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Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law

by
Donna M. Gitter*

INTRODUCTION

“‘You Did It!’: The European Biotechnology Directive At Last.”¹ “Biotech Patents, At Last.”² So exulted articles in scholarly and trade journals which heralded the enactment in the European Union (E.U.) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (Directive),³ after nearly ten years of raucous debate among various E.U. government institutions⁴ and segments of

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1. Robin Nott, *‘You Did It!’: The European Biotechnology Directive at Last*, 20 EUR. INTEL. PROP. REV. 347, 347 (1998).

2. Ian Judge & Matthew Frankel, *IP Watch*, IP WORLDWIDE, July-Aug. 1998, LEXIS, General News Library, Magazines & Journals File.

3. 1998 O.J. (L 213) 13 [hereinafter Directive]. A directive is a type of E.U. legislation that targets one or more specific Member States, *see infra* note 4, and binds them with respect to the end to be achieved, while allowing each Member State some choice as to the method, and, sometimes, the extent, of implementation. It is distinguishable from a regulation, which is binding upon all Member States and mandates a particular means of attaining the stated goal. Thus, directives are more flexible and accommodating to national law, making them particularly useful in order to harmonize the laws within a certain area. *See* W. R. CORNISH, *INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADE MARKS AND ALLIED RIGHTS* 20-21 (3d ed. 1996).

4. In light of the coming into force of the Treaty on European Union, 1992 O.J. (C224) 1 [hereinafter Maastricht Treaty], on November 1, 1993, the term E.U. will be employed throughout this article, even where certain entities would have been called European Community (E.C.) institutions at the time in question. The fifteen Member States of the E.U. are: Belgium, Germany, France, Italy, Luxembourg, the Netherlands, Denmark, Ireland, the United Kingdom, Greece, Portugal, Spain, Sweden, Austria and Finland. *See* RICHARD SCHAFFER ET AL., *INTERNATIONAL BUSINESS LAW AND ITS ENVIRONMENT* 88 (4th ed. 1999). The principal E.U. institutions involved in the legislative process are the European Commission (Commission), the European Parliament (Parliament) and the Council of Ministers (Council). The Commission, the executive and bureaucratic arm of the E.U., has the sole authority to propose new legislation. Thomas C. Vinje, *Harmonising Intellectual Property Laws in the European Union: Past, Present and Future*, 8 EUR. INTEL. PROP. REV. 361, 361 n.2 (1995). The Commission’s twenty members, who are appointed, function as members of a supranational body, rather than as national representatives. The Council, which coordinates economic policies of the Member States and approves legislation and international agreements, is a

the citizenry. The Directive, which came into force on July 30, 1998,⁵ has two major objectives. First, it is designed to foster effective and harmonized patent protection for biotechnological inventions⁶ throughout all of the E.U. Member States.⁷ By doing so, the E.U. intends to stimulate investment in the European biotechnology industry, which seeks to enhance its competitiveness vis-à-vis the United States (U.S.) and Japan.⁸ The Directive's second objective is to preserve a unique feature of European patent law which has no analogue in U.S. patent practice,⁹ namely the ability of E.U. Member States to consider the ethical dimension of biotechnological inventions when determining whether to grant a patent.¹⁰

However, not all the parties concerned with the European biotechnology industry have greeted the Directive with enthusiasm. Indeed, the Directive is arguably one of the most heavily lobbied pieces of legislation that the European Parliament has ever considered.¹¹ In particular, Articles 5¹², 6¹³ and

body of delegates, one from each Member State. SCHAFFER, *supra*, at 88. The Parliament is a body of 626 elected representatives from the various Member States. The approval of the Parliament is required for all international agreements, and it has co-decision powers with the Council on measures dealing with the single market and other important matters, including consumer protection, the environment and health. See SCHAFFER, *supra*, at 91. For a description of the legislative process culminating in the enactment of the Directive, see *infra* Part II.A.

5. See Nott, *supra* note 1, at 347.

6. For the purposes of the Directive:

[b]iotechnology is understood to comprise all the techniques that use or cause organic changes in any biological material (such as animal and plant cells or cell lines, enzymes, plasmids and viruses), microorganisms, plants and animals; or that cause changes in inorganic material by biological means. In its modern appearance, biotechnology includes the techniques of recombinant DNA . . . , gene transfer, embryo manipulation and transfer, plant regeneration, cell culture, monoclonal antibodies, and bioprocess engineering.

Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, EUR. PARL. DOC. (COM 88 496 final—SYN 159) 7-8 (1988) [hereinafter Commission Proposal of 1988].

7. See Directive, *supra* note 3, ¶¶ 1 to 7, at 13. Although the Recitals in the Directive are not operative, they serve to elucidate the intent of the drafters. See Nott, *supra* note 1, at 347.

8. According to a 1998 report, approximately 65% of all biotech patents originate from the U.S., and only about 15% from European nations. See Sean Milmo, *EU Biotech Industry Wins Major Battle*, CHEMICAL MARKET REP., May 18, 1998, at 5. Moreover, in 1997, the biotechnology sector employed some 140,000 people in the U.S., compared with only 39,000 in the E.U. U.S. biotech companies had revenues of \$17.4 billion in 1997, and invested \$9 billion in research and development, while European biotechnology sector revenues were only \$2.9 billion and research and development expenditures totaled less than \$2.1 billion. See ERNST & YOUNG, EUROPEAN LIFE SCIENCES 98, at 11, tbl. 3 (1998) [hereinafter EUROPEAN LIFE SCIENCES].

9. See Kevin J. Dunleavy & Milan M. Vinnola, *E.U. Biotech Directive Departs From U.S. Practices*, NAT'L L.J., May 24, 1999, at C11, C12 (stating that the "most significant difference" between the patentability of biological materials in the U.S. and the E.U. is the assessment of the morality of the invention when determining whether to grant a patent). But cf. Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 451-54 (1999) (citing an infrequently invoked and possibly moribund doctrine in U.S. patent law which bars a patent grant on the grounds of utility to inventions deemed to contravene morality).

10. See Directive, *supra* note 3, ¶¶ 37 to 45, at 16.

11. Dr. Nick Scott Ram, *Biotechnology Patenting in Europe: The Directive on the Legal Protection of Biotechnological Inventions: Is This the Beginning or the End?*, 2 BIO-SCIENCE L. REV. 43, 43 (1998).

12. See *infra* notes 113-15 and accompanying text.

13. See *infra* notes 18-19, 116-21 and accompanying text.

7¹⁴, which relate to ethical and moral standards, are the most controversial provisions in the Directive. Many opposed to patents on plants and animals, so-called "life patents,"¹⁵ contend that these provisions do not protect sufficiently against violations of ethical and moral standards, depredations of the environment and the exploitation of small farmers.¹⁶ Conversely, many supporters of the biotech industry have accepted the Directive as a necessary political compromise, while simultaneously lamenting what they perceive as its shortcomings. They oppose the use of patent law to protect what is broadly termed morality and ethics, contending that legislative regulations are a better vehicle for attaining compliance with standards for ethical research, public health and safety, animal welfare, environmental protection, and the preservation of genetic diversity.¹⁷

Regardless of one's view regarding the propriety of the E.U. biotechnology patent law provisions aimed at preserving ethics and morality, the fact remains that the Directive does incorporate such language, principally via Article 6, which declares that "[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public*¹⁸ or morality."¹⁹ The question then arises how this language is likely to affect the Directive's goals of achieving harmonization of patent laws throughout all of the E.U. Member States while preserving the ability of Member States to consider morality when determining whether to grant a patent. The complete answer to this query remains to be seen, as the majority of the Member States have not yet enacted the legislation and regulations necessary to implement the Directive, including the Article 6 morality provision,²⁰ and national courts have yet to

14. See *infra* notes 122-23 and accompanying text.

15. Patents on life forms such as micro-organisms have long been accepted in Europe, and are not the source of the controversy regarding the Directive. For example, the German Federal Supreme Court permitted patent protection for yeast in 1975. See *Baker's Yeast (Backerhefe)*, Federal Supreme Court, 1975 GRUR 430 (BGH 1975), reprinted in 6 INT'L REV. INDUS. PROP. & COPY-RIGHT L. 207-19 (1975).

16. See *infra* Part II.A.

17. See *infra* note 272.

18. The nearest English translation of *ordre public* is "public interest" or "public policy." See CORNISH, *supra* note 3, at 195 n.86.

19. Directive, *supra* note 3, art. 6.1, at 18. Article 6 then enumerates a non-exhaustive list of inventions that "shall be considered unpatentable," including:

(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.

