

Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine

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NOTE

PROTECTING SOCIETY FROM PATENTLY OFFENSIVE INVENTIONS: THE RISK OF REVIVING THE MORAL UTILITY DOCTRINE

Benjamin D. Enerson†

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INTRODUCTION

Over the last century, scientific progress in the field of biotechnology¹ has grown exponentially. The ability to clone humans, once the subject of science fiction literature,² is now a “raeliety.” On December 28, 2002, Raelian leader Claude Vorilhon³ announced that his company, Clonaid, cloned the first human, a female child named “Eve.”⁴ The harsh criticism, skepticism, and fear⁵ that followed the

¹ Biotechnology is “applied biological science (as the synthesis of enzymes, genes, and antibodies for medical use).” WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 219 (Philip Babcock Gove et al. eds., 3d ed. 1986). The definition of the word in common usage may be broader. E. Vermeersch & Tom Claes, *Biotechnology, Patents and Morality: Towards a Consensus*, at <http://www.flwi.ugent.be/philosophy/claes/research/patents.htm> (“[T]he way it is used nowadays also covers diverse practices in an array of fields[, including] molecular biology and genetics (e.g. manipulation of DNA in genetic engineering), biomedical science (e.g. *in vitro* fertilisation), agriculture (e.g. *in vitro* propagation or cloning of plants), [and] medical science (e.g. recombinant vaccines).”).

² See, e.g., ALDOUS HUXLEY, *BRAVE NEW WORLD* (1932). For a modern analysis of the ethical issues presented in *Brave New World*, see Bernard Gert, *Thinking About Huxley’s Brave New World: Was It Wrong To Create a Genetic Hierarchical Society? Is It Wrong To Prevent One?, in ETHICS AND LAW IN BIOLOGICAL RESEARCH* 107 (Cosimo Marco Mazzoni ed., 2002).

³ Mr. Vorilhon “claims to be a direct descendant of extraterrestrials who created human life on Earth through genetic engineering.” *Raelian Leader: Cloning First Step to Immortality*, at <http://www.cnn.com/2002/HEALTH/12/28/human.cloning/index.html> (Dec. 29, 2002).

⁴ *Id.*

⁵ See, e.g., Paul Lesko & Kevin Buckley, *Attack of the Clones . . . and the Issues of Clones*, 3 COLUM. SCI. & TECH. L. REV. 1, 1 (2002) (noting that Advanced Cell Technology’s cloning of a human embryo in November 2001 caused “a worldwide uproar”); Philip M. Boffey, *Fearing the Worst Should Anyone Produce a Cloned Baby*, N.Y. TIMES, Jan. 5, 2003, §4, at 10 (“But with several renegade groups supposedly racing to produce the first cloned baby, it is almost inevitable that sooner or later someone will succeed. It’s time to start preparing ourselves mentally for that eventuality.”); Bill McKibben, *A Threat to Our Coherent Human Future*, WASH. POST, Jan. 6, 2003, at A15 (claiming that “[t]he threat posed by such work to the human species and to our societies is far greater even than the possibility that Rael or his competitors may have damaged the particular children they set out to clone”); *Vatican Slams “Brutal” Clone Claim*, at <http://www.cnn.com/2002/HEALTH/12/28/cloning.vatican/index.html> (Dec. 28, 2002) (quoting the Vatican as stating that the Raelians are of a “brutal mentality” lacking “ethical consideration”). But see Richard Cohen, *Unsettling, Maybe, but Not Unethical*, WASH. POST, Jan. 2, 2003, at A19 (“We cannot permit either our repugnance for a weird cult or our fear of the different to produce a retreat from a knowl-

Raelian announcement—which appears to be “‘an elaborate hoax’”⁶—epitomizes the worldwide concern that biotechnology generates.

Biotechnology is immensely important to the economies of both the United States and Europe.⁷ Genetics companies have obtained thousands of patents for products in the United States since 1980, and the industry now employs well more than 60,000 people.⁸ Patents provide the “prerequisite” for growth in new industries and foster the “birth and growth of many new companies.”⁹ Yet despite these positive effects on national economies, not everyone has welcomed biotechnology because many of its achievements—such as the ability to clone humans—are controversial.

Scholars have questioned what role, if any, patent law¹⁰ should play in protecting inventions that can generate a wave of controversy.¹¹ If patent law is to remain relevant in this era of unprecedented biotechnological advancement, the question arises as to whether patent examiners or courts should be able to deny a patent application or invalidate patents they deem immoral. The European Union has answered this question in the affirmative by enacting Directive 98/44/EC on the legal protection of biotechnological inventions (the “Biotech Directive”).¹² In contrast, United States courts have not recently invalidated patents on moral grounds,¹³ although the Patent and Trademark Office (PTO) still claims to consider the moral utility of potential patents.¹⁴ Increasing concern about human cloning and

edge that is almost certain to be used anyway and that—just maybe—could save or enrich lives.”).

⁶ Kenneth Chang, *Saying That Hoax Is Possible, Journalist Leaves Cloning Tests*, N.Y. TIMES, Jan. 7, 2003, at A12.

⁷ See PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY: FUNDAMENTALS OF GLOBAL LAW, PRACTICE AND STRATEGY 252 (3d ed. 1999).

⁸ See Harriet M. Strimpel, *Comments on the Proceedings of the Conference on Biotechnology, Patents and Morality*, in BIOTECHNOLOGY, PATENTS AND MORALITY 283, 287 (Sigrid Sterckx ed., 1997).

⁹ *Id.* at 289.

¹⁰ Patent protection in the United States derives from Article I, Section 8 of the Constitution: “The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8. Patent protection in Europe is derived from international agreements. See *infra* Part I.C.

¹¹ See, e.g., Lesko & Buckley, *supra* note 5, at 31–39.

¹² See Eur. Parl. Directive 98/44/EC on the Legal Protection of Biological Inventions, 1998 O.J. (L 213) 13, at http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf [hereinafter Biotech Directive].

¹³ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

¹⁴ See, e.g., Media Advisory, Patent and Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998), at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm> (“It is the position of the PTO that [certain] inventions . . . could . . . not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.”).

stem cell research in the United States and abroad has provoked debate over what constitutes patentable subject matter and whether patent examiners or courts should make ethical considerations when determining whether to deny or invalidate a patent.¹⁵ Should the United States follow the controversial morality provisions of the Biotech Directive by reviving its own means of invalidating patents deemed immoral? Criticism of the Biotech Directive and European Patent Convention's morality provisions shed light on this issue.

This Note addresses the recent criticism of the morality provisions of the European Patent Convention (EPC) and Biotech Directive and argues that moral and ethical concerns should not enter into consideration in determining the usefulness of an invention in the United States. Part I provides background on the status of moral and ethical considerations in the patent systems of the United States and Europe. This Part specifically attends to the Biotech Directive's new role and the likely effect of its morality provisions. Part II focuses on recent criticism of the EPC and Biotech Directive morality provisions. Part III applies this criticism to the moral utility doctrine and concludes that courts and patent examiners should ask only *whether* a particular invention may be useful to the public, not whether the public *should* use such an invention.

I

PATENT PROTECTION AND MORALITY IN THE UNITED STATES AND EUROPE

A. Economic Advantages of the Patent System

The patenting and drug approval process in the United States is not cheap. Drug manufacturers claim that it costs \$500 million and takes twelve to fourteen years to patent a new drug.¹⁶ On average, only one in ten drugs makes it to market.¹⁷ Research in biotechnology and the patenting of inventions in the United States is a lengthy process involving expensive, high-risk investments backed by many expectations about patent laws and the patenting process.

Those who patent biotechnological inventions also know that adequate patent protection is extremely important. Patents protect inventors by awarding them a limited-term monopoly to prevent others from commercially benefiting from the invention.¹⁸ In return for this

¹⁵ See, e.g., 148 CONG. REC. S5520-25 (daily ed. June 13, 2002) (statement of Sen. Hatch).

¹⁶ David Noonan, *Why Drugs Cost So Much*, NEWSWEEK, Sept. 25, 2000, at 22, 26.

¹⁷ *Id.*

¹⁸ EUROPEAN PATENT OFFICE, EUROPEAN PATENTS 3, 11, at http://www.european-patent-office.org/epo/pubs/brochure/europat/pdf/europat_e.pdf [hereinafter EUROPEAN PATENTS]. Several arguments support patent protection, including the "ownership," "re-

protection, the inventor must fully disclose the invention.¹⁹ Once published, patent applications and grants are a “prime source” of information for scientists²⁰—perhaps “lay[ing] the groundwork for a chain reaction of inventive ideas.”²¹ This so-called patent-for-disclosure bargain creates incentives to invest in research and development²² while encouraging inventors to develop their inventions for commercial purposes.²³

The limited-term monopoly further allows inventors not only to recoup development costs, but also to generate a fair return on their investment.²⁴ If the patented invention becomes profitable and acceptable to the public, the period of patent protection may afford the inventor an opportunity to build a business or entire industry that stimulates both the national and international economies.²⁵ Effective patent protection encourages research and development and fosters technological innovation, competition and overall economic growth as well:²⁶

Experience gained in all industrial nations shows that technological progress and successful economic development go hand in hand with *strong* patent protection and a *smoothly* functioning patent system. In the history of industrial societies there is no instance of a country having undergone favourable economic and technological development in the absence of adequate patent protection.²⁷

Because adequate patent protection is crucial to biotechnological development,²⁸ patent laws themselves must be sound enough to protect the inventor’s expectations and provide the incentive to seek a patent, as an inventor is not required to patent any invention.

ward,” “incentive,” and “disclosure” theories. These theories are not mutually exclusive, but supplement each other. PATENT LAW AND EUROPEAN PATENT CONVENTION 5–6 (1991) [hereinafter EUROPEAN PATENT LAW]. The “ownership theory” assumes that any invention naturally belongs to the person who invented it; therefore, any use of the invention without the inventor’s consent is “intellectual theft.” *Id.* at 5. The “reward theory,” based on notions of fairness, assumes that every service that increases technology deserves to be rewarded. *Id.* The “incentive theory” assumes that inventions will be made only if there is incentive, in the form of a limited-term monopoly to generate an adequate return, to invest in inventions. *Id.* The “disclosure theory” “presupposes that the inventor makes his new technical knowledge available to the public.” *Id.* at 6.

¹⁹ EUROPEAN PATENTS, *supra* note 18, at 3.

²⁰ *Id.*

²¹ U.S. DEP’T OF COMMERCE, PATENTS: SPUR TO AMERICAN PROGRESS 5 (1969) [hereinafter AMERICAN PATENTS]

²² See EUROPEAN PATENTS, *supra* note 18, at 3.

²³ See AMERICAN PATENTS, *supra* note 21, at 5.

²⁴ See EUROPEAN PATENTS, *supra* note 18, at 5.

²⁵ See AMERICAN PATENTS, *supra* note 21, at 6.

²⁶ See EUROPEAN PATENTS, *supra* note 18, at 5.

²⁷ EUROPEAN PATENT LAW, *supra* note 18, at 6 (emphasis added).

²⁸ *But see generally* VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE (1997) (arguing that the patent system exploits and colonizes non-Western society).

B. Status of the Moral Utility Doctrine in the United States

For an invention to be patentable subject matter in the United States, it must be new and useful,²⁹ novel³⁰ and nonobvious.³¹ The Supreme Court in *Brenner v. Manson* noted that to be “useful” an invention must provide a benefit to the public.³² The Revised Interim Utility Guidelines Training Materials of the United States Patent and Trademark Office require that the application must show specific, substantial, and credible utility.³³ The Guidelines are silent, however, as to whether an invention must have moral utility.

