad and are not justified by the underlying inventions.[425] A careful balance has to be struck between not granting an inventor patents that are too limited and not granting him/her patents that are too broad in order to serve the purpose of patent law (technological innovation).[426] In view of the foregoing, it may be concluded that the PTO strikes this balance better than the EPO, the approach of which may be considered to be out of balance.[427]

D. Scope of Patents

Both under the patent regimes of the U.S. and the EU, the patent offices grant patents for genetically modified animals, as well as their offspring.[428] The terms applied in Directive 98/44 article 8 ("propagation and multiplication") are, however, broader

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[423] In fact, this has happened since the broad Harvard mouse patent, *supra* note 106, was granted. Most, but not all, patents granted after 1988 have a more limited scope. *See, e.g.*, *supra* notes 111–116.

[424] *See Onco-mouse/Harvard II*, Case T 19/90, 1990 O.J. E.P.O. 476 (TBA 1990). Also see the final patent granted in *Onco-mouse/Harvard III*, Case V 6/92, 1992 O.J. E.P.O. 589 (Examining Div. 1992).

[425] *See supra* notes 111–116.

[426] *See supra* Part I.D.

[427] *Compare* the Act, 35 §§ U.S.C. 100–122 (2000); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980), *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1427 (BPAI 1987), *aff'd*, 846 F. 2d 77 (Fed. Cir. 1988), the Harvard mouse patent, *supra* note 106, *and* the patents mentioned in notes 111–16, *with* EPC, *supra* note 179, art. 53(b), Directive 98/44, *supra* note 185, art. 4 (1)(a),(2); Case G 1/98, *Novartis II*, 2000 O.J. E.P.O. 111 (Enlarged Bd. of App. 1999), *and Onco-mouse/Harvard III*, 1992 O.J. E.P.O. at 589.

[428] *Compare* the Harvard mouse patent, *supra* note 106, (claiming a "transgenic non-human mammal . . . or an ancestor"), *with* the patent granted in the *Onco-mouse/Harvard III*, 1992 O.J. E.P.O. at 589 (claiming a "transgenic non-human mammalian . . . or an ancestor of said animal"). *See also* Directive 98/44, *supra* note 185, art. 8 (extending patent protection to material obtained through propagation or multiplication of patented products); *e.g.*, U.S. Patent No. 5,648,597 (1997) (claiming "a transgenic mouse or progeny thereof"); U.S. Patent No. 5,221,779 (1993) (claiming " transgenic mouse offspring produced by the mating").

than the terms found in patents granted so far for transgenic animals under U.S. patent law ("offspring," "progeny," and similar terms). The latter do not include clones of the animals concerned, whereas the term "multiplication" in Directive 98/44 article 8 especially addresses these reproductions of the patented animals.

E. Third Party Interests

Under U.S. patent law, no exception to the scope of patents granted on transgenic animals exists,[429] in contrast to European patent law that provides for detailed and specific exceptions for both breeders and farmers (Directive 98/44 article 10 and 11).[430] Note that the exhaustion rule of Directive 98/44 article 10 is triggered only if the material is acquired in the EU; thus, U.S. farmers will have to go to Europe to acquire the preferred materials. It may be doubted whether U.S. breeders' and farmers' economic interests will be seriously affected by the absence of such an exemption.[431] If, however, their interests suffer, it may be doubted whether an exemption, as articles 10 and 11 of Directive 98/44 provide, will be sufficient to protect these interests. Patentees could prevent any loss of income by demanding higher prices at the initial acquisition of the animals or animal material—and the European exemptions would then be useless.[432]

Pursuant to the decision in *Animal Legal Defense Fund*, it seems that third parties, such as animal rights groups and farmers, cannot bring direct actions to challenge the validity of a patent issued under U.S. law, e.g., with respect to its subject matter,

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[429] *See supra* Part II.D.3(f).

[430] See *supra* Part III.D.5(f).

[431] *See* Hecht, *supra* note 104, at 1073 (suggesting that patentees will not find it economically necessary to enforce their rights to the full extent and collect royalties); Walter, *supra* note 46, at 1041–42 (suggesting that the benefits of the transgenic animals will lower costs for farmers drastically, even if the higher acquisition prices and royalties are included and that inventors would without patent protection license out their animals more selectively). The latter suggestion is based on the assumption that alternative legal instruments, like the general law of contracts, will not provide enough protection to the inventor. This assumption is reviewed and confirmed. *See* ENZING, *supra* note 174, at 21; Straus, *supra* note 219, at 929; Von Pechmann, *supra* note 174.

[432] *See* Walter, *supra* note 46, at 1042.

contents or scope.[433] This may seriously hamper the influence "outsiders" can exercise on the development of the patent law with respect to biotechnological inventions.[434] Under European patent law, third parties—like referenced ones—have opportunities to express their opinions with respect to the patenting of a certain invention. EPC article 99 provides for an opposition procedure that can be initiated by "anyone" until nine months after the patent is granted (clause 1). The TBA of the EPO has taken oppositions filed under EPC article 99 very seriously and has included them in its review—for example, regarding to the exclusions of EPC article 53(a).[435] This approach was recently confirmed by the President of the EPO.[436] Also, Directive 98/44 article 6 provides for a broad test of *ordre public* and morality. In view of the foregoing, it can be concluded that the concerns of third parties are likely to be heard during, or shortly after, the review of a patent application filed under the EPC. These concerns, however, cannot be expressed in a like manner at a similar time in the U.S. Obviously, other means, such as negotiating with interest groups, lobbying at a

[433] *See* Quigg v. Animal Legal Def. Fund, 900 F.2d 195 (9th Cir. 1990); MERGES, *supra* note 62, at 751–95; Hecht, *supra* note 104, at 1059–60 (referring to challenges on other grounds than "inequitable conduct" (fraud) or "double patenting"). The animal rights groups and farmers (plaintiffs) in *Quigg* objected to the patenting of transgenic animals on moral and economic grounds, respectively. The doctrines of "inequitable conduct" and "double patenting" are not suitable for addressing these objections.