Id. art. 6.2, at 18-19. Other provisions in the Directive designed to preserve morality are Articles 5 and 7. See *infra* notes 113-15, 122-23 and accompanying text.

20. Pursuant to the Directive, Member States were required to "bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000." Directive, *supra* note 3, art. 15, at 20. As of September 2, 2000, only Denmark, the United Kingdom and Austria had amended their national laws in accordance with the Directive. See *MEPs Clamour for Ad-Hoc Bioethics Committee*, EUR. REP., Sept. 2, 2000, LEXIS, World News Library, European News Sources File. Conversely, the Netherlands and Italy are pursuing an action before the European Court of Justice opposing the Directive. See *infra* notes 129, 275-80, and accompanying text. Moreover, German and French lawmakers have demanded an immediate rene-

interpret such laws. Analysis of the Directive reveals, however, that the morality provision is likely to impede the Directive's dual goals. First, with respect to harmonization, although the Directive does mandate a minimum level of patent protection that all Member States must attain with respect to biotech inventions,²¹ Article 6 is exceedingly vague as to the legal standard that will be applied in order to determine whether an invention ought to be denied patent protection on the grounds of immorality. Consequently, Article 6 will be subject to conflicting interpretations, thereby precluding harmonization.²² With respect to its second stated goal, preservation of the right of patent offices and courts in each Member State to deny patent protection to any invention deemed contrary to morality or public policy, the Directive is likely to prove inadequate, a point on which, ironically, both its advocates and detractors agree.²³

Part I of this Article examines the emergent biotechnological inventions that are currently stirring controversy in the E.U. on moral and ethical grounds, and addresses the importance of patent protection to their inventors. Part II summarizes both the legislative debate surrounding the enactment of the Directive, and the provisions of the Directive governing patentability of biotechnological inventions. Part III focuses on the prospective effect of these provisions, especially the Article 6 morality provision, on the Directive's stated goal of harmonizing European patent law. Specifically, Part III examines the inconsistent legal tests applied in the judicial decisions rendered pursuant to the morality provision of the European Patent Convention (EPC),²⁴ upon which the Directive's Article 6 was modeled essentially verbatim, and to which all E.U. Member States are signatories. Part IV addresses the inability of the Directive's Article 6 morality provision to foster compliance with standards for ethical research, public health and safety, animal welfare, environmental protection, and the preservation of genetic diversity. Finally, Part V proposes revisions to the Directive that would enhance its ability to meet the challenges facing the E.U. biotechnology industry.

gotiation of the Directive. They contend that the Directive's Article 5, which permits patenting of a gene that has been isolated from the human body, *see infra* notes 100-03, 113-15 and accompanying text, is not only counter to human dignity, but also threatens to impede scientific research. *See, e.g.,* Alison Abbott & Ulrike Hellerer, *Politicians Seek to Block Human-Genes Patents in Europe*, 404 NATURE 802, 802 (2000); Ralph Atkins & Timm Kragenow, *Germany Imposes Extra Gene Patent Limits*, FIN. TIMES (London), Aug. 11, 2000, at 6; *Community Law Takes Precedence Over National Law*, EUR. REP., June 21, 2000, LEXIS, World News Library, European News Sources File; *Council of Europe Calls for Revision of Biotechnology Directive*, EUR. REP., July 15, 2000, LEXIS, World News Library, European News Sources File; Quirin Schiermeier, *German Agencies Sound Alarm on Risks of Broad Gene Patents*, 406 NATURE 111, 111 (2000).

21. The Directive provides that "Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive." Directive, *supra* note 3, art. 1.1, at 18.

22. *See infra* Part III.

23. *See infra* Part IV.

24. This instrument, known as the European Patent Convention, was signed into existence in Munich as the Convention on the Grant of European Patents, Oct. 5, 1973, art. 53, 1065 U.N.T.S. 255, 272, 13 I.L.M. 270, 286 [hereinafter EPC]. *See infra* text accompanying notes 132-37.

I.

BIOTECHNOLOGICAL INNOVATION IN THE E.U. AND THE NEED FOR PATENT PROTECTION

A. *Current Innovations in the European Biotechnology Industry*

In 1997, Scottish researchers from the Roslin Institute and PPL Therapeutics PLC of Edinburgh sought a patent for one of the most renowned and controversial biotech inventions in recent years, Dolly, the cloned sheep. Although among the most famous biotech inventions on any continent, Dolly is but one development of the European biotech industry. From the early 1980s through the beginning of 1998, the European Patent Office (EPO) received a total of 15,000 patent applications for biotechnological inventions.²⁵ Of these, roughly 4,000 concern genetic engineering,²⁶ approximately 1,000 are for transgenic plants,²⁷ about 500 are for transgenic animals, and over 2,000 relate to DNA sequences isolated from the human genome²⁸ that are used to develop therapies and medicines.²⁹

With respect to plants, inventors use transgenesis to pursue four major goals. First, scientists wish to raise the consumer value of plants or the foods derived therefrom, leading to the creation of firmer tomatoes, potatoes with a longer shelf life and higher-protein soya. Second, researchers seek increasing yields through the creation of genetically altered hybrid grains that produce more under the same cultivation conditions. Third, some inventions help plants develop resistance to the pests afflicting specific species. Fourth, certain inven-

25. Ulrich Schatz, *Patentability of Genetic Engineering Inventions in European Patent Office Practice*, 29 INT'L REV. INDUS. PROP. & COPYRIGHT L. 2, 2-3 (1998). For a discussion of patent application procedure in the European Patent Office (EPO) in Munich, see *infra* note 139 and accompanying text.

26. Genetic engineering refers to various techniques, developed during the last thirty years, which "permit the controlled transfer of specific genes or groups of genes from one cell or organism to another, thereby creating cells or organisms that would not likely occur in nature or through conventional breeding practices." Reid G. Adler, *Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting*, 1 HARV. J.L. & TECH. 1, 1 n.3 (1988).

27. A transgenic plant or animal is one whose DNA, or hereditary material, has been added to DNA from different animals or plants at early stages of development. U.S. CONGRESS, OFFICE OF TECH. ASSESSMENT, *NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE*, at 93-94 (1989). See *infra* Part III.B.2 for a discussion of *Harvard/Onco-mouse*, which concerns a transgenic animal, and *Greenpeace Ltd. v. Plant Genetic Systems N.V.*, which involves a transgenic plant.

28. A genome is all the genetic material contained in any one cell of a particular organism. The human genome is comprised of roughly three billion pieces of information, contained on individual genes, and is responsible for determining everything from an individual's appearance to his chance of contracting certain diseases. See Nicholas Wade, *Human Life Is Cracked by Scientists: A Shared Success*, N.Y. TIMES, June 27, 2000, at A1.

29. Schatz, *supra* note 25, at 2-3. With respect to human DNA sequences, researchers seek to isolate all such sequences that form a human being's genetic makeup and to match them to gene functions, with the ultimate goal of developing products and technologies that will identify and correct the genetic defects that cause illnesses. See generally Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 164-77 (1996) (examining the medical applications of the genotechnology industry).

tions aid in the development of plants resistant to particular herbicides,³⁰ which can then be used selectively.³¹

Similarly, with respect to animals, inventors employ transgenesis to raise yields and improve quality. For example, the "Beltsville pig," an animal containing a human gene, was developed to grow quicker and leaner than the usual varieties.³² Scientists also use mammals, which are genetically similar to human beings, for pharmacological research.³³ For example, researchers at Harvard University created the Harvard Onco-mouse, which has been given a genetic defect to make it more susceptible to breast cancer, and therefore particularly suitable for testing cancer drugs.³⁴ Many other patent applications are for animals that function as bioreactors to produce human metabolic products in their blood or milk. The most famous example is Tracy, a sheep whose germ line contains a genetic construction comprising a human gene plus "promoter," which causes Tracy's milk glands to produce proteins identical to human ones.³⁵ These transgenically created proteins are then removed from the milk and used in the medical treatment of human beings. Examples of such proteins enumerated in the patent application for Tracy are human insulin, tissue plasminogen activators, and alpha-1-anti-trypsin, a drug used to treat severe lung inflammation and emphysema.³⁶

Scientists have also isolated human genes, allowing them to produce pharmacological products in microbiological reactors. One very controversial application of such technology involves relaxin, a human hormone naturally produced in a woman's ovaries which serves to relax the muscles used in giving birth. Although the gene that produces relaxin is activated only at the onset of labor, inventors have been awarded a patent that claims the isolation of this gene from the ovarian cells, and its insertion into the genome of a bacterium from which artificial relaxin can then be produced commercially and used to prevent complications in labor.³⁷ A second example of such technology involves another human protein, tissue plasminogen activator, which is necessary for the body to break down blood clots. Recently, researchers have isolated the gene that encodes this protein, and have transmitted it to various micro-organisms, thereby facilitating the production of this protein in pure form and the desired quantity, for use by those who lack it.³⁸

30. See *infra* Part III.B.2.b for a discussion of such a plant in *Greenpeace Ltd. v. Plant Genetic Systems N.V.*

31. Schatz, *supra* note 25, at 3.

32. See *infra* note 81 and accompanying text.

33. Schatz, *supra* note 25, at 3.

34. See *infra* Part III.B.2.a for a discussion of the *Harvard/Onco-mouse* case.

35. The creators of the cloned sheep Dolly, PPL Therapeutics PLC of Edinburgh, Scotland, also created Tracy. In *Sheep's Clothing, A Balm for Lung Disease*, BUS. WK., Sept. 20, 1999, at 82.