1. Federal Courts’ Decreased Reliance on the Moral Utility Doctrine

In *Lowell v. Lewis*, Justice Story stated that for an invention to be “useful,” it cannot conflict with the “sound morals of society.”³⁴ This requirement is referred to as the moral utility doctrine. Throughout the twentieth century, courts invalidated patents for items, such as

²⁹ See 35 U.S.C. § 101 (2001).

³⁰ *Id.* § 102.

³¹ *Id.* § 103.

³² *Brenner v. Manson*, 383 U.S. 519, 534 (1966) (“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”).

³³ See U.S. PATENT & TRADEMARK OFFICE, REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 3, at <http://www.uspto.gov/web/menu/utility.pdf> (last visited Jan. 12, 2004).

³⁴ 15 F. Cas 1018, 1019 (C.C. Mass. 1817) (No. 8568). Justice Story states:

All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word “useful,” therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention.

Id.

The question of how narrowly one should interpret Justice Story’s formulation is unclear. In *Brenner v. Manson*, Justice Fortas noted:

Narrowly read, it does no more than compel us to decide whether the invention in question is “frivolous and insignificant”—a query no easier of application than the one built into the statute. Read more broadly, so as to allow the patenting of any invention not positively harmful to society, it places such a special meaning on the word “useful” that we cannot accept it in the absence of evidence that Congress so intended. There are, after all, many things in this world which may not be considered “useful” but which, nevertheless are totally without a capacity for harm.

383 U.S. at 533.

Some scholars question whether the “usefulness” requirement should be a prerequisite to patentability. See WARD S. BOWMAN, JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL 33 (1973) (“Usefulness is a proper precondition for *reward*, but not for *patentability*. The market performs more reliably than patent examiners in determining usefulness in a price-oriented patent system.”). Bowman also argues that the market is a better judge of usefulness than courts or the PTO. *Id.* at 47 (“Skepticism about either the courts’ or the Patent Office’s taking on the task of predicting usefulness or attempting to judge and reward relative merit is reinforced by the judgment that the market, imperfect as it is, is a better assessor of usefulness.”).

gambling machines, on the ground that they were immoral.³⁵ Recently, however, courts have not broadly applied the moral utility doctrine in the United States to reject patent applications or invalidate existing patents.³⁶ In *Juicy Whip, Inc. v. Orange Bang, Inc.*, the Court of Appeals for the Federal Circuit upheld the validity of a patent that “[has] the capacity to fool some members of the public. . . . through imitation in a manner that is designed to increase product sales.”³⁷ The *Juicy Whip* court noted that the rule which would mandate invalidating patents because one can use the item for deceptive or illegal purposes is no longer good law.³⁸ In fact, most patent attorneys in the United States believe that the “American view” is that “morality should . . . have nothing to do with patents.”³⁹

The moral utility doctrine is not completely dead, though. Although courts do not apply the doctrine in their decisions, they still refer to Justice Story’s classic formulation of utility. For example, the court in *Geneva Pharmaceuticals, Inc. v. Glaxosmithkline PLC* noted that a patent possesses utility “if it will operate to perform the functions and secure the results intended, and its use is not contrary to law, moral principles, or public policy.”⁴⁰ Thus, courts will not necessarily apply the moral utility doctrine.⁴¹ Further, some commentators are divided as to its place in patent law. Professor Peter Rosenberg notes that “[w]hat is immoral varies from generation to generation. . . . [and] cases denying the protection of the law on the ground of immorality

³⁵ See, e.g., Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1063 (1988) (noting that patents, such as gambling machines, were invalidated for being immoral well into the middle of the twentieth century).

³⁶ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

³⁷ *Id.* at 1368.

³⁸ See *id.* at 1367 (“[Y]ears ago courts invalidated patents on gambling devices on the ground that they were immoral but that is no longer the law.” (citations omitted)).

³⁹ Ronald Schapira, *Biotechnology Patents in the United States*, in BIOTECHNOLOGY, PATENTS AND MORALITY, *supra* note 8, at 171, 172.

⁴⁰ *Geneva Pharms., Inc. v. Glaxosmithkline PLC*, 213 F. Supp. 2d 597, 610 (E.D. Va. 2002) (quoting *Callison v. Dean*, 70 F.2d 55, 58 (10th Cir. 1934) (emphasis added)).

⁴¹ Compare *Whistler Corp. v. Autotronics Inc.*, 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Texas 1988) (holding a patent for a radar detector, designed for the exclusive purpose of circumventing the law, useful and noting that it is a matter for legislatures and Congress to prohibit such devices), and *Juicy Whip, Inc.*, 185 F.3d at 1366–68 (upholding the patent for a device that may fool members of the public, while noting that it would defer to Congress if it were to make the patenting of such devices illegal), with *Geneva Pharmaceuticals, Inc.*, 213 F. Supp. 2d at 609–10 (continuing to apply a moral standard to determinations of the usefulness of a patent), and *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft*, 945 F.2d 1546, 1552 (Fed. Cir. 1991) (noting that the usefulness requirement “has . . . been interpreted to exclude inventions deemed to be immoral”), and *Am. Standard Inc. v. Pfizer Inc.* 722 F. Supp. 86, 150 (D. Del. 1989) (noting that to be useful, the patent’s “purpose must not be illegal, immoral or contrary to public policy”).

are not of this generation."⁴² However, Professor Donald Chisum argues that, although narrow, moral utility as a public policy doctrine requires that "[a] patent will be withheld only if the invention cannot be used for any honest and moral purpose."⁴³

Decreased reliance on the moral utility doctrine to invalidate patents seems curious in light of the Supreme Court's holding in *Diamond v. Chakrabarty* that a live, human-made organism constituted patentable subject matter.⁴⁴ In *Chakrabarty*, the respondent sought to patent a "human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil."⁴⁵ Noting the significant value⁴⁶ and utility⁴⁷ of such an invention, the Court failed to address its moral utility, focusing instead on whether the invention was "natural."⁴⁸ The holding opened the door to patenting more than just human-made bacteria, as scientists and inventors began to patent more complex life-forms such as transgenic animals in the United States, all in the absence of serious challenge to the morality of such patents.⁴⁹

2. *The Patent and Trademark Office's Purported Reliance on the Moral Utility Doctrine: Ex parte Murphy, the Newman Application, and the University of Missouri Patent*

Despite the PTO's purported reliance on the moral utility doctrine when examining patent applications, a brief review of the PTO's decisions regarding controversial biotechnological inventions reveals a history devoid of ethical considerations. Notably, the Patent Board of Appeals hesitated to invalidate a patent for a gambling device in its 1976 decision *Ex parte Murphy*.⁵⁰ The Board of Appeals noted: "[W]hile some may consider gambling to be injurious to the public morals and the good order of society, we cannot find any basis in [35 U.S.C. § 101] or related sections which justify a conclusion that inventions which are useful only for gambling ipso facto are void of patentable utility."⁵¹ The Board of Appeals opined that legislative bodies

⁴² PETER D. ROSENBERG, PATENT LAW BASICS § 8.05 (10th ed. 2002) (footnote omitted).

⁴³ DONALD S. CHISUM, 1 PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 4.03 (1995).

⁴⁴ 447 U.S. 303, 309–10 (1980).

⁴⁵ *Id.* at 305.

⁴⁶ *Id.*

⁴⁷ *Id.* at 310.

⁴⁸ *See id.* at 309 ("The laws of nature, physical phenomena, and abstract ideas have been held not patentable."). The briefs of the parties involved in the litigation, however, did address the moral and ethical concerns associated with such inventions. *See id.* at 316–17.

⁴⁹ *See infra* Part I.D.

⁵⁰ 200 U.S.P.Q. (BNA) 801 (Bd. App. 1977).

⁵¹ *Id.* at 802.

outside the PTO should determine whether such devices are patentable: “[W]e think this Office should not be the agency which seeks to enforce a standard of morality with respect to gambling, by refusing, on the ground of lack of patentable utility, to grant a patent”⁵²

Twenty-two years later, in 1998, reports revealed that Stuart Newman, a cellular biologist, sought to patent a technique for producing a half-human, half-animal species.⁵³ Such an invention is exactly what biotechnology patent opponents feared, and the Newman application process represented perhaps the closest the PTO has come to denying a patent application for being immoral. Ironically, rather than seeking to create such an animal-human hybrid, Newman designed the application to “reignite debate about the ethics of genetic engineering and the patenting of life forms.”⁵⁴ The PTO denied Newman’s application because it “embrace[d]” a human being, and thus did not constitute patentable subject matter.⁵⁵ The Newman application resulted in the issuance of a “media advisory” in which the PTO claimed to continue to rely on Justice Story’s formulation of utility. This advisory, however, failed to operate as a revival of the moral utility doctrine because the PTO’s revised 2001 examiner guidelines concerning utility make no mention of morality or public policy issues.⁵⁶ Furthermore, then-PTO commissioner Bruce Lehman stated: “[I]f an applicant presents a scientifically plausible use for the claimed invention, it will be sufficient to satisfy the utility requirement.”⁵⁷

In the same year, the University of Missouri sought to patent a controversial invention involving “‘a method for producing a cloned mammal.’”⁵⁸ The PTO granted the patent, which involved ways to transplant a nucleus from (1) a cultured mammalian cell, (2) a mammalian embryo, (3) a mammalian fetus, or (4) an adult mammal to a recipient mammalian oocyte to produce a cloned mammalian embryo and, ultimately, a cloned mammal.⁵⁹ Opponents of the patent included the Center for Technology Assessment (CTA), which contended that the patent amounted to human cloning and that “[t]he PTO has the legal authority under both national and international law to reject patents that offend public morality or order but did not do so

⁵² *Id.* at 803.

⁵³ See *Group Faults PTO for Issuing Patent on ‘Method of Producing Cloned Mammal,’* 64 PAT. TRADEMARK & COPYRIGHT J. 81 (2002) [hereinafter *Group Faults*].

⁵⁴ *Id.* (“Newman, who opposes such patents, is allied with social activist Jeremy Rifkin, a longtime foe of intellectual property protection for biological organisms and genetic compounds.”).

⁵⁵ See *Patent Application Is Disallowed As ‘Embracing’ Human Being*, 58 PAT. TRADEMARK & COPYRIGHT J. 203 (1999).

⁵⁶ See *Group Faults*, *supra* note 53, at 81.

⁵⁷ See *id.* at 81–82 (quoting Bruce Lehman, PTO Commissioner).

⁵⁸ U.S. Patent No. 6,211,429 (issued Apr. 3, 2001).

⁵⁹ *Id.*

in the case of the Missouri patent."⁶⁰ Both the Missouri patent and Newman application demonstrate the continuing controversy surrounding biotechnological patents. Furthermore, they demonstrate both the federal courts' and the PTO's reluctance to revive the moral utility doctrine in full.

C. Patent Protection in Europe and the Morality Provisions of the European Patent Convention

Patent protection in Europe arises from several international treaties, such as the Paris Convention, the Patent Cooperation Treaty, and the European Patent Convention (EPC).⁶¹ Of these agreements, the EPC is the most important for an inventor desiring to patent an invention in Europe today. The EPC established the European Patent Organization, consisting of the Administrative Council and the European Patent Office (EPO).⁶² The EPO is responsible for implementing the EPC.⁶³ The EPC effectuates a "first-to-file system;"⁶⁴ requires that an applicant permit the subject matter of his prospective patent to be published early; and provides a centralized system through which an applicant can receive a bundle of national patents.⁶⁵ The EPC functions to give a valid European patent application the effect of a regular national application;⁶⁶ as a registration system, it creates a group of national patents which "may only be challenged and enforced individually within the national jurisdictions of the designated Contracting States."⁶⁷

Thus, an inventor seeking to patent an invention in one or more European Union (EU)⁶⁸ Member States may choose one of two methods: (1) file the patent with a national patent office and subsequently file the patent in other countries to obtain protection; or (2) file the

⁶⁰ See *Group Faults*, *supra* note 53, at 81.