[434] *But see* Drahos, *supra* note 161, at 447. Drahos strongly opposes this lax situation. He argues that civilians should have a voice in the developments, because of the profound influence patent law has on their life. Arguably, Drahos' position does not seem more justifiable with respect to biotechnological inventions than with other types—mechanical and chemical inventions could have strong influences on the civilian life, as history has shown. The complexity of the invention at issue presents a problem to direct civilian participation. The influence might be useful only when the inventions are truly understood. *See* VAN DE GRAAF, *supra* note 36, at 66 (stating that external societal influences influences on patent litigation may, however, increase the legitimacy and, therefore, the certainty of the patent).

[435] For the TBA's final considerations and interests-balancing illustrated through opposition procedures, see *Onco-mouse/Harvard II*, Case T 19/90, 1990 O.J. E.P.O. 476 (TBA 1990). *See also Onco-mouse/Harvard III*, Case V 6/92, 1992 O.J. E.P.O. 589 para. 2 (Examining Div. 1992).

[436] *See* Kober, *supra* note 375.

political level, and raising broad public attention to the issues concerned may very well be available in the U.S.[437]

European patent law generally provides for compulsory licensing in cases of "public interest."[438] These licenses are rarely granted by the national authorities, e.g., the minister of economic affairs,[439] a court,[440] or a patent office.[441] Nonetheless, the system of compulsory licensing may provide a basis for protection of the

[437] These means are shown by the various bills that have been initiated in Congress, which served the interests of animal rights groups and/or farmers. *See* Hecht, *supra* note 104, at 1057–58.

[438] *See, e.g.*, EPC, *supra* note 179, art. 73; Dutch Patent Act, Dec. 15, 1994, Stb. 1995, 51 (amended by statute on Dec. 14, 1995, Stb. 1995, 668), arts. 57–58; WICHERS HOETH, *supra* note 53, at 59, 69.

[439] Dutch Patent Act art. 57

[440] *Id*. art. 58

[441] For example, in the Netherlands, compulsory licenses for *algemeen belang* [public interest] have been granted just twice, both by the Dutch Patent Office, shortly after the Second World War. *See* Dutch Patent Office, 1946 BIE, Nov. 25, 1946, at 9. The minister of economic affairs had considered a compulsory license just once, and rejected it. The minister determined that the "public interest" must eclipse the general governmental policy goals, which the case did not do. *See* Decree of the Minister of Economic Affairs, BIE 1981, Jan. 9, 1980, at 185. "Public interest" is not the individual corporation's interest in competitive advantage, unless the product concerned could be marketed by another party for a lower price, and other circumstances necessitate such. *See* Chamber of Appeal, Patent Office, BIE, Feb. 17, 1932, at 136; Chamber of Appeal, Patent Office, BIE, July 19, 1972, at 236. Furthermore, the Dutch Supreme Court has approached the issue of compulsory licenses and authorization of patent infringement carefully and restrictively. *See* Dutch Supreme Court, BIE, Apr. 21, 1995, at 409 (holding that, in principle, the interests of third parties should not be protected by allowing patent infringement).

Six years before, the President of the District Court of The Hague had allowed infringement (a de facto compulsory license). It held that patients' interest in having access to certain medicines outweighed the patentee's stated financial interest, which could be safeguarded by damages or other compensation. President of the District Court of The Hague, Nov. 21, 1989, No. 89/2069 (unpublished). Both cases addressed section 168 of book of 6 of the Dutch Civil Code, which could serve as a defence to a patentee's claim for prohibition of infringement, and hence could lead to a de facto compulsory license.

In Germany, the *Bundesgerichtshof* [Supreme Court] has determined that *öffentliche Interesse* [public interest] is to be defined and applied according to the circumstances of the case, and a balancing between the patentee's interests and the societal interests. In case other, similar but not identical and infringing products are available, the balance favours the patentee: a "public interest" for a compulsory license is not present. *See* 1996 GRUR INT'L 948; de Ranitz, *Dwanglicenties: Heden Verleden en Toekomst* [*Compulsory Licenses: Past, Present and Future*] 2 IER 42–47 (1992).

interests of third parties that have a pressing need to make use of the invention. U.S. patent law does not provide for compulsory licensing.[442] Recently, an international discussion has arisen among governments, patentees, and other interested parties about the need for compulsory licenses for patented inventions, such as medicines, which are of profound importance to humanity. This discussion derives from the exclusionary power of the patentee, which may directly harm those in need of the patented invention.[443]

V. HARMONIZATION

A. General Remarks

The foregoing shows that the extent to and the manner in which transgenic animals can be patented under U.S. and European patent law differs significantly. This is analogous to the content and scope of patents that are granted by the respective patent offices. The discrepancies concerned may damage the continuous and successful technological innovation that is pursued by patent law.[444] Lack of clarity, uncertainty, and differing requirements for, and standards of, protection would not contribute to the incentive of the mostly globally active inventors in the field of biotechnology. On the contrary, it would increase the

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[442] *See* MERGES, *supra* note 62, at 189.