36. Schatz, *supra* note 25, at 3; In *Sheep's Clothing, A Balm for Lung Disease*, *supra* note 35, at 82.

37. See *infra* Part III.B.1.b for a discussion of the *Hormone Relaxin* case.

38. Schatz, *supra* note 25, at 3-4.

B. The Need for Biotechnology Patents

Supporters of the E.U. biotech industry are well aware that the creation of the aforementioned inventions, which are vitally important to the E.U. economy, requires substantial investment of time and money. Indeed, the Directive recognizes that "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,"³⁹ and, further, that such inventions require "a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable."⁴⁰ The protection referred to in the Directive is patent protection, which stimulates invention, whether in the biotech industry or any other, in the E.U. or abroad, in several ways.⁴¹

First, patent law awards and enforces a limited monopoly,⁴² so that an inventor can recoup the costs of investment in research and development.⁴³ Absent this state-enforced monopoly, the inventor would likely soon face competition from others who would copy the new invention. Liberated from the need to invest heavily in research and development, these free riders could undercut the inventing firm's price and deny it a fair return. Thus, in the absence of adequate patent protection, an inventor has little incentive to invest in the development of new products and processes.⁴⁴ This is particularly true for the small start-up companies that presently perform most biotech research in Europe

39. Directive, *supra* note 3, ¶ 1, at 13.

40. *Id.* ¶ 2, at 13.

41. Notably, the idea for patent protection is believed to have originated in Europe, when the Council of Venice enacted the first patent statute in 1474, offering a ten-year monopoly to the inventor of any machine or process that improved or expedited silk-making. David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 FORDHAM INT'L L.J. 990, 996 (1993).

42. A patent does not grant the right to exploit an invention, but merely permits the holder to preclude others from reproducing the invention for a limited period of time. See Directive, *supra* note 3, ¶ 14, at 14 ("[A] patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes . . ."). See also Schatz, *supra* note 25, at 12 (stating that a patent grant "does not mean its proprietor can actually use his invention, let alone exploit it industrially," but merely that he can prevent others from doing so). This is referred to as the "negative character" of a patent right. Currently, under the Agreement on Trade-Related Aspects of Intellectual Property Rights, to which both the U.S. and the E.U. are parties, a patent grants an inventor a monopoly that can last up to twenty years. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS - RESULTS OF THE URUGUAY ROUND vol. 31; 33 I.L.M. 81, 96 (1994).

43. Bringing a technology-based pharmaceutical product to market requires an average of \$300,000,000 and over twelve years. *EuropaBio*, at <http://www.europa-bio.be/publications/patent04.htm> (visited March 13, 2000). Moreover, an estimated 90% of biotech companies have drugs that fail or are delayed, incurring research costs for projects that may never produce a profit. Lisa Buckingham, *Shock for Shares as Treatments Fail to Yield Hoped-For Dividends*, GUARDIAN (London), Apr. 28, 1998, at 3.

44. See Scalise & Nugent, *supra* note 41, at 997. See also Commission Proposal of 1988, *supra* note 6, at 6 ("The primary purpose of the modern patent system is to promote technical innovation as the major factor of economic growth by encouraging inventive activity through rewarding inventors for their creative efforts. The patent system thus secures costly investment in research and development and industrial exploitation of research results.").

and depend especially heavily upon patent protection in order to recoup their considerable research and development costs.⁴⁵

Second, patents stimulate the biotech industry by requiring full disclosure of the patented subject matter to the public. Without such protections, inventors would invoke the trade secrets doctrine, thereby engendering duplicative and superfluous research.⁴⁶ Indeed, as noted by one scholar, the cloned sheep, Dolly, was first announced publicly in the February 27, 1997 issue of *Nature*, just a few days before the publication of the European patent application. Thus, without patent protection for biotech inventions, firms might be reluctant to invest in research and development at all, or, at a minimum, would shield such inventions in absolute secrecy.⁴⁷

Finally, the patent system encourages competitors to “invent around” or improve upon a patented invention.⁴⁸ According to a former U.S. Assistant Commissioner for Patents:

[t]here are only rare instances of any situations where somebody obtains a patent on something that gives them a real monopoly in a field. What it really does when a patent is granted is stimulate others to invent around it, to improve upon it, to find a different way to do the same thing, and it spurs competition rather than restricts competition.⁴⁹

Thus, although a patent is considered to accord a “limited monopoly” to an inventor, it actually advances technology by stimulating innovation.

45. See EUROPEAN LIFE SCIENCES, *supra* note 8, at 11 (stating that almost 75% of European biotech firms have fewer than 50 employees, the industry average is less than 40 employees, and 20% of such companies have fewer than 10 employees). See also Third Report of the Committee on Legal Affairs and Citizens' Rights on the Commission Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, EUR. PARL. DOC. (COM 88 0496 final—C3-0036/89—SYN 159) 27 (1992) [hereinafter 1992 Committee Report] (stating that the vast majority of firms in the European biotech sector are small or medium-sized enterprises).

46. See Scalise & Nugent, *supra* note 41, at 997. See also Commission Proposal of 1988, *supra* note 6, at 6 (explaining that “the patent system encourages an early and beneficial dissemination of knowledge in the field of activity involved which, without such protection, might be kept secret.”).

47. See Schatz, *supra* note 25, at 2 n.1.

48. See Report of the Committee on Legal Affairs and Citizens' Rights on the Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, EUR. PARL. DOC. (COM 95 0661 final—C4-0063/96-95/0350(COD)) 31 (1997) [hereinafter 1997 Committee Report] (noting that patents stimulate the biotech industry by providing a “quid pro quo” whereby “[t]he inventor publishes his invention, which can thus provide a basis for further research,” in return for an exclusive right to the invention). See also Adler, *supra* note 26, at 11 (stating that the patent system “encourages competition to ‘invent around’ or improve upon a patented invention”).

49. *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 27 (1987) (testimony of Rene D. Tegtmeyer, Assistant Commissioner for Patents).

II.

THE E.U. DIRECTIVE ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

A. *The Political Debate Surrounding Enactment of the E.U. Biotechnology Directive*

In October 1988, the European Commission,⁵⁰ recognizing the importance of patent protection for biotech inventions,⁵¹ which were governed by a patchwork of national legislation and regulations and international conventions,⁵² issued its Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions (the Commission Proposal of 1988).⁵³ The Commission, impelled to act by what it viewed as an impending crisis facing the European biotech industry, declared that:

[w]hereas the two leading nations in biotechnology, the United States of America and Japan, have been able continuously to adapt their patent protection according to the latest needs of the industry, science and consumers, the Member States, representing comparable potential of intellectual manpower and capital, are immobilized by a not yet completed and . . . in part outdated legal framework.⁵⁴

In proposing the Directive, the Commission hoped to stimulate the European biotechnology industry in several ways. First, the establishment of a harmonized system of patent law for biotech inventions would eliminate barriers to the exchange of information and technology among Member States.⁵⁵ In addition, the Proposed Directive would foster vigorous trade, which would otherwise be "hampered by the fact that export of self-reproducible biotechnological products into areas with uncertain, weak or even non-existent protection is less than attractive for obvious reasons."⁵⁶ Moreover, harmonization and legal certainty with respect to patent protection throughout the E.U. would enhance investment opportunities in the biotech industry. This would, in turn, stimulate E.U. firms to repatriate their funds, previously invested overseas, and attract foreign investors.⁵⁷

50. See *supra* note 4.

51. See *supra* Part I.B.

52. The international agreements regulating E.U. biotech patents at the time of the Commission Proposal of 1988, which are still in force, include: (1) the EPC, see *supra* note 24 and *infra* Part III.A, pursuant to which the original eleven member nations adopted; (2) the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, Nov. 27, 1963, Eur. T.S. No. 47 [hereinafter The Strasbourg Convention]; and (3) the International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89, T.I.A.S. No. 10199 [hereinafter UPOV]. The Strasbourg Convention of 1963 established the principles governing the EPC, and UPOV is an international convention among forty-four nations that is aimed at protecting new plant varieties and ensuring plant breeders a fair return on their investments. See Scalise & Nugent, *supra* note 41, at 1012 & nn. 107-08; *The International Union for the Protection of New Varieties of Plants*, at <http://www.upov.int/eng/ratify/pdf/ratifymem.pdf> (last modified Sept. 24, 2000).