⁶¹ Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 268 [hereinafter *European Patent Convention*]; Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 9 I.L.M. 978; Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 2, 828 U.N.T.S. 107, revised by Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1538, 828 U.N.T.S. 303; IAN MUIR ET AL., *EUROPEAN PATENT LAW: LAW AND PROCEDURE UNDER THE EPC AND PCT* §§ 1.01-1.06, at 1-3 (2d ed. 2002); GERALD PATERSON, *THE EUROPEAN PATENT SYSTEM: THE LAW AND PRACTICE OF THE EUROPEAN PATENT CONVENTION* § 1-12, at 6 (2d ed. 2001).

⁶² A description of the EPO is available at <http://www.european-patent-office.org>.

⁶³ See PATERSON, *supra* note 61, at 4.

⁶⁴ The "first-to-file" system is different from the American patent system, which uses a "first-to-invent" system. GERALD PATERSON, *A CONCISE GUIDE TO EUROPEAN PATENTS: LAW AND PRACTICE* § 1-02, at 2 (1995).

⁶⁵ *Id.* §§ 1-02-1-04, at 2-3.

⁶⁶ MUIR ET AL., *supra* note 61, § 1-04, at 2.

⁶⁷ See PATERSON, *supra* note 61, at 3.

⁶⁸ The European Union (EU) has not succeeded in establishing a "Community patent" system. See JOSEPH STRAUS, *THE PRESENT STATE OF THE PATENT SYSTEM IN THE EUROPEAN UNION* 3 (1997).

patent with the European Patent Office to receive a bundle of national rights in designated EU Member States.⁶⁹ Regardless of the chosen route, national office or EPO patents “have the same effect and are subject to the same conditions.”⁷⁰

Prior to the grant of a European patent, the EPO substantively examines the patentability of each invention.⁷¹ The patent must have an “industrial application,” be new, and involve an inventive step.⁷² Even if an invention meets these criteria, Article 53(a) of the EPC provides an important exception: the EPO will not grant patents against *ordre public* or morality.⁷³ Yet the EPC provides a qualification that “exploitation shall not be deemed to be so contrary [to *ordre public* or morality] merely because it is prohibited by law or regulation in some or all of the Contracting States.”⁷⁴ The Guidelines for Examination in the European Patent Office (EPO Guidelines) also recognize that the EPO will exclude few inventions on this basis, as it applies a test to “consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.”⁷⁵ Should an inventor succeed in obtaining a patent through the EPO, the bundle of national patents lasts for a term of twenty years from the date of the filing of the application.⁷⁶

⁶⁹ See *id.* at 5–6.

⁷⁰ *Id.* at 6; European Patent Convention, *supra* note 61, at art. 2(2).

⁷¹ See MUIR ET AL., *supra* note 61, at 2.

⁷² European Patent Convention, *supra* note 61, art. 52(1).

⁷³ *Id.* art. 53(a) (providing that “European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to *ordre public* or morality”). It is important to note that the Biotech Directive’s morality provision does not refer to the “publication” but simply to the “exploitation” of a patent. See Biotech Directive, *supra* note 12, art. 6(1).

It is important to distinguish between *ordre public* and morality to fully appreciate the morality provisions. Philip Grubb has formulated the following distinction:

It has been suggested that the difference between *ordre public* and morality is that adultery in private may or may not be considered immoral, but if you do it in the street and frighten the horses, that is contrary to *ordre public*. But a breach of *ordre public* means more than just what English law would call disturbance of the peace; under German law it would mean a violation of a basic constitutional right such as the right to life, personal freedom, human dignity, and freedom from bodily harm. *Ordre public* means the proper order of society.

GRUBB, *supra* note 7, at 256.

⁷⁴ European Patent Convention, *supra* note 61, art. 53(a).

⁷⁵ PATERSON, *supra* note 61, at 433 (quoting The Guidelines of the European Patent Office, Section C-IV, 3.1). Note, however, that the court appears to apply an “unacceptability test” as well as this “abhorrence test.” See *infra* note 185 and accompanying text.

⁷⁶ European Patent Convention, *supra* note 61, at art. 63(1).

In contrast to the judicially created moral utility doctrine and its diminishing role in the United States,⁷⁷ the European community codified such a requirement into its patent registration laws in 1973.⁷⁸ However, this requirement remained dormant until scientists sought to patent a transgenic animal, known as the "Harvard Mouse."⁷⁹ Subsequent cases show that the question of whether the patent office should invalidate a patent because it is contrary to public morality is beginning to frequent the European patent system. However, the EPO currently appears reluctant to invalidate patents as against public morality.⁸⁰

D. Patenting the Harvard Mouse in the United States and Europe: The Moral Utility Doctrine on Vacation and Article 53(a) at Work

When the Supreme Court declared human-made living organisms patentable subject matter in *Diamond v. Chakrabarty*,⁸¹ it opened the way for patents of new micro-organisms or plants developed with biotechnology. But with the growing biotechnological industry, patents such as the Harvard Mouse⁸²—a mouse that scientists genetically altered to make it more susceptible to cancer⁸³—amassed serious concerns over the question of patentable subject matter both in the United States⁸⁴ and Europe.⁸⁵ The process of patenting the Harvard Mouse in the United States and Europe illustrates the contrasting approaches of these two patent systems.

⁷⁷ See, e.g., Merges, *supra* note 35, at 1062–63 (explaining that by the 1970s, courts were upholding patents on gambling devices because they were "wary of . . . an indeterminate moral standard").

⁷⁸ See European Patent Convention, *supra* note 61, at art. 53(a).

⁷⁹ See *infra* Part I.D; PATERSON, *supra* note 61, § 7-44, at 434–36.

⁸⁰ See Howard Florey/Relaxin, 1995 O.J. E.P.O. 388 (Opposition Div.), *reprinted in* 1995 EUR. PAT. OFF. REP. 541, 552 (upholding ethical challenge to patent and recognizing that the EPO is not the "right institution to decide fundamental ethical questions"); Plant Genetic Systems/Glutamine Synthetase Inhibitors, 1995 EUR. PAT. OFF. REP. 357, 366–67 (Tech. Bd. App.) (upholding ethical challenge to patent, noting that moral requirements will be applied on a case-by-case basis, and stating that the concept of patentability should be as wide as possible); see also *infra* Part II.B (discussing the role of the EPO courts in considering the morality of potential inventions).

⁸¹ 447 U.S. 303 (1980).

⁸² U.S. Patent No. 4,736,866 (issued Apr. 12, 1988). The "Harvard Mouse" was the first transgenic animal to be patented in the United States. See JoAnne Eichelberger Seibold, *Can Chakrabarty Survive the "Harvard Mouse"?*, 2 U. FLA. J.L. & PUB. POL'Y 81, 81–82 (1988–1989). A transgenic animal is an animal that has foreign DNA, specifically a gene, introduced into its genome. Today, many different transgenic animals are available for sale to scientific laboratories.

⁸³ Seibold, *supra* note 82, at 82.

⁸⁴ See, e.g., *id.* at 96–99.

⁸⁵ See David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 FORDHAM INT'L L.J. 990, 1014–16 (1992–1993).

Shortly after the *Chakrabarty* decision, many cases raised questions concerning its scope.⁸⁶ Yet the PTO Board of Patent Appeals and Interferences' decisions broadly applied *Chakrabarty*,⁸⁷ leading the Commissioner of Patents and Trademarks to formally "announce [] the PTO's intention to issue patents on non-naturally occurring, nonhuman multicellular living organisms."⁸⁸ In the first case, *Ex parte Hibberd*, the Board of Appeals and Interferences cited *Chakrabarty*, stating that "the Supreme Court . . . has already interpreted the scope of Section 101 to cover everything under the sun made by man."⁸⁹ The Board further held that the Plant Patent Act⁹⁰ and Plant Variety Protection Act⁹¹ did not narrow or restrict the scope of patentable subject matter under 35 U.S.C. § 101.⁹² In the case which followed, *Ex parte Allen*, the Board of Patent Appeals and Interferences upheld a patent of human-made polyploid Pacific oysters—a significantly more complex organism than the bacteria in *Chakrabarty*—as patentable subject matter.⁹³ The PTO followed its pattern of applying *Chakrabarty* broadly by awarding a patent for the Harvard Mouse fewer than four years after receiving the application.⁹⁴ For these biotechnological patent applications following *Chakrabarty*, the PTO's focus ostensibly revolved around whether the inventions constituted patentable subject matter, rather than whether these inventions were immoral.⁹⁵ Although the PTO granted the Harvard Mouse patent fairly quickly, the

⁸⁶ See *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1426–27 (1987); *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443, 444 (1985).

⁸⁷ See *Allen*, 2 U.S.P.Q.2d (BNA) at 1426–27; *Hibberd*, 227 U.S.P.Q. (BNA) at 445; Seibold, *supra* note 82, at 88.

⁸⁸ *Bill on Animal Patenting is Approved by House Panel*, 36 PAT. TRADEMARK & COPYRIGHT J. 271, 272 (1988).

⁸⁹ *Hibberd*, 227 U.S.P.Q. (BNA) at 447 (footnote omitted).

⁹⁰ 35 U.S.C. § 161 (2000).

⁹¹ 7 U.S.C. § 2321 et seq. (2000).

⁹² See *Hibberd*, 227 U.S.P.Q. (BNA) at 444, 445–47.

⁹³ See *Allen*, 2 U.S.P.Q.2d (BNA) at 1426–27.

⁹⁴ See U.S. Patent No. 4,736,866 (issued Apr. 12, 1988); Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1, 26–27 (2001); Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 252 (2000) ("The United States Patent Act does not exclude any particular inventions from the scope of patentable subject matter. In addition, the patent laws consistently have been broadly interpreted with regard to the scope of patentable subject matter.")

⁹⁵ This is not to suggest that the patenting of animals was not controversial in the United States:

The idea of the patenting of higher organisms has encountered severe criticism for ethical and economic reasons, particularly in the USA, where a moratorium on the grant of animal patents was introduced for a certain period of time, where hearings were held to discuss ethical ramifications and where a special bill, the "Transgenic Animal Patent Reform Act," was presented to the House of Representatives.

Harvard/Onco-mouse, 1989 O.J. E.P.O. 451 (Examining Div.), *reprinted in* 1990 EUR. PAT. OFF. REP. 4, 10.

patent nevertheless caused controversy in the United States. However, the public addressed their ethical concerns in legislative and public debates, not in patent examiners' offices or in courtrooms.⁹⁶

The Harvard Mouse got caught in a "mousetrap" in Europe when the Examining Division of the EPO first rejected the patent application for failure to constitute patentable subject matter.⁹⁷ More importantly, noting that "patent law is not the right legislative tool for regulating problems which may arise [from ethical questions]," the Examining Division did not refuse the patent under Article 53(a) on the ground that it was immoral.⁹⁸ On appeal, the Technical Board of Appeal reversed the Examining Division's decision by broadly interpreting the scope of patentable subject matter under the EPC.⁹⁹ However, it remanded the case to the Examining Division to determine whether the patent violated *ordre public* or morals under Article 53(a) of the EPC.¹⁰⁰ The Board rejected the Examining Division's conclusion that patent law is not the right tool to make moral considerations:

[P]recisely in a case of this kind there are compelling reasons to consider the implications of Article 53(a) EPC in relation to the question of patentability. The genetic manipulation of mammalian animals is undeniably problematical in various respects, particularly where [it makes] . . . an animal abnormally sensitive to carcinogenic substances and stimuli and consequently prone to develop tumours, which necessarily cause suffering. There is also a danger that genetically manipulated animals, if released into the environment, might entail unforeseeable and irreversible adverse effects.¹⁰¹

The Board wanted the Examining Division to weigh "the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other."¹⁰² On remand, the Examining Division determined that in the overall balance, the invention did not violate Article 53(a).¹⁰³

⁹⁶ Cynthia M. Ho, Note, *Building a Better Mousetrap: Patenting Biotechnology in the European Community*, 3 DUKE J. COMP. & INT'L L. 173, 184-85 (1992).