[443] *See* F.M. Scherer, *Taking Stock: The Law and Economics of Intellectual Property Rights: The Pharmaceutical Industry and World Intellectual Property Standards*, 53 VAND. L. REV. 2245, 2249 (2000); Rosemary Sweeney, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM. L. & POL'Y J. 445, 463–67 (2000); Melody Peterson, *Suits Accuse Drug Makers of Keeping Generics Off the Market*, N.Y. TIMES, May 10, 2001, at C1; Sheryl G. Stolberg & Jeff Gerth, *Keeping Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A1; Karl Vick, *African AIDS Victims Losers of a Drug War; US Policy Keeps Prices Prohibitive*, WASH. POST, Dec. 4, 1999, at A1. Given the scope of this article, the details of this debate are not discussed further.

[444] *See* SHERWOOD, *supra* note 53, at 67, 191 (comparing European and U.S. patent law); Josh Lerner, *Patent Policy Innovations: A Clinical Examination*, 53 VAND. L. REV. 1841, 1842–45 (2000); North, *supra* note 53, at 131–32; (discussing the interaction between patent law policy and economy); *supra* Part I.D (providing an extensive economic analysis).

"appropriability problem."[445] Harmonization is needed![446] Although the international intellectual property framework was not reviewed above, since the end of the nineteenth century, governments and international organizations have attempted to harmonize national patent law.[447] The Convention of Paris for the Protection of Industrial Property provides to its members, including EU member states and the U.S., international patent protection.[448] It provides, inter alia, a priority right for inventors, who also have the opportunity to file multiple applications simultaneously with the offices of the members.[449] In 1967, numerous countries formed the World Intellectual Property Organization (WIPO) with the purpose of harmonizing patent law.[450] Although some achievements have hereinafter been made, the most important initiative of WIPO, creating a universal application procedure, has failed.[451] The Geneva Patent Harmonization Treaty (GPHT)[452] derives from WIPO. It provides

[445] *See* K.W. Dam, *The Economic Underpinnings Of Patent Law*, 1994 J. LEGAL STUD. 246, 246–47 (providing extensive analysis of the stimulating function of patent law, the influences on the incentive of inventors, and the problem of appropriability).

[446] *See* Marney L. Cheek, *The Limits of Informal Regulatory Cooperation in International Affairs: A Review of the Global Intellectual Property Regime*, 33 GEO. WASH. INT'L L. REV. 277, 280–81 (2001); Kate H. Murashige, *Harmonization of Patent Laws*, 16 HOUS. J. INT'L L. 591, 591–92 (1994); North, *supra* note 53, at 131–32; Carrie P. Smith, *Patenting Life: The Potential and the Pitfalls of Using the WTO to Globalize Intellectual Property Rights*, 26 N.C. J. INT'L L. & COM. REG. 143, 180–81 (2000).

[447] *See generally* Gerald J. Mossinghot & Vivian S. Kuo, *World Patent Systems Circa 20XX, A.D.*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 523, 525–40 (1998) (describing patent treaties and regional patent systems).

[448] Convention of Paris for the Protection of Industrial Property, Mar. 20, 1883 (as revised July 14, 1967), 21 U.S.T. 1583; 24 U.S.T. 828 U.N.T.S. 305.

[449] *See id*. art. 4.

[450] Convention Establishing WIPO, July 14, 1967, 21 U.S.T. 1770, 828 U.N.T.S. 3.

[451] *See* Dotson, *supra* note 200, at 923 (noting that WIPO has never recognized patent protection for transgenic animals, and concludes, therefore, that it may not be the appropriate organization to address the discrepancies in transgenic patent law); North, *supra* note 53, at 137–38 (describing similar attempts by others). One of the reasons for the failure in creating a universal application procedure is related to the essential differences between the first-to-file systems effective in the EU, Japan and most of the world, and the first-to-invent system that is effective in the U.S. *See generally*, Kevin Cuenot, Note, *Perilous Potholes in the Path Toward Patent Law Harmonization*, 11 J. L. & PUB. POL'Y 101 (1999) (providing a historic and legal overview of the failure to harmonize patent laws). First steps towards harmonization are being made, however. *See supra* note 316.