53. Commission Proposal of 1988, *supra* note 6.

54. *Id.* at 22.

55. See *id.*

56. *Id.*

57. See *id.*

With its 1988 proposal for a biotech directive, the Commission set in motion a debate that raged throughout the E.U. for nearly ten years. This protracted deliberative process, lengthy even by E.U. standards,⁵⁸ resulted in part from the highly controversial nature of the subject matter, as well as the fact that the legislature used for the first time a new co-decision procedure, which gave more power to the Parliament.⁵⁹ Once the Commission sent the Proposed Directive to the European Parliament,⁶⁰ which has the role of suggesting amendments to the Commission's proposals,⁶¹ the legislation faced opposition from a huge segment of European society, led by Parliament's Green Party,⁶² who were supported in their efforts by advocates for small farmers.⁶³ Due to vociferous opposition and lobbying by these citizens, the 1988 Proposed Directive did not get a formal reading before the Parliament until October 1992.⁶⁴ Parliament then called for major reforms of the Proposed Directive, including forty-six amendments, a number of which the Commission incorporated into a modified text issued on December 16, 1992.⁶⁵ After more than two years of wrangling between the Parliament and the Council of Ministers regarding the Amended Directive,⁶⁶ with the latter generally supporting it, the Parliament rejected the Amended Directive in March 1995, primarily on ethical grounds.⁶⁷ The Commission then presented a new draft in January 1996,⁶⁸ which, after further debate and amendment,⁶⁹ Parliament finally approved on July 6, 1998.⁷⁰

During this ten-year period, the most passionate arguments against the Directive by the Greens and others were based upon moral, ethical and philosophi-

58. Because the E.U. accepts input from all sources when considering legislation that will supersede the national law of the Member States, change occurs only at an incremental pace.

59. Sven J. R. Bostyn, *The Patentability of Genetic Information Carriers*, 1 INTEL. PROP. Q. 1, 1 (1999). For a detailed description of the co-decision procedure under Article 189(b) of the Maastricht Treaty, *supra* note 4, pursuant to which the E.U. Parliament and the Council jointly adopt E.U. legislation, see Vinje, *supra* note 4, at 362, Fig. 1.

60. See *supra* note 4.

61. Thomas C. Vinje, *Recent Developments in European Intellectual Property Law*, 13 J.L. & COM. 301, 301 n.3 (1994).

62. The term "Greens," when used in the context of the E.U. debate regarding patenting biotechnological inventions, refers to all persons harboring moral, ethical and/or environmental objections to patenting living matter, and includes, among others, animal rights activists and environmentalists. Scalise & Nugent, *supra* note 41, at 1024.

63. *Biotechnology: Ethics, Patents and the Human Body*, EUR. REP., Jan. 25, 1992, at 5, LEXIS, World News Library, European News Sources File.

64. Vinje, *supra* note 4, at 367.

65. Amended Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, 1993 O.J. (C 44) 36; see also Vinje, *supra* note 4, at 367.

66. See *supra* note 4.

67. See Vinje, *supra* note 4, at 367. See also Andy Coghlan, *Europe Kills Off Patents on Life*, NEW SCIENTIST, March 11, 1995, at 7.

68. Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, EUR. PARL. DOC. (COM(95) 661 final—95/0350 (COD)) (1995). See also Gert-Jan van de Kamp, *The New Directive on the Legal Protection of Biotechnological Inventions*, 7 EUR. ENVTL. L. REV. 234, 235 (1998).

69. See *MEPs Resume Debate on Protecting Biotechnology Inventions*, EUR. REP., Feb. 5, 1997, LEXIS, World News Library, European News Sources File.

70. Directive, *supra* note 3. See also Ian Judge & Matthew Frankel, *European Parliament Approves Biotech Directive*, IP WORLDWIDE, Sept.-Oct. 1998, LEXIS, General News Library, Magazines & Journals File.

cal grounds, and proved particularly difficult to resolve through legislative and judicial pronouncements.⁷¹ First, many opposed to patents on plants and animals, including some Green Party members, were concerned about the monopoly over genetic resources that life patents would foster.⁷² Further, they contended that biotechnological advances ought to be shared for the benefit of all humankind, and that living matter is part of the "‘heritage of Humanity and Nature in general’" and should not be classified as "‘private property.’"⁷³ In turn, Parliament acknowledged the problems of access to biotechnological inventions and monopolistic powers of patent holders in its Third Report of the Committee on Legal Affairs and Citizens Rights (1992 Committee Report).⁷⁴ Parliament concluded that facilitating patentability of biotechnological inventions is but one consideration in the restructuring of the biotech industry,⁷⁵ and that legal policy in the E.U. "must be more than a set of arrangements aimed at bringing about favorable conditions of competition."⁷⁶ This decidedly continental European perspective on the preferred goals of patent law is not widely shared in the U.S., as demonstrated by the protests from Europe when a U.S. research institute participating in the Human Genome Project⁷⁷ sought to patent human gene sequences.⁷⁸

71. See generally Michael E. Sellers, *Patenting Nonnaturally Occurring, Man-Made Life: A Practical Look at the Economic, Environmental, and Ethical Challenges Facing Animal Patents*, 47 ARK. L. REV. 269, 290-91 n.144 (1994) (explaining that it is "unlikely that legislative or judicial line-drawing on [animal patenting] will substantially affect a particular person's beliefs").

72. Darrell G. Dotson, Comment, *The European Controversy Over Genetic-Engineering Patents*, 19 Hous. J. INT'L L. 919, 943 (1997).

73. *Id.* at 943-44 (quoting *EP Greens Launch a Campaign Against the Draft EEC Directive on Patenting Biotechnological Inventions*, REUTERS, Jan. 25, 1992).

74. See 1992 Committee Report, *supra* note 45, at 35-36.

75. *Id.* at 35.

76. *Id.* at 27.

77. The Human Genome Project, which was initiated by the U.S. Congress in 1988-89 and commenced in 1990, is an international effort to map and sequence the genes on all twenty-three pairs of chromosomes and decipher their contribution to the composition of the human being. See Malinowski & O'Rourke, *supra* note 29, at 166, 190.

78. In 1991 and 1992, an international debate arose when the U.S. National Institutes of Health (NIH), a governmental biomedical research institute, filed patent applications for thousands of human gene fragments sequenced in NIH laboratories. Malcolm Gladwell, *NIH Seeks Patent Protection for Human Genes*, WASH. POST, Feb. 13, 1992, at A16; Leslie Roberts, *Genome Patent Fight Erupts*, 254 SCIENCE 184 (1991); Leslie Roberts, *NIH Gene Patents, Round Two*, 255 SCIENCE 912 (1992). The international scientific community protested these applications, contending that the information contained therein should be part of the public domain. Robin Herman, *The Great Gene Gold Rush*, WASH. POST, June 16, 1992, at Z11 (describing reactions of experts to gene patenting). These scientists lamented that the award of such patents would foster secrecy among scientists, hamper international collaboration among researchers, and hobble the biotech industry. In protest, leading French human genome researchers handed over French research results on the Human Genome Project to the United Nations Educational, Scientific and Cultural Organization (UNESCO) in Paris. Declan Butler, *Who Owns the Building Blocks of Life?*, INDEP. (London), Nov. 2, 1992, at 14; Christine Gorman, *The Race to Map Our Genes*, TIME, Feb. 8, 1993, at 57. More than two hundred genome scientists from around the world also signed a declaration calling for the results of the Human Genome Project to be freely accessible to all. Butler, *supra*. Ultimately, NIH abandoned its patent application in early 1994, not on ethical grounds, but because the sequences lacked proven utility, one of the requirements for patentability. Michael Waldholz, *NIH Gives Up Effort to Patent Pieces of Genes*, WALL ST. J., Feb. 11, 1994, at B1.