⁹⁷ See *Harvard/Onco-mouse*, 1990 EUR. PAT. OFF. REP. at 7-9 (holding that Article 53(b) prohibits granting the patent because it applies to an animal variety).

⁹⁸ *Id.* at 11. The argument that a legislative body and not the patent system should consider the morality, and therefore that the EPC should remove Article 53(a), is common. See PATERSON, *supra* note 61, at 433. However, Gerald Paterson counterargues that public order and morality provide the foundation for every legal system, and it is useful to allow third parties to object to the patenting of certain inventions. See *id.* at 434.

⁹⁹ *Harvard/Onco-mouse*, 1990 O.J. E.P.O. 476 (Tech. Bd. App.), *reprinted in* 1990 EUR. PAT. OFF. REP. 501, 509-11.

¹⁰⁰ *Harvard/Onco-mouse*, 1991 EUR. PAT. OFF. REP. 525, 526 (Examining Div.).

¹⁰¹ *Harvard/Onco-mouse*, 1990 EUR. PAT. OFF. REP. at 513.

¹⁰² *Harvard/Onco-mouse*, 1991 EUR. PAT. OFF. REP. at 526. The Examining Division noted that the case had attracted a lot of public attention. *Id.*

¹⁰³ *Id.* at 528. "When the EPO announced in 1992 that it intended to approve the Onco-mouse patent application, protests arose throughout Europe. . . . [As of 2001,] the outcome of the opposition proceedings ha[d] not yet been decided, and it [was] expected

E. Role of the Biotech Directive in the European Patent System

Scholars and journalists heralded the Biotech Directive,¹⁰⁴ which the European Union enacted after years of debate¹⁰⁵ in order to remobilize the European patent system.¹⁰⁶ Yet “[n]ever has a piece of European Union legislation lit such a huge bonfire of public controversy.”¹⁰⁷ Prior to its enactment, the Commission ordered an advisory committee on biotechnological ethics to “comb[] through” the Directive’s provisions “to prevent Frankenstein-like inventions [from] being legitimised by a patent.”¹⁰⁸ As a result, the Directive “represents a compromise between the biotech industry and its supporters . . . and the various factions opposing the Directive on moral, ethical, environmental, and economic grounds”¹⁰⁹ Article 6(1) of the Directive provides: “Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality.”¹¹⁰ Although the EU enacted Article 6(1) as a compromise, it is one of the Directive’s most controversial provisions.¹¹¹ The Directive further excludes the following items from patentability:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes; [and]
- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.¹¹²

to be affected by the [then] recent Directive.” Gitter, *supra* note 94, at 29–30. The EPC allows either the EPO itself or third parties to raise objections to patents. See PATERSON, *supra* note 61, at 434. Recently, third parties have objected to certain patents on moral grounds. See discussion *infra* Part I.F.

¹⁰⁴ Biotech Directive, *supra* note 12.

¹⁰⁵ Gitter, *supra* note 94, at 1.

¹⁰⁶ STRAUS, *supra* note 68, at 4 (“Whereas the United States [has adapted its patent system to meet revolutionary technological developments], the European patent system has remained virtually unaffected by these developments and appears immobilized.”). The European Commission has also proposed a “Community Patent” system, which would “give inventors the option of obtaining a single patent legally valid throughout the European Union.” *Commission Proposes the Creation of a Community Patent*, EUR. UNION ONLINE, at http://www.europa.eu.int/comm/internal_market/en/indprop/patent/2k-714.htm (July 5, 2002).

¹⁰⁷ *Biotechnology: Moral Maze Continues To Dominate Patent Debate*, EUR. ENV’T, Oct. 25, 1994.

¹⁰⁸ *Id.*

¹⁰⁹ Gitter, *supra* note 94, at 13.

¹¹⁰ Biotech Directive, *supra* note 12, art. 6, ¶ 1. This provision is similar to that of Article 53(a) of the European Patent Convention. See European Patent Convention, *supra* note 61, art. 53(a).

¹¹¹ Gitter, *supra* note 94, at 2–3.

¹¹² Biotech Directive, *supra* note 12, art. 6, ¶ 2(a)–(d).

The Biotech Directive requires patent offices and courts to continue to confront the questions of whether patents are contrary to public morals.¹¹³ The EU enacted the Directive to update an “outdated legal framework” and to follow the two leading nations in biotechnology—the United States and Japan—that have successfully adapted their patent protection to recent technological changes.¹¹⁴ The Commission sought to stimulate the European biotechnology industry in several ways.¹¹⁵ The Commission wanted “effective and harmonized protection . . . in order to maintain and encourage investment in the field of biotechnology”¹¹⁶ and thus “eliminate barriers to the exchange of information and technology among Member States.”¹¹⁷ Furthermore, the Directive would counteract existing trade barriers that could “impede the proper functioning of the internal market”¹¹⁸ and “lead to further disincentives to trade.”¹¹⁹ Finally, with “harmonization and legal certainty,” this new patent protection would “enhance investment opportunities in the biotech industry” within Europe, “attract[ing] foreign investors.”¹²⁰

Although the Directive binds only European Union Member States,¹²¹ it will affect the majority of those Contracting States to the EPC because there is a large overlap between EU Member States and EPC Contracting States.¹²² Since the EPC already has Article 53(a) to invalidate patents that are against the *ordre public* or morality, what will the Biotech Directive’s similar morality provisions add?

An EU directive obliges all Member States to ensure the provision’s effectiveness.¹²³ Because each Member State must update its national patent laws to comply with the Biotech Directive’s morality provisions, the national bundle of patents that the EPC grants will currently be enforced within national jurisdictions with similar patent laws. Thus, the Directive’s morality provisions will have a broader effect on European biotech patents than does EPC Article 53(a), which

¹¹³ *Id.* at art 6, ¶ 1.

¹¹⁴ Gitter, *supra* note 94, at 9.

¹¹⁵ See Biotech Directive, *supra* note 12, ¶¶ 1–9.

¹¹⁶ *Id.* ¶ 3.

¹¹⁷ Gitter, *supra* note 94, at 9; see Biotech Directive, *supra* note 12, ¶ 7.

¹¹⁸ Biotech Directive, *supra* note 12, ¶ 5.

¹¹⁹ *Id.* ¶¶ 5, 7.

¹²⁰ Gitter, *supra* note 94, at 9.

¹²¹ See Biotech Directive, *supra* note 12, at art. 1, ¶ 1. Article 1, paragraph 2 of the Biotech Directive notes that the Directive “shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.” *Id.* at art. 1, ¶ 2.

¹²² See MUIR ET AL., *supra* note 61, at 308–09 (listing the current members of the EPC); STRAUS, *supra* note 68, at 1 n.3 (listing the current EU Member States).

¹²³ See Biotech Directive, *supra* note 12, at art. 1, ¶ 1 (“[Member States] shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.”); PATERSON, *supra* note 61, at 13.

acts as more of a screening device to patent registration.¹²⁴ However, the Member States have been slow to incorporate the Biotech Directive into their national laws, demonstrating the continuing controversy over the Directive. Article 15 of the Biotech Directive provides: "Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000."¹²⁵ Despite this provision, as of July 2002, only six Member States had incorporated the Directive into their national laws.¹²⁶ A recent report by the Commission to the European Communities concludes: "If such a situation were to continue, it would have the effect of considerably hampering the development of biotechnology in Europe."¹²⁷ However, by a Decision of the Administrative Council of the EPO, the EPC incorporated the Directive's "main provisions," including Article 6, into its "Implementing Regulations."¹²⁸ Two recent decisions reflect the uncertain effect of the enactment of the Biotech Directive.

F. "Mousing Around" Again: After the Biotech Directive

Patents do not give positive rights of exploitation, yet third parties challenge these rights in opposition proceedings. It is suggested that third parties challenge patents because (1) "it is easier and cheaper to oppose a patent than to mount a lobbying campaign for a piece of legislation," and (2) "patents appear to be a potent symbol of commercial exploitation."¹²⁹ A third possible reason is the amount of media attention that opposition proceedings produce. Third parties can draw even more attention to their causes by lodging opposition proceedings in addition to petitioning legislators. The following two cases evidence this point.

I. *R. v. Leland Stanford/Modified Animal*

[T]issues are obtained directly in the operating room as fetal parts after elective or medically-indicated abortion Without maintaining strict sterility, these parts are taken immediately to a gross dissection room. The desired tissues are identified, dissected out

¹²⁴ See *supra* Part I.C.

¹²⁵ Biotech Directive, *supra* note 12, at art. 15, ¶ 1.

¹²⁶ COMM'N EUR. COMMUNITIES, REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL: DEVELOPMENT AND IMPLICATIONS OF PATENT LAW IN THE FIELD OF BIOTECHNOLOGY AND GENETIC ENGINEERING 6 (July 10, 2002), at http://www.europa.eu.int/eur-lex/en/com/rpt/2002/com2002_0545en01.pdf [hereinafter DEVELOPMENT AND IMPLICATIONS REPORT].

¹²⁷ *Id.*

¹²⁸ *Id.* at 7. For a text of the implementation, see Notice Concerning the Amendment of the Implementing Regulations to the European Patent Convention (July 1, 1999) (on file with author).

¹²⁹ See GRUBB, *supra* note 7, at 260.

. . . . Tissue has been introduced [into the mice] by a number of routes: intravenously, intrarenally, intrasplenically, or subcutaneously.¹³⁰

On December 22, 1988, Stanford University filed an application with the EPO for the patenting of "chimeric immunocompromised non-human mammals" (the "Stanford patent").¹³¹ In their patent application, the researchers described the process of transplanting human fetal tissues into "immunocompromised" mice or horses.¹³² An animal is "immunocompromised" if it has a severely deficient immune system, although it may still contain functioning immune system organs.¹³³ The inventors envisioned introducing into these hosts "fetal tissue, fetal liver tissue providing stem cells, thymus tissue, where the thymus grows into a competent thymus organ, and lymph node tissue, where the lymph node tissue grows into a competent lymph node, and the stem cells are processed to produce functional human B- and T-cells." The inventors described the potential benefits of this patent thus:

The cells grow and produce products native to the cells, including progeny cells, which may find use in research, production of antibodies, production of physiologically active products, as transplants, and in numerous other applications. The method involves introduction of the cells in an appropriate site or environment in the animal host to provide a chimeric host.¹³⁴

When the EPO awarded these researchers a patent on March 1, 1995, three groups immediately opposed the patent before the Opposition Division (OD) of the EPO.¹³⁵ Seeking to invalidate the Stanford patent on the ground that it violated Article 53(a) of the EPC, the opponents argued that "it was intrinsically unethical and against the general moral principles of Western society to grant patents on life."¹³⁶ However, the OD stated that Article 6(2) of the Biotech Directive,¹³⁷ incorporated into the EPC's regulations, demonstrates that it is not intrinsically unethical in Western society to patent animals.¹³⁸ The OD next "weighed up the potential medical benefits of the [Stanford patent] against the possible suffering of the animals," concluding

¹³⁰ Eur. Patent No. 0322240 (issued Mar. 1, 1995).