[452] *See* Czmus, *supra* note 168, at 459–60.

for some initial steps towards harmonization of the first-to-file systems of the EU and Japan, and the first-to-invent system of the U.S.[453] Furthermore, it determines that the patent duration is twenty years, and provides for a single format of the patent application.[454] In the course of the General Agreement on Tariffs and Trade (GATT), the countries concerned formulated the Trade-Related Aspects of Intellectual Property Rights (TRIPS).[455] TRIPS confirms the duration of patents, as provided for under the GPHT. In the course of TRIPS, parties attempt to bring the first-to-file system (EU) and the first-to-invent system (U.S.) closer towards one another and to take away the discrepancies that derive from the application of these different systems.[456]

TRIPS also contains provisions that influence the substantive patent law of its members. For example, article 27(1) sets forth a minimum standard for patentable subject matter. It determines that patents must be available for "inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[457] Also, article 27(2) provides that members may exclude inventions from patentability, if the commercial exploitation of these inventions must be prevented in view of the public order or good morals, including the protection of human, animal and plant life and the protection of the environment. Article 27(3) provides for an exclusion from patentability of animals and plants, and essentially biological processes for the production of plants and animals, which are not microbiological or biological processes.[458] These and other provisions of TRIPS only provide for minimum standards and exceptions thereto, however, which are not defined in detail. Members of TRIPS can decide to

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[453] *See id.*

[454] *See id.*

[455] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], ANNEX 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS], *available at* http://www.wto.org/english/docs_e/legal_e/final_e.htm.

[456] *See* Czmus, *supra* note 168, at 462.

[457] TRIPS, *supra* note 454, art. 27(1).

[458] The EU has made use of this provision; the U.S. has not. *See* Cheek, *supra* note 446, at 292–96.

make use of the exceptions or not (the EU has made use of this exception; the U.S. has not). They also can go beyond TRIPS and provide more extensive protection under their patent regimes. Thus, the few substantive provisions of TRIPS do not form a solid basis for harmonization of the regimes discussed.[459] Another treaty, the Patent Cooperation Treaty (PCT), provides for the filing of one application that serves as an application in all forty-four members.[460] The U.S. and the EPC—and its members—are also PCT members but the PCT only addresses the application and not the substantive examination of its compliance with the requirements for patentability and, therefore, does not serve harmonization in this respect too well either.

In view of the foregoing, harmonization should be pursued by the respective patent offices and/or by the national and regional (EU) legislators—the latter being in a position to substantially change the regimes under which the patent offices grant or deny patents. The failed attempts to achieve this on a broad international level may justify bi- or trilateral legislative actions.[461] Such action should be concentrated on the substantive requirements for, and exclusions from patentability.[462] Hence, this article now turns to a proposal concerning the manner in which those individual requirements and exclusions in the patent laws of the U.S. and the EU could best be harmonized with regard to transgenic animals.

B. Patent Requirements Revisited

1. Novelty and Nonobviousness

The different novelty standards applied under U.S. and EU patent law (respectively the first-to-invent and first-to-file

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[459] *See* Cheek, *supra* note 446, at 292–96; Carlos M. Correa, *The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection*, 16 EUROPEAN INTELL. PROP. REV. 327 (1994).

[460] The Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645; 1160 U.N. T. S. 231.

[461] *See* Cheek, *supra* note 446, at 289–92, 300–09, 315–21; Cuenot, *supra* note 450, at 102–08; Czmus, *supra* note 168, at 459, 462.

[462] *See* Michael Meller, *Principles of Patentability and Some Other Basics for a Global Patent System*, 83 J. PAT & TRADEMARK OFF. SOC'Y 359, 359–60 (2001).

standards) need harmonization. Their specific workings, including the definitions of what constitutes prior art, the grace periods granted, and prior use exceptions, as well as the procedural complexities that derive from them are disregarded here.[463] Although the different standards applied profoundly influence the manner in which inventions are patentable, and therefore need harmonization, the patenting of transgenic animals are not influenced any more greatly than that of other inventions.[464] Furthermore, although both standards lead to a different conclusion as to what constitutes prior art, the examination of that art does not seem to be different in the U.S. and the EU. In principle, the substantive application of the nonobviousness adhered to under U.S. and EU patent law does not differ significantly.[465] Under both regimes, the biotechnological steps taken are acknowledged and inventors can obtain patents with broad claims for their transgenic animals.

Generally, however, the claims of U.S. patents for transgenic animal patents seem to be narrower than the claims of EU patents.

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[463] *See* Cuenot, *supra* note 450, at 113; Meller, *supra* note 462, at 362 (discussing "novelty"); Toshiko Takenaka, *Impact of 1999 Patent Reforms: A Comparative Law Perspective*, 7 CASRIP NEWSL. 2 (2000).

[464] A general note: only the patent laws of the U.S. and the Philippines still apply the first-to-invent standard. In the U.S., patents can be granted to the first one to "conceive" or to "reduce the invention to practice." Novelty is tested against worldwide publications existing prior to the application filing, and against all uses within the U.S. 35 U.S.C. § 102(a)–(b) (2000). Conversely, pursuant to the patent law in the EU, patents are granted to the first one to file a patent application, and novelty is tested according to all communications and uses before such filing. EPC, *supra* note 179, art. 54(1), (2). Arguably, the first-to-invent standard creates a greater risk for granting the patent to an applicant that is not the inventor, or his successor in right, than is the case with the first-to-file standard. Also, the first-to-invent standard, with its complex substantive and procedural characteristics, seems to benefit larger inventors and companies, whereas the first-to-file standard leads to equal consideration of all inventors, whether small or large. *See* Mossinghot & Kuo, *supra* note 447, at 542; Murashige, *supra* note 446, at 608–09. *But see* Meller, *supra* note 462 (arguing that the first-to-invent standard, with its relative novelty requirement, is better suited to deal with communications in present times—the fact that scientists and researchers collaborate in development of inventions and frequently share information, e.g. by e-mail). EPC article 55(1)(a)–(b) is not as harsh as he argues. Of course, the narrow exceptions of EPC article 55(1)(a)–(b) cannot negate Meller's argument, since they are only focused on a period of six months prior to the filing of the application, whereas the research and development usually takes several years before completion.