Second, animal rights activists and others opposed to patenting life forms wished to prevent the pain suffered by animals subject to biotech experimentation, particularly transgenic animals created by genetic manipulation to be prone to disease.⁷⁹ Notable in this regard is the Harvard Onco-mouse, a transgenic animal that was created to be susceptible to cancer and continues to stir intense controversy in the E.U.⁸⁰ Another example is the "Beltsville pig," which was inserted at the embryonic stage with a gene originating from human genetic material that is responsible for producing a growth hormone. Although these pigs did indeed grow faster, carry less fat and pass these traits on to their offspring, as intended, they also suffered from arthritis and were more susceptible to infections.⁸¹ Moreover, European Parliament officials expressed ethical concerns that a patent right in an animal "leads to the presumption that animals are merely production machines or research tools to be redesigned and used for the convenience of humankind."⁸²

In addition to harboring moral and ethical reservations about patenting plants and animals, many Greens and other environmentalists contended that such patents present great environmental risks. First, they argued that genetic engineering increased the likelihood of inadvertently releasing a pathogen into the environment.⁸³ Furthermore, they warned that even the release of putatively "safe" genetically engineered organisms could threaten the delicate ecological balance of the natural environment. For example, the overuse of specially bred plants and animals could threaten the diversity of the natural gene pools of various species.⁸⁴

Forming an alliance with the Greens were European farmers, especially small family farmers, who challenged biotech patents on economic grounds. They contended that their costs of operation would rise significantly if they were forced to pay licensing fees and royalties to obtain and reproduce patented plants and animals. The expense of obtaining costly biotech inventions impacts small family farmers especially severely vis-à-vis their corporate counterparts, as small farmers can neither afford the high start-up costs nor achieve the economies of scale necessary to reap the rewards of biotechnological advances. Thus, small farmers feared that large farming corporations would eventually dominate

79. See 1992 Committee Report, *supra* note 45, at 31-33.

80. See *infra* Part III.B.2.a.

81. See 1992 Committee Report, *supra* note 45, at 33.

82. 1997 Committee Report, *supra* note 48, at 44.

83. See Scalise & Nugent, *supra* note 41, at 1024.

84. 1992 Committee Report, *supra* note 45, at 37-38 (noting that German farmers were reported to be using as few as six winter wheat varieties on 75% of their arable land, and over 90% of the beet harvest in the Netherlands was from only three varieties, leading to concerns that this trend would grow more prevalent with the spread of varieties developed via genetic engineering); 1997 Committee Report, *supra* note 48, at 43 ("The patenting of living material will be a further incentive to develop only *new high-performance varieties and races* adapted to the increased industrial trends in agriculture. Their use will place further curbs on regional and ecologically appropriate crop varieties and will further reduce genetic diversity.").

the market with patented plants and animals, thereby driving small farming operations out of business.⁸⁵

B. Provisions of the Directive

The version of the Directive ultimately enacted in 1998⁸⁶ represents a compromise between the biotech industry and its supporters, on the one hand, and the various factions opposing the Directive on moral, ethical, environmental and economic grounds, on the other.⁸⁷ As stated in the Recitals of the Directive's Preamble, the Directive is designed to ensure the "effective and harmonised protection throughout the Member States" so ardently desired by the biotech industry "in order to maintain and encourage investment in the field of biotechnology."⁸⁸ Indeed, some scholars have noted that, although the Recitals indicate that E.U. institutions are merely pursuing the goal of harmonization,⁸⁹ without creating a separate body of patent law that offers rights beyond those available under national laws,⁹⁰ the unstated goal of the Directive is actually to strengthen patent protection throughout the E.U.⁹¹ With regard to accommodating the Greens and other opponents of patents on plants and animals, the Preamble emphasizes that "inventions must be excluded from patentability where their commercial exploitation offends against *ordre public* or morality."⁹² An examination of the operative provisions of the Directive demonstrates the intent of its drafters to protect biotechnological inventions under national patent law,⁹³ while preserving the ability of Member States to consider the ethical dimensions of biotechnological inventions when determining whether to grant patents.⁹⁴

85. See 1992 Committee Report, *supra* note 45, at 65-66; 1997 Committee Report, *supra* note 48, at 42-43. See also Scalise & Nugent, *supra* note 41, at 1025.

86. Directive, *supra* note 3.

87. See Ram, *supra* note 11, at 45 (stating that the Directive was developed through compromise and that the various interested parties made concessions).

88. Directive, *supra* note 3, ¶ 3, at 13.

89. See *id.* ¶¶ 3, 5, 6 and 7, at 13.

90. See *id.* ¶ 8, at 13.

91. See Vinje, *supra* note 4, at 361 ("Generally speaking, EU institutions are pursuing the goal not only of harmonising intellectual property legislation, but also, and at least as vigorously, of strengthening it at the same time."). Indeed, this view is supported by language in the Directive, which, despite asserting that "legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law," nonetheless provides that those national rules "must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfill the requirements for patentability." Directive, *supra* note 3, ¶ 8, at 13 (emphasis added).

92. Directive, *supra* note 3, ¶ 37, at 16. See also *id.* ¶¶ 38-42, at 16 (further discussing the concepts of *ordre public* and morality embodied in the Directive).

93. Article 1.1 of the Directive provides that "Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive." *Id.* art. 1.1, at 18.

94. Article 6.1 of the Directive provides that "[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality." *Id.* art. 6.1, at 18.

1. *What Is Patentable Under the Directive*

The Directive is divided into five chapters, the first of which sets forth the extent of plant and animal patentability.⁹⁵ Within Chapter I, Article 3.1 confirms that it is possible to patent "biological material,"⁹⁶ provided that the usual patent criteria are satisfied, meaning that the invention is new, involves an inventive step and has an industrial application.⁹⁷

Article 3.2 of the Directive provides that "[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."⁹⁸ This provision confirms that the novelty requirement for a patent has been met where biological material that occurs naturally has instead been isolated or produced by a technical process. Patent protection does indeed exist in such cases because the technical processes used to identify, purify and classify the material and to reproduce it are man-made and cannot be accomplished by nature alone, rendering the material a patentable invention rather than a mere discovery.⁹⁹ A particular application of this principle is illustrated in Article 5, which provides patent protection for certain elements isolated from the human body.¹⁰⁰ Pursuant to Article 5.1, "[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene" is unpatentable.¹⁰¹ However, isolated elements, including human genes, are patentable under Article 5.2, which provides that "[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."¹⁰² Thus, Article 5.2 confirms that the results of research on the human genome can be patented, so long as the industrial usefulness of such research can be demonstrated.¹⁰³

95. *Id.* Chap. 1, at 18-19.

96. "Biological material" is defined in Article 2 of the Directive as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system." *Id.* art. 2.1, at 18.

97. *Id.* art. 3.1, at 18. The criteria set forth in Article 3.1 of the Directive, also known as novelty, nonobviousness and usefulness, derive from the EPC and the Strasbourg Convention, two European patent treaties upon which the Directive is modeled. EPC, *supra* note 24, art. 52(1), 1065 U.N.T.S. at 271, 13 I.L.M. at 285, and the Strasbourg Convention, *supra* note 52, art. 1.

98. Directive, *supra* note 3, art. 3.2, at 18.

99. *Id.* ¶ 21, at 15.

100. Such patent protection was strongly opposed by the Greens and their allies. See Scalise & Nugent, *supra* note 41, at 1026-27. See also *Biotechnology: Ethics, Patents and the Human Body*, EUR. REP., *supra* note 63; Claire O'Brien, *European Parliament Axes Patent Policy*, 267 SCIENCE 1417 (1995); Rory Watson, *European Parliament Tackles Biotechnology*, 313 BRIT. MED. J. 964 (1996).

101. Directive, *supra* note 3, art. 5.1, at 18.

102. *Id.* art. 5.2, at 18.

103. Specifically, Article 5.3 of the Directive provides that "[t]he industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application." *Id.* art. 5.3, at 18.