¹³¹ *Id.* As described above, the researchers sought a bundle of national patents in the following countries: Austria, Belgium, Switzerland, Germany, Spain, France, Great Britain, Greece, Italy, Liechtenstein, Luxembourg, the Netherlands, and Sweden. *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *See R. v. Leland Stanford/Modified Animal*, 2002 EUR. PAT. OFF. REP. 16, 18 (Opposition Div.). By the time of oral arguments, only one opponent of the patent remained. *Id.*

¹³⁶ *Id.* at 21.

¹³⁷ *See supra* notes 112-14 and accompanying text.

¹³⁸ *See Leland Stanford/Modified Animal*, 2002 EUR. PAT. OFF. REP. at 22.

that the substantial and enormous medical benefits outweighed the “hypothetical potential risks.”¹³⁹ The OD premised its conclusion on two basic points. First, it explained that Article 53(a) would not justify “deny[ing] a patent . . . merely on the basis of possible, rather than conclusively documented hazards.”¹⁴⁰ Second, and more importantly, the court noted that it “is not vested with carrying out the task of monitoring and estimating such risks; this is rather a matter for the numerous regulatory authorities charged with regulating research and medical practice.”¹⁴¹

The opponents to the Stanford patent also argued that “it is ethically unacceptable to create animal-human chimeras such as those of the [Stanford] patent, and in doing so to take cells and tissue from aborted fetuses or children aged below three years of age as a source of human tissues.”¹⁴² The OD concurred that at first glance the use of these cells “instinctively appears distasteful, *if not immoral*.”¹⁴³ Yet the OD explained that

as long as a claimed invention has a legitimate use, it cannot be the role of the EPO to act as a *moral censor* and invoke the provisions of Article 53(a) EP.C to refuse on ethical grounds to grant a patent on legal research and directed to an invention indisputably associated with medical benefits.¹⁴⁴

In passing, the OD acknowledged the controversial nature of the invention¹⁴⁵ but thought “[i]t would be presumptuous . . . to interfere in [the] public debate.”¹⁴⁶

2. *The Edinburgh Patent*

There has developed a pressing need to isolate and maintain *in vitro* embryonic stem cells from other murine strains and more especially from other species including other laboratory animals (e.g. rats, rabbits and guinea pigs), domesticated animals (e.g. sheep, goats, horses, cattle, pigs, birds, fish, etc.) and primates.¹⁴⁷

On April 24, 1995, the University of Edinburgh sought to patent the “[i]solation, selection and propagation of animal transgenic stem cells” (the Edinburgh patent).¹⁴⁸ The creators described their inven-

139 *Id.*

140 *Id.*

141 *Id.*

142 *Id.* at 23.

143 *Id.* (emphasis added).

144 *Id.* (emphasis added).

145 *Id.* (noting that the invention had been “the subject of intensive discussion in the media and among members of the public”).

146 *Id.*

147 Eur. Patent No. 695351 (issued Dec. 8, 1999).

148 *Id.*

tion as "relat[ing] to methods of isolating and/or enriching and/or selectively propagating animal stem cells, genetically modified animal cells and animals for use in said method, transgenic animals providing a source of such cells and selectable marker constructs for producing genetically modified cells and transgenic animals."¹⁴⁹ The EPO granted the Edinburgh patent after the Biotech Directive took effect. Subsequently, national and international press alleged that the patent constituted human cloning.¹⁵⁰ Much of the initial uproar regarding the Edinburgh patent resulted from its ambiguous language referring to the preparation of a transgenic animal. Because a human is a type of animal in scientific usage, opponents thought that this patent encompassed human cloning methods.¹⁵¹ The University of Edinburgh subsequently sought to amend its patent to limit its application to nonhumans.¹⁵²

On April 14, 2000, the OD gave its preliminary opinion on the amended set of claims, stating that the subject matter of the Edinburgh patent's claims regarding stem cell research did not violate Article 53(a) of the EPC.¹⁵³ "[T]he governments of Germany, Italy and the Netherlands, and the German branch of Greenpeace, are among the parties that . . . lodged oppositions to the [Edinburgh] patent," and oral arguments started on July 22, 2002.¹⁵⁴ In a recent opinion, the OD held that the original Edinburgh patent violated Article 53(a) but that the amended Edinburgh patent is "to be maintained . . . [since it] no longer includes human or animal embryonic stem cells, but still covers modified human and animal stem cells other than embryonic stem cells."¹⁵⁵ Thus, despite both the public outcry concerning the Stanford and Edinburgh patents and the Biotech Directive, the EPO has been reluctant to apply the morality provisions of the EPC.

¹⁴⁹ *Id.* "A stem cell is an (1) undifferentiated cell (2) that can divide without limit and (3) whose progeny includes both further stem cells or cells destined to differentiate." GEERTRUI VAN OVERWALLE, EUR. COMM'N, STUDY ON THE PATENTING OF INVENTIONS RELATED TO HUMAN STEM CELL RESEARCH 8 (2001). For an explanation of the basic concepts relating to human stem cell research, see *id.* at 8-38.

¹⁵⁰ *Id.* at 58.

¹⁵¹ *Id.* at 58-59.

¹⁵² *Id.* at 59.

¹⁵³ *Id.* at 60.

¹⁵⁴ Press Release, European Patent Office, Opposition Hearing on Genetic Stem-cell Patent at the European Patent Office (July 18, 2002), available at http://www.european-patent-office.org/news/pressrel/2002_07_18_e.htm.

¹⁵⁵ Press Release, European Patent Office, "Edinburgh" Patent Limited After European Patent Office Opposition Hearing (July 24, 2002), available at http://www.european-patent-office.org/news/pressrel/2002_07_24_e.htm.

II
CRITICISM OF THE BIOTECH DIRECTIVE'S
MORALITY PROVISIONS

Biotechnology demands strong, clear patent laws. Research in biotechnology is not only controversial, but also extremely important. "Without biotechnology, we are effectively prevented from devising the much needed solutions to dietary, health, environmental and other problems that plague us at record rates."¹⁵⁶ The European Union recognized the "fundamental importance" of biotechnological research in passing the Biotech Directive,¹⁵⁷ but critics of the morality provisions recognize the risk such provisions raise of dampening the desirable economic benefits of strong biotechnology patent laws.

A. Do the Biotech Directive's Morality Provisions Create a
Competitive Disadvantage?

Opponents of the morality provisions claim that excluding patents on the ground of immorality will competitively disadvantage Europe with respect to the United States and Japan.¹⁵⁸ If the Biotech Directive competitively disadvantages Europe, then it seems to have failed its stated purpose of benefiting Europe's biotechnology industry and economy.¹⁵⁹ EU states now surpass the United States in the number of biotechnological companies and publications,¹⁶⁰ but "the long delay in granting procedures at the EPO" still hampers those seeking patent protection in Europe.¹⁶¹ The cases of the Harvard Mouse, the Stanford patent, and the Edinburgh patent¹⁶² demonstrate that the Directive permits third parties to protract the granting process at the EPO by challenging the validity of a patent on moral grounds.¹⁶³ Pro-

¹⁵⁶ James R. Chiapetta, Comment, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 WM. MITCHELL L. REV. 155, 160 (1994).

¹⁵⁷ Biotech Directive, *supra* note 12, ¶ 1.

¹⁵⁸ See Deryck Beyleveld et al., *The Morality Clauses of the Directive on the Legal Protection of Biotechnological Inventions: Conflict, Compromise and the Patent Community*, in PHARMACEUTICAL MEDICINE, BIOTECHNOLOGY AND EUROPEAN LAW 157, 161 (Richard Goldberg & Julian Lonbay eds., 2000). Beyleveld terms this the "local objection." *Id.* The second principal ground for exclusion is a "general objection" that "morality as such has no business being considered within the patent system." *Id.*

¹⁵⁹ See *supra* Part I.E.

¹⁶⁰ See DEVELOPMENT AND IMPLICATIONS REPORT, *supra* note 126, at 31.

¹⁶¹ See *id.* at 35.

¹⁶² See *supra* Parts I.D, I.F.

¹⁶³ Beyleveld and others respond to objections that the morality provisions will place Europe at a competitive disadvantage. They note:

(a) Whether or not Europe is placed at a competitive disadvantage against the United States and Japan will depend on what criteria of morality are employed.

(b) Being placed at a competitive disadvantage against the United States/ Japan could, in certain cases, have morally bad consequences which could override the *prima facie* immorality involved in granting a patent. Thus,

cedural delay as well as legal uncertainty and failure to harmonize systems may competitively disadvantage Europe's patent system as compared with that of the United States or Japan.

1. *Legal Certainty and Ambiguity: Kingdom of the Netherlands v. European Parliament and Council*

I would however firstly note . . . that the Directive breaches the principle of legal certainty, because it lacks the clarity necessary for the Member States to determine how to accurately implement the directive. This has been fully proved in the time that has past [sic] since the adoption of the directive. The fact . . . that the directive has yet to be implemented in the majority of the Member States of the European Union, despite the fact that the time-limit for implementation expired . . . is also clear proof of this.¹⁶⁴

Drafters of the Biotech Directive acknowledged that biotechnological inventions require a strong and clear set of patent laws to protect biotech inventors' expectations:

Biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development . . . [I]n particular . . . the field of genetic engineering, research and development require a considerable amount of high-risk investment . . . [O]nly adequate legal protection will make them profitable.¹⁶⁵

Yet the Biotech Directive allows the exclusion of patents based on undefined terms (*ordre public* or morality) that contradict the Directive's express goal of providing "adequate legal protection" for these "high-risk investments." For these reasons, the Netherlands sought to annul the Biotech Directive after its enactment.¹⁶⁶

considerations of morality could even argue for permitting particular patents.

(c) It is by no means axiomatic that patents . . . are necessary to encourage the investment required to protect European economic interests in biotechnology.

(d) If, all things considered, it would be immoral . . . to grant a particular patent, then the patent must be denied; the fact that this would place Europe at a competitive disadvantage is no overriding objection.

Beyleveld et al., *supra* note 158, at 161.

¹⁶⁴ The Norwegian Statement at the Oral Hearing on 13 February 2001 Before the Court of Justice of the European Community in Case C-377/98; the Kingdom of the Netherlands Against European Parliament and Council of the European Union Concerning the Directive on the Legal Protection of Biotechnological Inventions, at <http://odin.dep.no/ud/norsk/handelspolitikk/032061-990022/index-dok000-b-n-a.html> (last visited Oct. 30, 2003) [hereinafter Norwegian Statement].

¹⁶⁵ Biotech Directive, *supra* note 12, ¶¶ 1, 2 (emphasis added).

¹⁶⁶ See Norwegian Statement, *supra* note 164.