[465] *See* Meller, *supra* note 462, at 367–69 (discussing "unobviousness").

This may indicate that the EPO applies a lower nonobvioussness (inventive step) standard than the PTO. Such application may be related to the pre-grant opposition system of EPO article 99, the first-to-file system, and the opportunity for compulsory licensing under EU patent law.[466] The lower standard for the inventive step in the EU may also derive from the exclusion from patentability of animal races of EPC article 53(b). This exclusion forces applicants to construct broad claims, not including one race but higher taxonomical units, even though their invention may be directly aimed at one animal variety or race only. The EPO does not apply the enablement requirement in a strict manner, and therefore small inventive steps pass muster so as to make the patenting of transgenic animals possible.[467] Pursuant to both the U.S. and EU patent laws, insertion of genes into an animal, wherein they are expressed, may lead to a patent on the animal. One could argue, however, that the inventions involved—insertion and expression of genes—do not justify a patent on the entire animal. The mechanical equivalent would be to grant the inventor of a lens a patent on the camera to which it is attached.[468] This practice derives from the characteristics of the inventions involved; they cannot be separated and distinguished from the animal, which, in turn, can reproduce itself. Presently, there seems to be no alternative for this manner of protection of the inventions involved. Further research into the specific workings and influence of the inventions concerned may be deemed necessary.[469] Nevertheless,

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[466] *See* D.J. Abraham, *Shinpo-Sei: Japanese Inventive Step Meets U.S. Nonobviousness*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 528, 529–30 (1995) (stating that the Japanese Patent Office's lower nonobviousness requirement may come from several factors, among which are the ones mentioned above, present in the EU).

[467] The proposal for a uniform application of a common standard for enablement is described *infra* Part V.B.6.

[468] *See* Harvard College v. Canada, [1998] 3 F.C. 510, *rev'd*, [2000] 4 F.C. 528 (Can.) (refusing to issue the patent for the Harvard mouse, holding that the insertion and expression of the gene in the mouse may be novel, but the mouse was not); R. Stephen Crespi, *Patents and Plant Variety Rights*: *Is There an Interface Problem?* INT'L REV. INDUS. PROP. & COPYRIGHT L. 168–84 (1992) (analogizing of the mechanical parts to the car as a who and stating that this deviation from traditional patent law occurs with respect to both plant and animal biotechnological inventions).

[469] *See* Ryan M.T. Iwasaka, Note, *Chakrabarty to Chimeras: The Growing Need for Evolutionary Biology in Patent Law,* 109 YALE L.J. 1505, 1519 (2000). Iwasaka proposes a test for novelty and nonobviousness that is based on a methodology used in

patent law harmonization is not needed as far as the patentability of transgenic animals *as such* is concerned.

In the EU, however, a patent on a gene will, by operation of law, embrace the animal in which it is incorporated and expressed. This approach definitely evades legal discussion about the novelty of the animal, and its subjection to patent law, but completely ignores its traditional principles and requirements. It is in line with the general pro-patent approach to inventions that comprise insertion and expression of genes into animals. It may be called a cheap solution (rigorous expansion of the contents and scope of a patent) for an expensive problem (lack of insight into the *actual* invention while, protecting it in view of the reproductive capacities of the vehicle, the animal). The same applies to the EPO's application of the inventive step requirement to applications that claim higher taxonomical units than races, or species.[470] In this respect, it may be deemed appropriate to bring the patent law of the EU in line with the patent law of the U.S., where the original restrictive approach for nonobviousness is upheld.

2. Animal Races

In the EU, animal races are excluded from patentability if they are mentioned specifically in the application, but they are patentable if the application is directed at higher or lower taxonomical units. Since they are thus patentable anyhow, by overbroad patents that embrace entire zoological orders, it would be more appropriate to follow the U.S. approach, meaning that an inventor can openly apply for a patent on a particular variety of an

evolutionary biology; the human interference with the animal in its natural evolutionary course should be appraised according to factors such as the probability that the genetic mutation would have occurred without that interference, and the existence of the animal contrary to natural selection. He argues that such a test would be more formalistic and would be more certain than the tests presently applied. In the author's view, Iwasaka's proposal offers a starting point for development of an appropriate novelty and nonobviousness test for an invention that consists of insertion and expression of strange genes in an animal. It acknowledges that present standards derive from different times and are not optimally suited for application to these types of inventions.

[470] *See infra* Part V.B.2, .6.

animal race. This will allow inventors to specify their invention and will prevent issuance of patents that do not cover their load.[471]

3. Sexually Produced Offspring

In the U.S., the products of entirely sexual (biological) processes may be patentable. The EU approach differs only slightly, but enough to ensure that the products of processes of sexual reproduction are only patentable if the processes have been carried out with some human intervention. The latter approach is most in compliance with the aim of patent law: stimulation of technological progress through an exchange of information (containing the particulars of a novel *biotechnological* advancement) and a patent. Thus, the patent laws involved should be harmonized by adopting the EU approach.