2. *What Is Not Patentable Under the Directive*

Articles 4, 5, and 6 of the Directive identify creations that are not patentable. First, Article 4 of the Directive precludes patent protection for plant and animal varieties,¹⁰⁴ although plants and animals are not per se unpatentable,¹⁰⁵ and for “essentially biological processes for the production of plants and animals.”¹⁰⁶ A process for the production of plants and animals is “essentially biological” if it “consists entirely of natural phenomena such as crossing or selection.”¹⁰⁷

The exclusion of essentially biological processes and plant and animal varieties from patent protection in part indicates ethical objections to human intervention in the generation of animals and plants, objections that may be raised on moral and public policy grounds.¹⁰⁸ For the most part, however, these provisions derive from earlier treaties that date from a time when new varieties of plants and animals could be achieved only through cross-selection and breeding,¹⁰⁹ and the law sought to protect farmers from paying royalties when they bred plants and animals on their farms. Although Article 4.1 of the Directive may seem to bar unnecessarily patents on transgenic¹¹⁰ plants and animals, its language is qualified by Article 4.2, which provides patent protection to inventions concerning plants or animals “if the technical feasibility of the invention is not confined to a particular plant or animal variety.”¹¹¹ Article 4.2 inevitably will engender debates about the extent to which a particular invention is applicable to different plant and animal varieties if the research has focused on a single variety.¹¹²

104. *Id.* art. 4.1(a), at 18. The concept of plant varieties is defined in Article 2.3 of the Directive, which refers to Article 5 of the Council Regulation (EC) 2100/94 of 27 July 1994 on Community Plant Variety Rights, 1994 O.J. (L 227) 1 [hereinafter Plant Variety Regulation].

105. See *supra* notes 96-97 and accompanying text.

106. Directive, *supra* note 3, art. 4.1(b), at 18. Article 4.3 allows an exception to Article 4.1(b), however, expressly providing patent protection for microbiological processes, along with products obtained by means of such processes. *Id.* art. 4.3, at 18. As noted by one scholar, the exception in Article 4.3 acknowledges that microbiological production techniques have been patentable for so long that, even when used for plant and animal production, they must be treated as patentable. CORNISH, *supra* note 3, at 194. For example, as stated at note 15, *supra*, the German Federal Supreme Court permitted patent protection for yeast as early as 1975. Cornish contends, however, that there is no scientific line between micro- and macro-biology, which renders this distinction increasingly ambiguous. See CORNISH, *supra* note 3, at 194.

107. Directive, *supra* note 3, art. 2.2, at 18.

108. See *supra* Part II.A for a discussion of the arguments raised in the E.U. by opponents of patents on plants and animals.

109. The Directive's Article 4 bar on patents for animals varieties, except for microbiological inventions, Directive, *supra* note 3, art. 4, at 18, tracks almost exactly the language from Article 53(b) of the EPC, *supra* note 24, which precludes patents on “plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.” EPC, *supra* note 24, art. 53(b), 1065 U.N.T.S. at 272, 13 I.L.M. at 286.

110. See *supra* note 27 for a definition of transgenic plants and animals.

111. Directive, *supra* note 3, art. 4.2, at 18.

112. The Directive's ban on patent protection for plant varieties is premised in part on the fact that inventors of a particular *plant* variety can avail themselves of alternative methods of plant variety protection, such as the Plant Variety Regulation, see *supra* note 104, and also the UPOV, see *supra* note 52, which was revised in 1991 to admit intergovernmental organizations, including the

Article 5 of the Directive, which deals with the patentability of humans,¹¹³ prohibits a patent on “[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements.”¹¹⁴ Nonetheless, as stated previously, elements isolated from the human body are patentable so long as their usefulness can be demonstrated.¹¹⁵

Limitations on patentability are also embodied in the Article 6 morality provision, which provides that “[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public*¹¹⁶ or morality; however exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.”¹¹⁷ Article 6.2¹¹⁸ then provides an illustrative, rather than comprehensive, list of processes and products that contravene this requirement and are therefore unpatentable, including processes for cloning human beings; processes for modifying the germ line genetic identity of human beings;¹¹⁹ processes for using human embryos for industrial or commercial purposes; and “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.”¹²⁰ The Directive makes clear that this list is not exhaustive.¹²¹

E.U. CORNISH, *supra* note 3, at 683. This presents an obstacle to inventors of *animal* varieties, however, in that no analogous system of protection exists for them. Cf. van de Kamp, *supra* note 68, at 236 & n.21 (noting that the EPO, in determining whether to grant a patent in cases regarding transgenic plants and animals under the EPC, has proved itself more likely to grant a patent for an animal invention in light of the fact that alternative legislation exists to protect inventors of plant varieties but not animal varieties).

113. Directive, *supra* note 3, art. 5, at 18.

114. *Id.* art. 5.1, at 18.

115. *See id.* arts. 5.2 and 5.3, at 18. *See also supra* notes 100-03 and accompanying text.

116. *See supra* note 18 for a definition of *ordre public*.

117. Directive, *supra* note 3, art. 6.1, at 18.

118. *Id.* art. 6.2, at 18-19.

119. Germ line gene therapy alters a person's reproductive cells so as to transmit genetic changes to a person's descendants. It is distinguishable from somatic cell gene therapy, which applies to differentiated cells such as the cells of the liver, blood or other organs, and which is patentable under the Directive. Bostyn, *supra* note 59, at 8 & nn.36-37. Many commentators have criticized the Directive's exclusion of germ line gene therapy processes from patent protection, in light of the fact that numerous inheritable diseases could potentially be cured by such therapy. In particular, one scholar noted that “[i]t seems retrograde and short-sighted to exclude from patentability a process which might have such a substantial benefit to humankind,” particularly in light of the fact that the Directive was enacted, at least in part, in order to improve human health. Nonetheless, this scholar noted that, given the complex ethical issues raised by such research, this exclusion “was probably inevitable in order to get the Directive approved.” Nott, *supra* note 1, at 349.

120. Directive, *supra* note 3, art. 6.2, at 19. Transgenic animals such as the Harvard Oncomouse, discussed *infra* in Part III.B.2.a, could well be subject to this provision.

121. Indeed, Recital 38 confirms that the list of immoral inventions set forth in the operative part of the Directive is not comprehensive, and gives as an additional example that “processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability.” Directive, *supra* note 3, ¶ 38, at 16. A chimera is a living creature created by combining the genetic material of animals of two different species in such a way that their genetic material does not mix in each cell throughout the animal, as it would for a hybrid animal. Instead, a chimera is made up of some cells that come entirely from one species and some cells that derive entirely from the other. *See Magnani, supra* note 9, at 445. Molecular biologists have possessed the ability to create animal-animal chimeras for more than a decade. In the mid-1980s, scientists in the United Kingdom announced the creation of a “geep,” an animal that was part goat and

Article 7 of the Directive provides that the Commission's European Group on Ethics in Science and New Technologies (EGEST) will evaluate all ethical aspects of biotechnology.¹²² This twelve-member group, which is completely independent of the Commission and is intended to be free from political and national interests as well, has a broad mandate. The opinions it delivers will concern not only biotechnology, but also other fields, such as information technology. In addition to delivering opinions at the Commission's request, this group will have the option of examining matters and rendering opinions on its own initiative.¹²³

3. *Implementation of the Directive*

Chapter V of the Directive provides for its implementation and ongoing refinement. Pursuant to Article 15, "Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000."¹²⁴ Moreover, under Article 16 of the Directive, the Commission is required to report to Parliament and the Council every five years on problems relating to human rights that arise from the Directive, and to report annually on the development of patent law in the field of biotechnology and genetic engineering.¹²⁵

III.

WILL THE DIRECTIVE FOSTER HARMONIZATION AMONG THE MEMBER STATES?

As of September 2, 2000, only three E.U. Member States had amended their national legislation, regulations and administrative provisions relating to biotechnology in compliance with the Directive.¹²⁶ Until all of the national legislatures have enacted and the national courts interpreted such legislation, it is impossible to determine to what extent the Directive will harmonize the patent laws of the Member States. One factor making harmonization particularly difficult is the Directive's Article 6, inserted as a concession to the Greens in Parliament, which precludes patents for inventions contrary to morality or public

part sheep. See Carole B. Fehilly et al., *Interspecific Chimaerism Between Sheep and Goat*, 307 NATURE 634 (1984); Sabine Meinecke-Tillmann & B. Meinecke, *Experimental Chimaeras – Removal of Reproductive Barrier Between Sheep and Goat*, 307 NATURE 637 (1984). In the United States, a patent application was filed on December 18, 1997 for a method of making creatures that are part human and part animal by combining the embryos of both and implanting these chimeric embryos into surrogate mothers. See David Dickson, *Legal Fight Looms Over Patent Bid on Human/Animal Chimeras*, 392 NATURE 423 (1998); Rick Weiss, *Patent Sought on Making of Part-Human Creatures: Scientist Seeks to Touch Off Ethics Debate*, WASH. POST, Apr. 2, 1998, at A12.

122. Directive, *supra* note 3, art. 7, at 19.

123. van de Kamp, *supra* note 68, at 237.

124. Directive, *supra* note 3, art. 15, at 20. Thus, although the Directive is not intended to displace national patent laws in the Member States, *id.* ¶ 8, at 13, the Commission is empowered to impose sanctions upon Member States that fail to alter their national laws in conformance with the Directive, *id.* arts. 1 and 15, at 13 and 20-21.