In *Kingdom of the Netherlands v. European Parliament and Council of the European Union*,¹⁶⁷ the Netherlands, Italy, and Norway (NIN) sought to annul the Biotech Directive for violating the principle of legal certainty, on the grounds that *ordre public* and morality are ambiguous terms.¹⁶⁸ NIN argued that “Article 6 gives insufficient guidance and the principles mentioned in the recitals for determining whether there is an infringement of *ordre public* or morality are general and equivocal.”¹⁶⁹ NIN recognized that because patent offices would “turn to the ethical and moral principles recognised in a Member State to supplement the standard legal examinations under patent law . . . therefore inevitabl[y] Article 6 [would] be interpreted and applied divergently.”¹⁷⁰ The Advocate General disagreed with NIN.¹⁷¹ First, the Advocate General noted that “*ordre public* and morality have a long and distinguished history as criteria for the lawfulness of the grant or exercise of intellectual property rights,”¹⁷² as Article 53(a) of the EPC illustrates.¹⁷³ The Advocate General further noted that European Union community trademark law “continues this pattern” by “provid[ing] for the refusal of registration or invalidity of a mark which is ‘contrary to public policy or to accepted principles of morality.’”¹⁷⁴ The Advocate General also explained that the Community legislature frequently resorts to the concept of *ordre public* in harmonizing measures, “thus apparently seeing no contradiction in conferring a degree of discretion on national authorities in an area subject to harmonisation.”¹⁷⁵ Regardless of the reasons for refusing to annul the Biotech Directive for breach of the principle of legal cer-

¹⁶⁷ Case C-377/98, *Kingdom of the Netherlands v. European Parliament and Council of the European Union*, 2001 E.C.R. I-7079, 2001 3 C.M.L.R. 49. The Netherlands, Norway, and Italy are not the only countries to protest certain provisions of the Biotech Directive; in early 2002, Luxembourg called for a renegotiation of the Biotech Directive due to concerns about Article 5, which concerns the patentability of certain parts of the human body. See *Biotechnology: Luxembourg Parliament Calls for Re-negotiation of Inventions Directive*, EUR. REP., Mar. 6, 2002.

¹⁶⁸ *Kingdom of the Netherlands*, 2001 3 C.M.L.R. ¶¶ A11, 35.

¹⁶⁹ *Id.* ¶ A94 (emphasis added).

¹⁷⁰ *Id.*

¹⁷¹ An Advocate General questions the parties and presents an opinion to the Court of Justice, which the court may or may not follow in rendering its judgment. Here, the court followed the opinion of the Advocate General. Compare *id.* ¶ A230 with ¶ R1. For general information on the structure of the Court of Justice, see the website of the Court of Justice of the European Communities at <http://curia.eu.int/en/instit/presentationfr/index.htm>.

¹⁷² *Kingdom of the Netherlands*, 2001 3 C.M.L.R. ¶ A95.

¹⁷³ The court’s response to the NIN’s concerns noted that Article 53(a) of the EPC is substantially similar to Article 6(1) of the Biotech Directive is insufficient. Article 53(a)’s morality provisions have been tested on relatively few occasions—and one would be hard pressed to say that their application in the Harvard Mouse instance proved that *ordre public* and morality are solid standards by which patent examiners should judge inventions. See *supra* Part I.D.

¹⁷⁴ *Kingdom of the Netherlands*, 2001 3 C.M.L.R. ¶ A96.

¹⁷⁵ *Id.* ¶ A98.

tainty, the compromise Directive may nonetheless “create more uncertainty and controversy.”¹⁷⁶

2. *Harmonization and Potentially Differing Applications of Moral Considerations*

As noted earlier, the Biotech Directive represents a compromise between the biotech industry and opponents of biotech research.¹⁷⁷ This agreement will not likely harmonize European patent law—one of the Biotech Directive’s stated goals¹⁷⁸—because concepts of morality change with time and place and vary even within a single country at a single time.¹⁷⁹

The Netherlands challenged the Directive out of concern that each Member State would apply a different standard of morality to patents.¹⁸⁰ Existing evidence demonstrates that some European Union Member States, for example, are more open to the idea of cloning than others.¹⁸¹ In fact, in seeking to annul the Directive, the Netherlands objected to the “notion that plants, animals and parts of the human body may be patentable.”¹⁸² In response to these concerns, the Advocate General in *Kingdom of The Netherlands* explained that “[t]he application by national authorities of the concepts of *ordre public* and morality, however, will always be subject to review by the Court: Member States do not have an unlimited discretion to determine their scope.”¹⁸³ The Advocate General described the court’s standard for determining which inventions are contrary to *ordre public* or morals as similar to that applied by the EPO—namely, to “exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour.”¹⁸⁴ But the EPO does not apply this single standard consistently:

[H]armonization will . . . remain elusive under the Directive. As it is drafted, the ambiguity of the Directive’s Article 6 invites inconsistent interpretations, even from judges committed to achieving uniformity. An examination of cases decided by the EPO under the EPC’s morality provision . . . demonstrates that the morality provi-

¹⁷⁶ Ho, *supra* note 94, at 284.

¹⁷⁷ See *supra* Part I.E.

¹⁷⁸ Biotech Directive, *supra* note 12, ¶ 3.

¹⁷⁹ GRUBB, *supra* note 7, at 257 (noting that morality is a “shakier ground” to deny patents than *ordre public*).

¹⁸⁰ See *supra* Part II.A.1.

¹⁸¹ See Gitter, *supra* note 94, at 18 (“Article 6 will be subject to widely varying interpretations throughout the Member States, which differ greatly in their acceptance of emergent biotechnological inventions.”).

¹⁸² See *Kingdom of the Netherlands*, 2001 3 C.M.L.R. ¶ A10.

¹⁸³ *Id.* ¶ A101.

¹⁸⁴ *Id.* ¶ A101.

sion has been subject to inconsistent interpretations even by a *single* adjudicatory body.¹⁸⁵

Notably, in the face of controversial subject matter, the Opposition Division of the EPO has indicated that it would pass on excluding certain patents under Article 53(a) of the EPC: “[T]here is at present no consensus in European society about the desirability [of the Stanford patent], and public opinion is still being formed on this and related matters. It would be presumptuous for the EPO to interfere in this public debate.”¹⁸⁶ Furthermore, one could argue that even courts may inconsistently apply the standard asserted in *Kingdom of the Netherlands*.¹⁸⁷

Despite the court’s decision regarding harmonization and legal certainty, a recent report from the European Union recognizes that one advantage of the United States’ patent system is that the PTO has “guidelines [that provide] legal certainty by giving a clear definition of what can be considered a biotechnological invention and what is eligible for patent protection.”¹⁸⁸ These issues may continue to place the growth of Europe’s patent system and biotechnology sector behind that of the United States and Japan.

B. Patent Examiners as Moral Censors

The reluctance of patent examiners—trained to evaluate the technical merits of inventions—to evaluate morality is not surprising. On the other hand, granting controversial patents in the face of a mandatory morality consideration appears to have made the EPO a victim of special interest groups who are critical of biotechnology.¹⁸⁹

The strongest general criticism of the EPC and Biotech Directive’s morality provisions has come from the EPO courts them-

¹⁸⁵ Gitter, *supra* note 94, at 18; *id.* at 21 (noting that the EPO has applied a “‘public abhorrence’” standard as well as an “‘unacceptability’” test in Article 53(a) morality-based challenges to patents). Donna Gitter proposes refining the Directive so as to apply a consistent moral standard (either “abhorrence” or “unacceptability”), *id.* at 40, then further refining and clarifying these tests so as to “furnish proper guidance to the national courts and patents offices administering it.” *Id.* at 42. Grubb argues that patent examiners are as well suited as any member of society to apply the “abhorrence test.” See GRUBB, *supra* note 7, at 258. However, he notes that if the test applied is the balancing test articulated by the Technical Board of Appeals in the “Harvard Mouse” case, examiners would be “wholly incapable of such a task.” See *id.*

¹⁸⁶ R. v. Leland Stanford/Modified Animal, 2002 EUR. PAT. OFF. REP. 16, 23 (Opposition Div.) (applying the public abhorrence test).

¹⁸⁷ As the concepts of *ordre public* and morality differ from country to country, courts would apply these terms differently, producing varied results. Such varied results would conflict with the Directive’s goal of increasing harmony in the law of the European patent community.

¹⁸⁸ DEVELOPMENT AND IMPLICATIONS REPORT, *supra* note 126, at 37.

¹⁸⁹ Ho, *supra* note 94, at 284.

selves.¹⁹⁰ EPO courts initially voiced reservations about their ability to act as moral gatekeepers prior to the enactment of the Biotech Directive. When the Examining Division (ED) of the EPC first considered the patent application for the Harvard Mouse, questions arose about whether the patent violated *ordre public* or morality.¹⁹¹ In that case, the ED concluded that "patent law is not the right legislative tool for regulating problems" relating to the ethical considerations of animal patents.¹⁹² The Technical Board of Appeals disagreed, noting that this was precisely the kind of case in which "there are compelling reasons to consider the implications of Article 53(a) [EPC] in relation to the question of patentability."¹⁹³ On remittal, the ED concluded that the patent application violated neither *ordre public* nor morality.¹⁹⁴ Furthermore, when Greenpeace opposed the Plant Genetic Systems/Glutamine Synthetase Inhibitors patent of a genetically engineered plant, the Technical Board of Appeal once again noted that "[a]lthough it may be difficult to judge whether or not a claimed subject-matter is contrary to 'ordre public' or morality, the provisions of Article 53(a) [EPC] may not be disregarded by the EPO when assessing patentability."¹⁹⁵

Even after the Technical Board of Appeal's ruling in the Harvard Mouse case and the enactment of the Biotech Directive, both the Examining and Opposition Divisions remained reluctant to acknowledge and embrace their roles as moral gatekeepers. The Stanford Patent case illustrates that EPO courts continued to be loath to address the morality issue.¹⁹⁶ In that case, the Opposition Division (OD) noted that "as long as a claimed invention has a legitimate use, it cannot be the role of the EPO to act as moral censor and invoke the provisions of Article 53(a) EPC to refuse on ethical grounds."¹⁹⁷ The court also thought it "presumptuous" to interfere in the public debate regarding animal-human chimeras.¹⁹⁸ Although the EPO courts hesitate to act as moral censors, and their case law on the issue is "at best cursory,"¹⁹⁹

¹⁹⁰ Beyleveld et al., *supra* note 158, at 161.

¹⁹¹ See *supra* Part I.D.

¹⁹² 1989 O.J. E.P.O. 451 (Examining Div.), *reprinted in* 1990 EUR. PAT. OFF. REP. 4, 11.

¹⁹³ 1990 O.J. E.P.O. 476 (Tech. Bd. App.), *reprinted in* 1990 EUR. PAT. OFF. REP. 501, 513. The Technical Board of Appeals noted concern regarding the release of genetically modified animals into the wild. *Id.* However, most scientists would argue that this concern is not well founded. Chiapetta, *supra* note 156, at 180-81. Scientists also argue that patent law is not the correct context in which to discuss the difficult moral question of whether it is right for an animal to die in order to save a human life. *Id.* at 183-84.

¹⁹⁴ Harvard/Onco-mouse, 1991 EUR. PAT. OFF. REP. 525, 528 (Examining Div.).

¹⁹⁵ Plant Genetic Systems/Glutamine Synthetase Inhibitors, 1995 EUR. PAT. OFF. REP. 357, 368 (Tech. Bd. App.).

¹⁹⁶ 2002 EUR. PAT. OFF. REP. 16, 23 (Opposition Div.).

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ Ho, *supra* note 94, at 283.

the Biotech Directive ensures that courts will consider ethical aspects of patents—whether they believe such consideration to be proper or not. Nevertheless, the court has never denied a patent for being immoral,²⁰⁰ and the proceedings have undoubtedly slowed the patent process.