4. Morality

In the U.S., the beneficial utility of an invention is not deemed to be important. Most likely, the lack of beneficial utility (or immorality) of an invention will not be a limitation on its patentability. In the EU, the exclusion from patentability of inventions that are violating *ordre public* or morality is active and applied, albeit restrictively. Even though the exploitation of, for example, an extremely dangerous patented invention (lacking beneficial utility) is regulated by other laws than patent law in the U.S., one could argue that this does not sufficiently influence their development. Arguably, an inventor who knows that he will not receive a patent on an invention will have a lot of trouble developing it, acquiring the necessary funds and recouping the expenses afterwards. Also, one could argue that it is a matter of fairness that an inventor should, at least, have a reasonable expectation of its permitted exploitation after acquisition of the patent. In view of the far-reaching impact of biotechnology, the importance of responsible and restrictive development is emphasized, and such can be ensured best through the instrument

[471] *See* TRIPS, *supra* note 454, art. 27(3) (allowing member states to exclude animal races from patentability). The reason for this exclusion is that animal races can only be produced through biological and not technological means—is outdated and should be modified.

that so profoundly influences the rate at which biotechnological applications are developed, i.e., patent law. Obviously, a moral test is hard to apply, but so is the test of nonobviousness, or, in general contract law, the tests of equity or reasonableness and fairness. Naturally, legal rules must not be made dependent on the swiftly changing morality of the day, as their certainty and reliability is of great importance. The rules themselves, however, exist because of morality, and it should be possible to develop a fairly accurate and certain moral test that can be applied to a particular invention. In view hereof, it may be desirable to include consideration of all (including) features and consequences of an invention in the examination. U.S. patent law should be brought into line with the patent law of the EU in this respect.[472]

[472] The balancing test provided for by the EPC, *supra* note 179, article 53(a), and Directive 98/44, *supra* note 185, article 6 may need specification and is not certain enough yet. It does, however, provide a starting point for consideration of the moral impacts of an invention in patent examination. *See* Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Law*, 19 BERKELEY J. INT'L L. 40, 40–43 (2001). Note that Gitter ignores Case G 1/98, *Novartis II*, 2000 O.J. E.P.O. 111 (Enlarged Bd. of App. 1999), in her analysis. A fairly accurate moral test could be developed by a collective of lawyers, ethicists, biotechnologists, and anthropologists, with the aid of the general public, through a detailed and specific referendum. The test should be incorporated into the relevant patent acts involved, to make them as independent as possible from the "morals of the day" and to prevent administrative agencies, such as the PTO and EPO, from developing their own. Note in this respect the PTO's exclusion from patentability of human/animal chimaeras, *supra* note 118. For possible ethical rules, see *supra* note 158. The scholars, who favor exclusion of any moral limitation on patentability because patent law should only be directed at the technology, would possibly agree with the patentability of human beings; their exclusion is entirely based on the PTO's invocation of morality. Although they could be correct in agreeing thereto, further research needs to be done, and important policy decisions need to be taken, before these far-reaching standpoints can be appropriately defended. The same applies to the moral implications of patentability of transgenic animals, particularly because of the unclear biological distinction between animals and human beings. Moreover, one should not ignore that other inventions than those directed at transgenic animals are not at the crossroad of biology and technology, and therefore fit in perfectly with the patent system as it was originally framed. Debates about what is "good" and what is "wrong" are initiated now because of the involvement of organisms with a high psychological capacity. Legal scholars, legislators and patent officers cannot completely withdraw from this debate and hide behind the argument that patent law is only directed at technology. Patent law *was* directed at technology only; presently, it is directed at *biotechnology* as well.

5. Human-Based Inventions

Both the patent laws of the U.S. and the EU more or less exclude human-related inventions from patentability. EU patent law contains a statutory exclusion, whereas the exclusion in the U.S. is based on the policy of the PTO. In view of the broad impact of patentability of transgenic humans (or animals), it may be highly desirable to include a particular statutory provision in U.S. patent law that deals with this issue. Moreover, both regimes lack a clear definition of what constitutes a "human being" and what constitutes an "animal." In view of the rapidly advancing biotechnology, these definitions should be made and incorporated into patent law.[473]

6. Enablement

Both the patent regimes of the U.S. and the EU lack an appropriate and workable standard for disclosure of the invention by a patent applicant. That this is caused by the expression of a gene in an animal may not be readily observable. This lack of disclosure has both an internal and external impact (respectively towards the patent office and towards third parties who request samples) that should be addressed by the legislatures and/or patent offices of both the U.S. and the EU.

Nevertheless, in the U.S., the PTO applies a stringent test of enablement in the course of patent litigation. It requires that an invention be fully repeatable and patent applicants can narrowly and specifically describe their invention in the application (the animal that is or expresses the invention). Conversely, in the EU, the EPO does not apply a strict test of enablement, since otherwise no patents could be issued for transgenic animals. The exclusion of animal races, as continues to be the case in EU patent law, forces applicants to formulate their invention as broadly as possible so as to not claim explicitly an animal that belongs to a particular race. They will, therefore, claim a patent for an invention that is directed at a species or even higher taxonomical

[473] The definitions suggested by scholars may not suffice. *See supra* note 421. A multidisciplinary approach by lawyers, ethicists, and biologists may provide a workable definition.

units, and such a claim may be awarded, whereas from a biotechnological point of view their invention most likely does not affect these units, and only affect, a particular race or some races. This leads to overbroad patents, which are contrary to the goals of patent law. The EPO should, therefore, more strictly apply the enablement requirement, in line with the approach of the PTO. In case the EU prefers to allow transgenic animals to be patented, the EPC and the patent laws of the member states should be revised and the exclusion of patentability of animal races excluded; other requirements of patent law, such as the enablement requirement, should not be sacrificed.