125. *Id.* art. 16, at 21.

126. For a discussion of the resistance of some E.U. Member States to implementing the Directive, see *supra* note 20 and accompanying text, and see *infra* notes 129, 275-80 and accompanying text.

policy.¹²⁷ Article 6 will be subject to widely varying interpretations throughout the Member States, which differ greatly in their acceptance of emergent biotechnological inventions. The United Kingdom and Germany, for instance, are quite willing to grant patents on life forms,¹²⁸ while the Netherlands generally opposes the patenting of life forms per se.¹²⁹

Some scholars have dismissed the notion that patent officers and judges from nations opposed to plant and animal patents will interpret Article 6 so broadly as to preclude most biotechnology patents, given that European judges have already begun to communicate with one another in an effort to harmonize E.U. patent law.¹³⁰ Even if these scholars are correct, harmonization will nonetheless 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, upon which the Directive's morality provision is modeled nearly verbatim, demonstrates that the morality provision has been subject to inconsistent interpretations even by a *single* adjudicatory body.¹³¹

A. *The European Patent Convention Morality Provision*

Article 53(a) of the European Patent Convention (EPC),¹³² an international agreement currently in force among nineteen nations, including all of the E.U. Member States,¹³³ provides that European patents shall not be granted for "inventions the publication or exploitation of which would be contrary to 'ordre public'¹³⁴ or morality,¹³⁵ provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all

127. See *supra* notes 116-21 and accompanying text.

128. Since the mid 1970s, Germany and the United Kingdom have been especially willing to grant patents on life forms. See, e.g., *American Cyanamid v. Berk Pharm.*, 1976 R.P.C. 231 (1976) (approving patents on life forms in the United Kingdom); *Red Dove*, 1969 GRUR 672 (BGH 1969) (allowing patents on higher animals in Germany); *Baker's Yeast Decision*, *supra* note 15. The seminal *Red Dove* decision in 1969, in which the German Federal Supreme Court approved patents on higher animals, preceded by over 10 years the U.S. Supreme Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), in which the U.S. Supreme Court concluded that patentable subject matter was to "include anything under the sun that is made by man." *Id.* at 309.

129. In 1998, the Netherlands brought an action before the European Court of Justice opposing the Directive. See Case C-377/98, *Netherlands v. Parliament*, 1998 O.J. (C 378) 13. Italy has since joined the case as well. See *infra* notes 275-80 and accompanying text.

130. Nott, *supra* note 1, at 350-51.

131. See *infra* Part III.B.

132. EPC, *supra* note 24, art. 53(a), 1065 U.N.T.S. at 273, 13 I.L.M. at 286.

133. Signatories to the EPC include all fifteen of the E.U. Member States, see *supra* note 4, as well as Switzerland, Liechtenstein, Monaco and Cyprus. See Helen Gavaghan, *EU Ends 10-Year Battle Over Biopatents*, 280 SCIENCE 1188, 1188 (1998). See also *European Patent Office*, at <http://www.european-patent-office.org/epo/members.htm> (visited October 13, 2000).

134. According to the decision of the Technical Board of Appeal of the EPO in *Greenpeace Ltd. v. Plant Genetic Systems N.V.*, see *infra* Part III.B.2.b:

the concept of 'ordre public' covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order . . . or to seri-

of the contracting states.”¹³⁶ As is readily apparent, the language of Article 6 of the Directive is not only modeled upon, but is indeed nearly identical to that of EPC Article 53(a).¹³⁷

The EPC, which is completely independent of the E.U.,¹³⁸ was created in order to enable a patent applicant seeking patent rights in more than one contracting nation to file a single European Patent Application, which, if granted, becomes a national patent in each of the nations designated in the application.¹³⁹

ously prejudice the environment are to be excluded from patentability as being contrary to ‘ordre public.’

Greenpeace Ltd. v. Plant Genetic Systems N.V., T 356/93 - 3.3.4, 1995 O.J. E.P.O. 545 (Technical Bd. of App.), ¶ 5 [hereinafter *PGS*]. Thus, as mentioned previously “*ordre public*” is the equivalent of “public policy.” See *supra* note 18.

135. In *PGS*, the EPO Technical Board of Appeal declared that:

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

PGS, *supra* note 134, ¶ 6. It should be noted that the EPO recognized that “there was no European definition of morality,” and that the “interpretation of the concept of morality should be a matter for European institutions.” *Id.* ¶ 4 (citing EPC WORKING PARTY DOCUMENT IV/2767/61-E, at 7).

136. EPC, *supra* note 24, art. 53(a), 1065 U.N.T.S. at 273, 13 I.L.M. at 286. Regarding the qualification in Article 53(a) of the EPC “that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States,” the EPO Technical Board of Appeal explained in *PGS* that:

[t]his qualification makes clear that the assessment of whether or not a particular subject-matter is to be considered contrary to either ‘ordre public’ or morality is not dependent upon any national laws or regulations. Conversely and by the same token, . . . a particular subject-matter shall not automatically be regarded as complying with the requirements of Article 53(a) EPC merely because its exploitation is permitted in some or all of the contracting states. Thus, approval or disapproval of the exploitation by national law(s) or regulation(s) does not constitute per se a sufficient criterion for the purposes of examination under Article 53(a) EPC.

PGS, *supra* note 134, ¶ 7. One reason for this is that “a product could still be manufactured under a European patent for export to States in which its use is not prohibited.” GUIDELINES FOR EXAMINATION IN THE EPO, at C-IV, § 3.2, *reprinted in* 2 EUROPEAN PATENTS HANDBOOK 56/215 (2d ed. 1995) [hereinafter GUIDELINES FOR EXAMINATION].

137. See *supra* text accompanying notes 116-17. The only significant difference between the language of Article 6 of the Directive and Article 53(a) of the EPC is that the Directive omits the word “publication.” This omission precludes the body assessing the morality of a patent application under the Directive from denying a patent based upon the morality of the methods used to create the invention. In contrast, under Article 53 of the EPC, the EPO has discretion to reject a patent application based upon the morality of the methods used to create the invention, as well as upon the subsequent use of the invention after the patent had been awarded. See Richard Ford, *The Morality of Biotech Patents: Differing Legal Obligations in Europe?*, 19 EUR. INTEL. PROP. REV. 315, 316 (1997).

138. The governing bodies of the E.U. do not exercise any control over the EPC, and the EPO is not legally bound to follow the Directive. See Gavaghan, *supra* note 133, at 1188; Judge & Frankel, *supra* note 70. Experts believe that the Directive will influence the EPO’s decisions, however, since fifteen of the nineteen signatories to the EPC are E.U. Member States. Gavaghan, *supra* note 133, at 1188.

139. A European Patent Application can be filed at the EPO in Munich, at The Hague, or with the national patent office of the individual nation. The EPO then conducts an examination of the

Thus, the EPC does not grant a supranational patent, but provides a centralized system for obtaining a bundle of national patent rights¹⁴⁰ which are governed by the independent laws of the various contracting states, rather than the EPO.¹⁴¹

The EPC is therefore a patent registration system, not a legislative body, and as such, cannot foster harmonization of European patent law. While the EPC reduces the time and cost necessary to obtain patent rights in certain of the signatory nations, a governing precept of the EPC is that it may not replace or supersede the various national patent laws already in effect in the signatory nations. Consequently, under the EPC schema, the individual contracting countries may interpret and modify a single European patent, thus affording the patentee varying degrees of patent protection.¹⁴² In contrast, the Directive is intended to harmonize¹⁴³ intellectual property rights throughout the E.U. and requires Member States to amend their laws in compliance with it.¹⁴⁴ Further, the Directive is backed by the enforcement powers of the European Community, which can coerce legislative action in any Member State by threat of sanctions.¹⁴⁵

As signatories to the EPC, the E.U. Member States have already included in their national laws provisions that are based on the EPC Article 53(a) morality provision.¹⁴⁶ For example, the British Patents Act of 1977 provides, in relevant part, that "[a] patent shall not be granted for an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour."¹⁴⁷ Moreover, "behaviour shall not be regarded

patent application. The applicant must designate at the time of filing the countries of the EPC to which he wishes protection of his invention to extend. Examination of a patent application is divided into: (1) an examination of whether the application has met all formal requirements followed by (2) a substantive examination. During the formalities examination, the EPO also scrutinizes the application for compliance with the Article 53(a) morality provision. The substantive examination of each application is conducted by the Examining Division, the first level of such review, which consists of three technically qualified examiners of different nationalities. Within nine months from the date the Examining Division has granted a patent, any person may file a notice of opposition, which must contain a statement of the extent to which the European patent is opposed and the grounds upon which the opposition is based. Oppositions are conducted by the Opposition Division, which consists of three technical examiners, at least two of whom must not have taken part in the proceedings for the grant of the patent to which the opposition relates. An appeal to the Technical Board of Appeal lies from a decision of the Opposition Division. See PETER D. ROSENBERG, 3 PATENT LAW FUNDAMENTALS 19-102 to 19-106 (2d ed. 1999). Alternatively, a patent granted under the EPC can be challenged before the national patent offices or courts, in which case the decisions have only a national effect. See van de Kamp, *supra* note 68, at 235.