Several reasons exist as to why EPO courts are reluctant to consider or invalidate patents for being contrary to *ordre public* or morality. First, moral standards are difficult to ascertain.²⁰¹ Second, these patent authorities lack the “expertise or authority” to consider ethics.²⁰² Third, “moral ideas change quite rapidly as compared with patent lifetimes.”²⁰³ Fourth, moral ideas differ among European countries.²⁰⁴ Lastly, law should forbid abhorrent inventions independent of patent requirements,²⁰⁵ a criticism that the EPO courts have voiced.²⁰⁶

Further drafting problems with the morality provisions of the EPC and the Biotech Directive may increase the EPO courts’ reluctance to act as moral censors as well as their ability to judge what is immoral.²⁰⁷ First, the language of Article 6(1) of the Biotech Directive refers to the immorality of the “commercial exploitation” of the invention, not the immorality of granting monopolistic power to the inventor.²⁰⁸ When judging the immorality of “commercial exploitation,” the examiner may look backward at the ethical nature of the research used in the patent application or simply look forward to the future uses of the patent, as the language of the Directive offers no guidance either way. One may argue that the language of Article 6(1) seems to emphasize only the morality of the future “commercial exploitation” of the invention, leaving irrelevant the manner in which

²⁰⁰ Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair Use Exemption*, 76 N.Y.U. L. REV. 1623, 1655–56 (2001).

²⁰¹ Beyleveld et al., *supra* note 158, at 161. *But see id.* at 162 (“Moral standards are only difficult to judge if no standards are laid down for examiners or judges to employ.”).

²⁰² *See id.* at 161. *But see id.* at 162 (“If patent examiners lack moral expertise, they should be replaced by persons who have it.”).

²⁰³ *Id.* at 161. *But see id.* at 162 (contending that while some moral standards change, others remain relatively stable).

²⁰⁴ *Id.* at 161. *But see id.* at 162 (noting that some standards vary across Europe, but others do not).

²⁰⁵ *Id.* at 161. *But see id.* at 162 (“Although it may be true that technical procedures that are morally abhorrent should be forbidden by law and not merely denied patent protection, it does not follow that technical inventions that are morally abhorrent cannot *also* be denied patent protection.”).

²⁰⁶ *See* Harvard/Onco-mouse, 1989 O.J. E.P.O. 451 (Examining Div.), *reprinted in* 1990 EUR. PAT. OFF. REP. 4, 11 (“[T]he Examining Division concludes that the patent law is not the right legislative tool.”).

²⁰⁷ *See* Beyleveld et al., *supra* note 158, at 163–65.

²⁰⁸ *See* Biotech Directive, *supra* note 12, art. 6(1); Beyleveld et al., *supra* note 158, at 164.

the invention was researched and developed.²⁰⁹ However, supporters of incorporating morality into patent law recognize that Article 6(1) leaves room for “distorted reading[s].”²¹⁰

Second, as noted above, the Biotech Directive fails to define a standard for determining what is immoral or against *ordre public*.²¹¹ This problem not only lessens the likelihood of increased harmonization among EU Member States, but it will also make it difficult for the EPO courts to consider how to determine what is immoral or against *ordre public*.²¹²

Third, the Biotech Directive’s morality provisions leave open important procedural issues that the EPC does not address. Questions may arise as to whether the patent-granting authority should assess the morality of the invention at the time of the patent application.²¹³ If so, it is unclear whether the applicant is responsible for such a showing.²¹⁴ Additionally, it is unclear whether the EPO should apprise potential opponents to the application of its contents before the EPO grants the patent.²¹⁵

Yet the Biotech Directive did partially respond to the EPO courts’ difficulty with questions of morality by providing a list of items that the EPO will automatically exclude.²¹⁶ This list provides inventors in biotechnology with items to avoid attempting to patent because courts are certain to refuse to patent them. The problem arises when a proposed invention is not on this list but is nonetheless controversial. The Biotech Directive requires that inventors of such controversial items weigh the benefits of obtaining patent protection in Europe with the burden of delay on the Examining or Opposition Division in determining the invention’s morality. The health of European biotechnology may suffer as a result. Inventors of such items in the United States do not—and should not—face these questions.

²⁰⁹ See Beyleveld et al., *supra* note 158, at 166. Beyleveld and others argue that Article 6(1) of the Biotech Directive should instead focus on the morality of exercising “monopoly control” over the invention, so as to preclude a wider range of controversial inventions, and to look both backward and forward at the morality of patenting the invention. *Id.* at 165–67.

²¹⁰ *Id.* at 166.

²¹¹ See *supra* Part I.E.

²¹² *Id.*

²¹³ See Gitter, *supra* note 94, at 39.

²¹⁴ *Id.*

²¹⁵ See *id.*

²¹⁶ Biotech Directive, *supra* note 12, art. 6, ¶ 2(a)–(d); see *supra* note 112 and accompanying text.

III

LESSONS FOR THE UNITED STATES REGARDING THE FUTURE
OF THE MORAL UTILITY DOCTRINE

Suppose a patent examiner is considering whether to grant a patent for a biotechnological invention. The obvious question that the patent examiner must ask is whether the invention meets the statutory requirements for patentability. Should the patent examiner also ask whether society *should* benefit from this invention? To answer the second question, the patent examiner must make some ultimate judgment based on moral and ethical considerations.²¹⁷ Should patent law address these ethical issues and define what is or is not moral, or are these determinations better left to laws outside the patent system?²¹⁸ Europe's view differs from that of the United States.

Morality has been an integral part of European patent law since the European Patent Convention.²¹⁹ In contrast, courts and patent examiners in the United States appear to focus little on whether a patent or invention meets ethical requirements. Although the PTO still claims to evaluate the morality of patents, denial or invalidation of a patent for being immoral is rare.²²⁰ Some commentators in the United States claim that patent law is not the proper forum for determining ethical standards of scientific activity and that other agencies of the government should regulate the research or exploitation of controversial inventions.²²¹ Furthermore, courts seem uncertain whether to refer to or apply the moral utility doctrine at all when describing the requirements of usefulness.²²² Fortunately, in the face of the ever-growing controversy that biotechnological research produces, the United States may consider the European patent system's reliance on its morality provisions as well as criticism of that system. Consideration of the benefits and drawbacks of the European system may help the United States decide whether to revive the moral utility doctrine.

This Note detailed several different criticisms of the Biotech Directive and the EPC's morality provisions. The recently decided case

²¹⁷ See RICHARD P. FEYNMAN, *THE MEANING OF IT ALL: THOUGHTS OF A CITIZEN SCIENTIST* 44-47 (1998).

²¹⁸ See Strimpel, *supra* note 8, at 284; see also Ho, *supra* note 94, at 285 ("Patents are at best a blunt tool to regulate controversial matter because patents are not necessary to utilize or commercialize innovations.").

²¹⁹ See *supra* Part I.C.

²²⁰ See *supra* Parts I.B, I.D.

²²¹ See Margaret J. Lane, *Patenting Life: Responses of Patent Offices in the U.S. and Abroad*, 32 *JURIMETRICS J.* 89, 99 (1991) ("The continuing ethical and related considerations that have now become significant issues overseas need to be addressed, but not in the narrow context of patent offices. . . . Patent offices exist to grant patents, not to set moral standards for communities."); Schapira, *supra* note 39, at 172.

²²² See *supra* Part I.B.1.

of *Kingdom of the Netherlands v. European Parliament and Council of the European Union* addressed the concern that because "morality" is an ambiguous term that lacks legal certainty, the Biotech Directive could continue to place the European patent system at a competitive disadvantage.²²³ The court addressed a related concern, responding to criticism that the Biotech Directive will not achieve its goal of harmonizing the European patent laws.²²⁴ Several scholars have noted the validity of this argument because the definition of morality differs not only between EU Member States but also among EPO courts that are already applying differing standards.²²⁵ Furthermore, EPO courts have expressed reluctance to analyze the ethical implications of patents and have appealed to the legislature to clearly define the boundaries of patentability.²²⁶ The problems that critics and the EPO courts recognize with the European morality provisions illuminate the considerable risk in reviving the moral utility doctrine.

A. Doubt, Uncertainty, and Disharmony

Lack of legal certainty and potentially disparate applications of the moral utility doctrine may place the European patent system at a relative disadvantage to the United States and Japan. Doubt and uncertainty are valuable in scientific research: "[T]o solve any problem that has never been solved before, you have to leave the door to the unknown ajar. . . . Otherwise, . . . you might not solve it."²²⁷ However, doubt and uncertainty are of little value in the patenting process. The European Union has recognized that the United States' clear patent laws give it a competitive advantage over those in Europe: "The recent USPTO guidelines have provided legal certainty by giving a clear definition of what can be considered a biotechnological invention and what is eligible for patent protection, albeit not having touched upon 'ordre public' issues, in contrast to most other patent legislation in the developed countries."²²⁸ The effect of patent examiners' or courts' moral considerations of inventions may churn up instability in biotechnology: where property rights are involved, reliance interests are also involved.²²⁹ As mentioned earlier, reliance interests in the pat-

²²³ Case C-377/98, *Kingdom of the Netherlands v. European Parliament and Council of the European Union*, 2001 E.C.R. I-7079, 2001 3 C.M.L.R. ¶ 35.

²²⁴ See *id.* ¶ A98.

²²⁵ See Beyleveld et al., *supra* note 158, at 161-62; Gitter, *supra* note 94, at 4, 18, 21.

²²⁶ See Harvard/Onco-mouse, 1989 O.J. E.P.O. 451 (Examining Div.), reprinted in 1990 EUR. PAT. OFF. REP. 4, 11.

²²⁷ FEYNMAN, *supra* note 217, at 26-27.

²²⁸ DEVELOPMENT AND IMPLICATIONS REPORT, *supra* note 126, at 37; see *supra* note 188 and accompanying text.

²²⁹ See *Payne v. Tennessee*, 501 U.S. 808, 828 (1991).

enting of biotechnology are strong because research in biotechnology is a high-risk investment of extreme importance to the economy.²³⁰

Lack of harmony within the patent system could also become problematic for the United States. At first glance, the concerns regarding harmony within the EU seem to be inapposite. However, there could be disharmony within American patent law as patent examiners and courts struggle with the vagueness of what constitutes an immoral invention, while inventors struggle with the varied application of morality standards by different patent examiners or courts.²³¹ Not only do moral standards change depending on location, but they also change with time.²³² A patent examiner or court in the United States will not know whether it is to determine an invention's moral utility and, if so, whether it should consider the weight of public opinion, possibly outdated court precedent, or some other source of morality in conducting its determination. Furthermore, in applying the moral utility doctrine, the PTO and courts must grapple with the procedural issues left unaddressed by the Biotech Directive and EPC, such as whether the applicant must make a *prima facie* case that the invention meets the standard for morality initially or whether the applicant must defend the morality of the invention only upon challenge.²³³ Thus, the doubt, uncertainty and disharmony that could result from reviving the moral utility doctrine raises a variety of concerns.

B. Possible Economic Effects

Reviving the moral utility doctrine in the United States may result in several negative economic effects. First, implementing morality standards may deter inventors from filing patents in controversial areas and initiate a chain reaction of negative effects. Deterred inventors may decrease research funding and diminish the growth in a particular field of research, ultimately prohibiting inventors from creating alternative inventions that would be less controversial.²³⁴ For example, suppose an inventor wants to patent a transgenic mouse that makes a particular protein of great value to cancer researchers. Suppose also that this mouse has a ghastly appearance, and after a scientific magazine features the mouse on the cover, animal rights activists and those opposed to biotechnology in general cause an uproar. If a patent examiner or court denies or invalidates this patent for being immoral, the denial may negatively affect the grant and receipt of re-

²³⁰ See discussion *supra* Part I.A.

²³¹ See Beyleveld et al., *supra* note 158, at 161–62.

²³² See *id.*

²³³ See *supra* notes 213–15 and accompanying text; Gitter, *supra* note 94, at 39.