7. Third Party Interests

Clearly, third party interests are better protected by EU patent law than by U.S. patent law. First, anyone who objects to a certain patent can file opposition against it until nine months after its initial issuance.[474] Anyone can be heard through this procedure, and the EPO takes opposition seriously. The initial uncertainty of the patentee (until nine months after the grant) is compensated by his/her increased certainty afterwards. After issuance of the patent, most, if not all, objections against the patent are known and they have been considered by the EPO (and the newspaper reading public). The patent will less likely be subjected to societal objection and action on the political level. Second, designated authorities are empowered to issue compulsory licenses in case there is, for example, a pressing social need.[475] The specificity and narrowness of the underlying competence ensures that this situation will not lead to uncertain patents.[476] Hence, neither patentees nor society will suffer from an uncertain patent system.

A compulsory license does, of course, touch upon the exclusiveness of the patent right. One should bear in mind,

[474] EPC, *supra* note 179, art. 99.

[475] The compulsory licensing exemptions of the EPC and the patent laws of the EU member states derive from TRIPS, *supra* note 454, article 30. *See* Correa, *supra* note 458, at 330–33 (describing TRIPS' grounds for granting a compulsory license and their workings).

[476] *See* Mossinghot & Kuo, *supra* note 447, at 547 (arguing that compulsory licenses should be part of a global patent system).

however, that patent law does not provide absolute proprietary rights, but relative ones that are limited in many ways, such as duration. These limits are imposed for general societal reasons, for which the exclusive right itself was also created. Patent offices' application of the requirements of, and exclusions from, patentability changes continuously to meet the demands of our time, of new types of inventions and their inventors. This is especially so with animal biotechnology, which, for example, shown by the particularly low standard of novelty that is applied to enable patentability of entire animals. It does not make any sense to change the limits of the patent right only in favor of patentees and not to their detriment, in case both could be beneficial to society at large. Adequate pecuniary compensation to the patentee, and a listing of a specified and limited number of purposes for which these licenses can be granted, with sufficient opportunity of representation, review and appeal, should safeguard the interests of patentees while at the same time protect those of society.[477] In view hereof, U.S. patent law should be adapted to allow third-party interests to be included in the examination of the patent application, or to be set forth in another fashion. Additionally, a system for compulsory licensing of patents on transgenic animals should be set up, and the regimes of the U.S. and the EU harmonized accordingly.

Although development of a uniform global patent system may be considered ideal for adequate and appropriate patent protection, such a system is not likely to be formed in the near future.[478] Decisive steps should be taken by legislators to substantially harmonize the patent laws of the U.S. and the EU, at least insofar as the patentability of transgenic animals is concerned.

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[477] *See* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 843–44 (2001) (arguing that compulsory licenses should play a role in patent law for further research and to prevent anticompetitive behavior).

[478] *See* Meller, *supra* note 462; North, *supra* note 53, at 139.

CONCLUSION

Biotechnology promises various beneficial applications for both human beings and animals. Accordingly, research and development of these applications may be necessary. In view of the far-reaching and great impact of biotechnological applications on the environment, the formation and development of "life" and, thus, evolution, *responsible* development is necessary as well. Patent law may be the legal instrument by which the biotechnological developments can, on one hand, be stimulated and enhanced, and, on the other, be controlled and guided. The manner in, and extent to, biotechnological inventions, such as transgenic animals, can be patented by the inventors will have a profound influence on the pace at which their development takes place. Inventors need to make investments, and investments need, at the least, to be recouped. Society needs information about the state of technology at a certain moment, in order to stimulate continuance of technological developments. Patent law connects these interests; governments through their patent offices grant inventors temporary monopolies on the exploitation of their invention, in return for a description thereof. Therefore, patent law has become an instrument for enhancing biotechnological development as well. In view of the strong incentive most inventors have to apply for patents for their inventions, patent law may also serve society's interest in guiding and controlling the development of these inventions. Patent offices may assess the non-technological aspects of an invention, as described in the patent application—for example, the benefits of the invention for humankind and the dangers and other negative consequences that may derive from it. The balance that is struck will determine the rate at which biotechnological developments will proceed responsibly.

Both the patent regimes of the U.S. and the EU provide patents for transgenic animals, either directly or via a patent on a process that extends to the animal. In the EU, however, patent protection may also be obtained via a patent on a gene that has been inserted and expressed in an animal. This manner of protection for transgenic animals is not available in the U.S. Both European and U.S. patent law permit patents for products that, except for minor

alterations, exist in nature. The patent offices and/or courts apply a low standard for novelty and nonobviousness (inventive step), and for what constitutes "technology" and is "man-made." Thus, both regimes offer broad opportunities for an inventor to obtain a patent for his/her animal biotechnological inventions, including transgenic animals.