²³⁴ See Strimpel, *supra* note 8, at 284.

search funding for cancer and may subsequently diminish the growth in this area of scientific research. As a result, inventors will be less likely to create less controversial, beneficial research and inventions.

Second, since inventors need not seek patents for their inventions, they may keep their research private so the public will not scrutinize their work or benefit from its disclosure.²³⁵ For example, suppose that the PTO revives the moral utility doctrine. A scientist knows that her purportedly immoral invention will be unpatentable and, therefore, does not even seek a patent. Without disclosure of the methods involved and the invention sought, the public, including legislators, will be unable to scrutinize the research and its potential effects and consider whether the invention should be made illegal. Likewise, if this inventor chooses to patent this device and the PTO invalidates it on moral grounds, the public cannot benefit from disclosure of the invention and subsequently cannot scrutinize her research and its possible effects. The best result occurs when the PTO grants or denies a patent independent of moral constraints. If the PTO grants a patent for the controversial invention because it meets the criteria for patentability, then the patent is disclosed to the public and legislators. They may scrutinize the work and, if necessary, pursue legislative means to make such research or inventions illegal.

Third, introducing uncertainty and doubt into the United States' patent law system may have international repercussions. International investors prefer countries with "strong and effective" patent systems—namely, the United States and Japan.²³⁶ In enacting the Biotech Directive, the EU recognized that strong patent laws would attract foreign investors.²³⁷ Reviving the moral utility doctrine could spark a decline in international investment within the United States. Of further concern is that weakening the United States' patent system may result in "brain drain" because "inventors who know that the law of other countries provides better patent protection than their own national law are tempted to transfer their research and inventive activities abroad, or to keep their inventions secret and avoid the patent route altogether."²³⁸ As noted earlier, the biotechnology industry within the United States has provided a spark to the economy since its inception. Because no industrialized country has succeeded in favorable economic and technological development without a strong research industry and patent system,²³⁹ the United States cannot risk

²³⁵ *Id.*

²³⁶ F.K. BEIER ET AL., *BIOTECHNOLOGY AND PATENT PROTECTION: AN INTERNATIONAL REVIEW* 88 (1985).

²³⁷ See *supra* note 120 and accompanying text.

²³⁸ BEIER ET AL., *supra* note 236, at 88.

²³⁹ See *supra* note 27 and accompanying text.

losing research scientists, and perhaps entire industries, due to increasing uncertainty within the patent system.

Fourth, if the PTO or courts act as “moral gatekeepers,” this may divest the legislature of its responsibility to enact laws to respond to controversial inventions. If this happens, inventors who perform unpatentable research could still legally publish their methods and results, making them available to the public for “exploitation without limit.”²⁴⁰ In sum, the possible economic effects within the United States and abroad clearly demonstrate that courts and the PTO must consider the potential economic impact of reviving the moral utility doctrine.²⁴¹

C. Concerns About Using Patent Law To Address Important Policy Questions

Besides strictly economic concerns, courts and the PTO must address the value of reviving the moral utility doctrine in light of Supreme Court precedent and constitutional concerns. Like the EPO courts, courts in the United States are becoming equally critical of their ability to judge a patent’s moral utility. In *Juicy Whip, Inc. v. Orange Bang, Inc.*, the Court of Appeals for the Federal Circuit explained that invoking the moral utility doctrine to invalidate patents may no longer be good law.²⁴² The *Juicy Whip* court also cited *Brenner v. Manson* in noting that the “threshold of utility is not high” because inventions need only produce some identifiable benefit.²⁴³ In *Whistler Corp. v. Autotronics Inc.*, the district court held that a patent designed for the exclusive purpose of circumventing the law was useful.²⁴⁴ The *Whistler Corp.* court seriously questioned its ability to referee such matters, holding that “[a]bsent clear and convincing evidence to the contrary, this court cannot and should not substitute its own views in place of those of the PTO, the several legislatures, or the Congress.”²⁴⁵ In light of constitutional concerns and Supreme Court precedent, courts and the PTO must first consider whether moral and ethical constraints promote the progress of useful arts.²⁴⁶ They must also determine whether the moral utility doctrine is consistent with the

²⁴⁰ Strimpel, *supra* note 8, at 284.

²⁴¹ See Ho, *supra* note 94, at 283–85.

²⁴² 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

²⁴³ *Id.* at 1366 (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)).

²⁴⁴ 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Texas 1988).

²⁴⁵ *Id.*

²⁴⁶ See Ho, *supra* note 94, at 285. In the context of copyright law, Justice Holmes made the corollary argument in *Bleistein v. Donaldson Lithographing Co.*, 188 U.S. 239 (1903), that those trained only in law are poorly equipped to judge the worth of pictorial illustrations. See *id.* at 251–52.

Supreme Court's opinions in *Brenner v. Manson*²⁴⁷ and *Diamond v. Chakrabarty*.²⁴⁸

The *Brenner* Court noted that to be "useful" an invention must benefit the public.²⁴⁹ In contrast, the moral utility doctrine requires the patent examiner to go beyond the inquiry of whether the invention can benefit the public to ask the normative question of whether society should benefit from this invention.²⁵⁰ This latter question requires the patent examiner to make moral and ethical determinations beyond those recited by the Supreme Court's definition of utility in *Brenner*.²⁵¹ Furthermore, as scientists and engineers, patent examiners are inadequately equipped to determine whether a particular invention can benefit society. Their training and ability to determine whether society should benefit from a particular invention is unknown, and the search for a consensus regarding the "ethical 'oughts'" arguably should occur in the legislature, where these issues can receive wide attention and benefit from fruitful discussions among interested parties.²⁵²

In *Diamond v. Chakrabarty*, the Court faced several arguments regarding the harm that genetic research in biotechnology will cause and impliedly rejected the moral utility doctrine.²⁵³ The petitioner in *Chakrabarty* asked the Court to weigh the "potential hazards" in considering whether the invention is useful and, therefore, patentable under 35 U.S.C. § 101.²⁵⁴ Thus, the petitioner asked the Court to use a balancing test similar to a test that the EPO courts later developed in

²⁴⁷ 383 U.S. 519 (1966).

²⁴⁸ 447 U.S. 303 (1980).

²⁴⁹ See *Brenner*, 383 U.S. at 534. The PTO's Revised Interim Utility Guidelines Training Materials do not mention "moral utility" but cite *Brenner* approvingly. See *supra* note 33, at 4, 35.

²⁵⁰ This argument is based on the distinction that Professor Feynman made in his series of lectures at the University of Washington. Feynman argued that the "big question" of action is "Should I do this?" See FEYNMAN, *supra* note 217, at 44. He then divides this big question into two separate questions: (1) "If I do this what will happen?" and (2) "Well, do I want that to happen?" See *id.* Feynman argued that the question "If I do this what will happen?" is one of science, *id.* at 44-45, and the question "[D]o I want that to happen?" is one that requires moral judgments, *id.* at 45-46. Similarly, the *Brenner* Court apparently envisioned the patent examiner asking whether a particular invention provides some identifiable benefit to the public. See *Brenner*, 383 U.S. at 534. This is similar to Feynman's science-based question: "If I do this what will happen?" To extend the utility inquiry to include questions requiring moral judgments such as "Does society want this to happen?" stands in stark contrast to the *Brenner* Court's notion of utility.

²⁵¹ In contrast, the EPC requires patent examiners to ask whether society should benefit from a particular invention. European Patent Convention, *supra* note 61, at art. 53(a).

²⁵² See STEPHEN JAY GOULD, *ROCKS OF AGES: SCIENCE AND RELIGION IN THE FULLNESS OF LIFE* 55 (1999). Gould makes a similar argument to Feynman by noting that science and religion are "logically distinct and fully separate in styles of inquiry." *Id.* at 58-59.

²⁵³ *Diamond v. Chakrabarty*, 447 U.S. 303, 316-317 (1980).

²⁵⁴ *Id.*

their Harvard Mouse decisions.²⁵⁵ But the *Chakrabarty* Court refused to give any weight to the possible harm that the invention may cause, noting that granting, denying or invalidating patents will not stop genetic research or “its attendant risks.”²⁵⁶ More importantly for the sake of the moral utility doctrine, the Court noted that courts were not the proper forum for such analyses regarding the balancing of risks and benefits of controversial inventions:

[W]e are without competence to entertain these arguments—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.²⁵⁷

Thus, the *Chakrabarty* Court failed to invalidate the patent, rejecting the petitioner’s argument that a “gruesome parade of horrors” would occur as a result of patenting genetically engineered organisms.²⁵⁸ As a result, the Supreme Court’s holdings in *Brenner* and *Chakrabarty* seem to contradict the moral utility doctrine.

In the face of contrasting concerns, the United States should maintain its policy of separating ethical issues from patent law. Although the issues raised are extremely important, legislative bodies—not patent examiners—should confront them:

If, because of overriding social or ethical questions such as concern for the public safety, national security, or public morals, the policy-making bodies of our government conclude that it is not in the public interest to grant patents in an area of the useful arts, it is incumbent upon those bodies, as it has been in the past, to exclude legislatively that technology from the scope of patent protection. Congress clearly did so in 1946 and 1954 by excluding certain innovations in the field of atomic energy from the scope of the patent laws.²⁵⁹

²⁵⁵ *Chakrabarty* was decided several years before the “Harvard Mouse” got caught in the EPO courts’ “mousetrap.” However, the petitioner advocated a balancing approach in *Chakrabarty*, 447 U.S. at 316–17, similar to that elicited by the Technical Board of Appeal in the “Harvard Mouse” case. See Harvard/Onco-mouse, 1990 O.J. E.P.O. 476 (Tech. Bd. App.), reprinted in 1990 EUR. PAT. OFF. REP. 501, 513.

²⁵⁶ See *Chakrabarty*, 447 U.S. at 317.

²⁵⁷ *Id.*

²⁵⁸ See *id.* at 316.

²⁵⁹ Brief of Amicus Curiae Pharmaceutical Manufacturers Association at 19, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (No. 79-136) (footnote omitted).

The benefit of having a coexisting patent law system like the EPC is that the United States PTO can learn from the European patent system's mistakes and achievements. Furthermore, we can anticipate problems that would arise if the PTO were to revive the moral utility doctrine.

CONCLUSION

Imagine an invention so repugnant that it makes everyone's skin crawl, such as a process for creating a three-headed guard dog.²⁶⁰ Suppose also that the inventor decides to patent this invention, and it meets all the statutory requirements of patentability. Should a patent examiner decide whether to consider morality in granting or denying the patent? Criticism of the morality provisions of the Biotech Directive and the EPC indicates that the answer to whether or not such an invention is patentable must be independent of morality.

This Note does not suggest that science should be immune from ethical and moral judgments. However, the patent system should focus on whether society has a real-world use for a certain invention and not whether society should use this invention. Biotechnology is an important and rapidly growing sector of the world economy, and its continued vitality depends on a strong and stable patent system. The patent system should not become a theater for judging the morality of controversial inventions. The legislature can better address important moral problems because patent examiners and courts lack the ability to answer these difficult questions. Although patent examiners may hesitate to determine the morality of an invention, they do not officially endorse granting intellectual property protection to controversial inventions. The PTO's duty is to examine whether an invention meets the requirements for patentability (the "can society benefit" question), while Congress's responsibility is to determine what is patentable (the "should society benefit" question). Laws outside the patent system—and not patent law itself—should shape national policy regarding the morality of controversial inventions.

²⁶⁰ Arguably useful, but maybe not novel! See THOMAS BULFINCH, *BULFINCH'S MYTHOLOGY* 88 (1913); J.K. ROWLING, *HARRY POTTER AND THE SORCERER'S STONE* 160–61 (1998).