Given the degree of modification of the animals concerned, one may doubt whether the standards that patent offices apply in this context are appropriate. Greater insight into the actual impact of the biotechnological application on the animal is needed, in order to allow patent offices to determine more accurately where the influence and workings of the invention end and the natural animal remains. In the U.S., the PTO's examination of patent applications does not necessarily include considerations of a non-technical nature, such as the animal suffering that may derive from the claimed invention. Conversely, these considerations are included in the examination of patent applications for transgenic animals in the EU. The EPO's examination of the various interests occurs through a balancing test. It balances the expected benefits of the invention with the expected disadvantages, such as damages to the environment and animal suffering. Both patent regimes exclude inventions that embrace human materials from patentability to a greater or lesser extent. Nevertheless, both regimes lack clear definitions for what constitutes material of human origin, and what constitutes human beings and animals. The formation of these definitions, and their incorporation into patent law by the legislature or into the patent offices' guidelines, is very important, for the technology will provide more and more potentially interesting and useful possibilities to combine genetic parts of human beings with the genetic parts of animals.

In the U.S., animal varieties, races, and species can be patented. In the EU, only animal varieties that are not claimed as such can be patented. This forces applicants to draft broader claims—most likely broader than is justified by their actual invention. At the same time, the standard for enablement has been lowered by the EPO, whereby inventors can actually obtain these broad patents. This will not serve the prime goals of patent law and weakens the connection and balance that patent law provides

between the interests of patentees and the interests of society. In the U.S., inventors can focus their claim on their actual invention, regardless whether such comprises a variety, race, or species. Subsequently, the PTO can apply a strict and traditional standard for enablement, thus allowing for patents that are justified by the invention. This approach serves the goals of patent law in a better way. Given the autonomy of the national patent offices and courts in the EU, referenced exclusion from patentability of varieties and races, and the low standard of enablement set by the EPO, may not be adhered to on the national level. On one hand, this may serve as a safeguard against said broad unjustified patents and, on the other, this may create legal uncertainty for patentees. This may undermine the function of patent law, and particularly will frustrate the objectives of the EPC.

Both regimes give broad scopes to the patents granted on transgenic animals; offspring may be included. In the EU, however, the patent on the initial product generally also covers animals multiplied by non-sexual reproduction from those products, such as cloning. This seems to contrast with the overall situation in the U.S. Under U.S. law, "outsiders" do not have means at their disposal to influence the process through which the PTO grants patents. Also, they cannot challenge the scope, contents and validity of patents granted, other than on grounds of "prior art." Conversely, in the EU the EPC provides for an opposition procedure to anyone who objects to the application or issuance of a patent by the EPO, e.g., on moral grounds. This procedure recognizes the universal and far-reaching impact of animal biotechnology and gives interested parties a chance to be involved and heard. The patent regimes of the EU provide for farmers' and breeders' exceptions to the broad scope of transgenic animal patents—this may serve their economic need. The U.S. patent regime lacks such provisions. This may economically burden small breeders and farmers who want to acquire and use patented animal material. Also, the patent regimes of the EU generally provide for compulsory licensing, whereas such a system is foreign to U.S. patent law. Compulsory licensing may provide an escape to situations wherein a patentee ignores a pressing societal need for use of the patented invention and is not willing to

license at all for a reasonable royalty. Since the designated authorities in the EU rarely grant compulsory licenses, and if they do, only against reasonable royalties, patentees do not have to fear significant weakening of their position under a regime that provides for these licenses.

The European patent regime takes account of moral and societal concerns that are related to transgenic animals. The EPO considers these concerns directly under the exclusionary provisions of the EPC, and also pursuant to oppositions filed by "outsiders" in the opposition procedure. This is a signal of responsible patent policy, but the EPO's formalistic approach regarding EPC article 53(b)'s exclusion of animal varieties and, consequently, the low standard it sets for enablement conflicts with the goals and function of patent law as well. This is a signal of irresponsible patent policy. Conversely, the PTO's purely technological and narrow approach toward the patentability of transgenic animals ignores the important non-technological interests that are involved and is a signal of irresponsible patent policy. Its strict application of the enablement requirement is a signal of responsible patent policy and serves the primary objectives of patent law best. The low standards that are applied by both the EPO and the PTO for "traditional" conditions for patentability, such as novelty and nonobviousness, are indications of a pro-patent approach that may lead to patents that are unjustified by the inventions. This is a signal of irresponsible patent policy.

The discrepancies between U.S. and European patent law concern important issues; e.g., whether countries should enhance technological developments neutrally without paying attention to their moral and social consequences; or whether it should be recognized that patent law does not function in a social vacuum, but is one of the instruments with which we govern and direct our societies, both in their technical and ethical character. Clearly, this author favors the latter approach. Another issue would be the degree to which principles of patent law, for example full disclosure and repeatability of the invention in exchange for the patent, should be negated to accommodate the needs of present inventors and their inventions. Clearly, this author favors a conservative approach, deviating not too much from the initial

patent law approach, unless such can be founded in extensive legal and biological knowledge and understanding. The universal impact of biotechnology requires a universal stimulus and guidance. This can only be achieved by harmonization of patent law. This cannot be achieved easily through multilateral processes. Thus, it is necessary for legislators in the respective jurisdictions to pursue harmonization of their patent laws multilaterally and to adjust these laws fully to the need of our time. As they say, "procrastination is the thief of time," and it may also become the thief of many promising developments *or* the accomplice of irresponsibility and its impact on future life and society. *Cum tacent clamant!*[479]

[479] [By their silence, they emphasize it even more!]