140. See Janice McCoy, *Patenting Life in the European Community: The Proposed Directive on the Legal Protection for Biotechnological Inventions*, 4 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 501, 509 n. 45 (1993).

141. See Scalise & Nugent, *supra* note 41, at 1013.

142. *Id.* at 1012-13.

143. See *supra* notes 6-8 and accompanying text.

144. Directive, *supra* note 3, art. 15, at 20-21. Moreover, although the Directive provides that Member States' national patent laws "remain the essential basis" for protection of biotech inventions, it emphasizes that such laws "must be adapted or added to" so as to "take adequate account of technological developments involving biological material." *Id.* ¶ 8, at 13.

145. See *supra* note 124.

146. Rainer Moufang, *Patenting of Human Genes, Cells and Parts of the Body? The Ethical Dimensions of Patent Law*, 25 INT'L REV. INDUS. PROP. & COPYRIGHT L. 487, 503 (1994).

147. British Patents Act of 1977, ch. 37, Sec. 1(3)(a).

as offensive, immoral or anti-social only because it is prohibited by any law in force in the United Kingdom or any part of it.”¹⁴⁸ Other EPC signatory nations have similar provisions in their patent law.¹⁴⁹ Thus, the legal interpretations of Article 53(a) of the EPC will serve as a model for E.U. Member States, all of which are members of the EPC, as their legislatures and judiciaries grapple with the Directive’s morality provision.

B. Two Conflicting Morality Tests Under the European Patent Convention

Morality is an exceedingly complex standard to implement as a criterion of patentability. Already, in the four biotechnology cases in which the morality criterion has formed the basis for challenging a patent under the EPC, two distinct tests have emerged. First, the “public abhorrence” test denies a patent grant to any invention where public consensus determines that such a grant would be abhorrent.¹⁵⁰ Second, the “unacceptability” test denies a patent grant where the disadvantages of the patent to society would outweigh the advantages,¹⁵¹ or where, put somewhat differently, the grant of a patent would be unacceptable in light of the “conventionally accepted standards of conduct of European culture.”¹⁵² The “unacceptability” test is more stringent, since an invention that is not “abhorrent” may still be deemed so “unacceptable” as to preclude patent protection. Thus, variation in which of the two tests is applied results in inconsistent standards of patentability.

148. British Patents Act of 1977, ch. 37, Sec. 1(4).

149. Moufang cites as examples Sec. 4(2) of the Belgian Patent Act; Sec. 1(4)(i) of the Danish Patent Act; Sec. 2(1) of the German Patent Act; Art. L. 611-17 of the French Intellectual Property Code; Sec. 5(8)(a) of the Greek Patent Act; Sec. 13(1) of the Italian Patent Act; Sec. 1(3)(a) of the Luxembourg Patent Act; Sec. 5 of the Dutch Patent Act; Art. 2(1) of the Austrian Patent Act; Sec. 1(4)(1) of the Swedish Patent Act; Sec. 2(a) of the Swiss Patent Act; and Sec. 5(1)(a) of the Spanish Patent Act. He notes that there “may be slight differences in the precise wording” of these acts. Moufang, *supra* note 146, at 503 n.76.

150. The “public abhorrence” test was adopted in *In re Lubrizol Genetics, Inc.*, (*Lubrizol II*), EP-B1-122 791, 1990 O.J. E.P.O. 71 (Opp. Div.), *reprinted* in 21 INT’L REV. INDUS. PROP. & COPY. RIGHT L. 487 (1990) [hereinafter *Lubrizol*], and in *Hormone Relaxin*, 1995 O.J. E.P.O. 388 (Opp. Div.) [hereinafter *Relaxin*]. See *infra* Part III.B.1. This test derives from the GUIDELINES FOR EXAMINATION, *supra* note 136, at C-IV, § 3.1, *reprinted* in EUROPEAN PATENTS HANDBOOK 56/214 to 56/215, which provides that, in order to determine whether an invention is contrary to *ordre public* or morality, “[a] fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of a patent right would be inconceivable.” The GUIDELINES FOR EXAMINATION then explain that Article 53(a) “is likely to be invoked only in rare and extreme cases,” giving the example of a letter bomb. *Id.* See also EDWARD ARMITAGE & IVOR DAVIS, PATENTS AND MORALITY IN PERSPECTIVE (1994) (two former Comptrollers of the U.K. Patent Office, who were involved in the creation of the EPC, state that the morality exception ought to be invoked only where it is virtually “inconceivable” that the invention could be put to a moral use and the invention is clearly “abhorrent”).

151. This test was applied in *Harvard/Onco-mouse*, 1992 O.J. E.P.O. 588 (Examining Div.), *reprinted* in 1991 EUR. PAT. OFF. REP. 525, 527-28 [hereinafter *Harvard/Onco-mouse Decision of 3 April 1992*].

152. This test was adopted in *PGS*, *supra* note 134, ¶ 17.3. See also *infra* notes 242-46 and accompanying text. As noted previously, however, *supra* note 135, the PGS Board noted that “there was no European definition of morality,” and that the “interpretation of the concept of morality should be a matter for European institutions.” *PGS*, *supra* note 134, ¶ 4.

1. The "Public Abhorrence" Standard

a. *In re Lubrizol Genetics, Inc.*

The EPO first espoused the "public abhorrence" test in the 1992 decision *In re Lubrizol Genetics Inc. (Lubrizol)*,¹⁵³ in which the EPO Opposition Division¹⁵⁴ approved the patent granted for a hybrid transgenic plant as well as the method of rapidly producing such plants.¹⁵⁵ In March 1989, after mention of a patent grant to Lubrizol was published, eleven parties, including several political and environmental organizations, filed notices of opposition. These opposition groups demanded that the Opposition Division revoke the European patent, basing their arguments in part on the premise that such a plant patent contravened morality.¹⁵⁶

First, opponents of the Lubrizol patent contended that Article 53(a) of the EPC¹⁵⁷ precluded patenting of plant genetic resources, which should be freely available to all. Second, they argued that patenting plant inventions would engender a decrease in the number of plant varieties and ultimately lead to a loss of genes. Finally, those opposed to the Lubrizol patent argued that patent protection on plant inventions would offend religious sensibilities in Europe.¹⁵⁸ While these arguments opposing the Lubrizol patent actually deny the patentability of plants per se, the EPO disregarded such objections in principle to patents on plants and animals in the *Harvard/Onco-Mouse* case,¹⁵⁹ decided in the same year as *Lubrizol*. Nonetheless, the Opposition Division's deliberations in the *Lubrizol* case regarding the patentability of life forms illuminate the devel-

153. See *supra* note 150.

154. See *supra* note 139 regarding the role of the EPO Opposition Division.

155. More specifically, the patent contained claims relating to a DNA shuttle vector comprising T-DNA having inserted therein a plant gene comprising a plant promoter and a plant structural gene, a method for genetically modifying a plant cell and a plant produced according to the method contained in the patent application. See Hans-Rainer Jaenichen & Andreas Schrell, *The European Patent Office's Recent Decisions on Patenting Plants*, 12 EUR. INTELL. PROP. REV. 466, 466 (1993).

156. *Id.* See also *supra* note 139 regarding the procedure for filing an opposition to the grant of a patent in the European Patent Office.

157. See *supra* notes 132-37 and accompanying text.

158. See Jaenichen & Schrell, *supra* note 155, at 467.

159. See *infra* Part III.B.2.a. In all likelihood, such contentions will no longer be tenable under the Directive, which expressly provides patent protection for plants. See *supra* text accompanying notes 96-97, 105. As least as early as 1988, the Commission emphasized that "[w]here the principle is not completely accepted, . . . the argument can no longer be raised that all living matter must be excluded from patent protection on the ground that the mere fact of being alive disqualifies such inventions from being regarded as patentable." Commission Proposal of 1988, *supra* note 6, at 32. The Commission noted that the EPC contracting states incorporated principles regarding patentability of life forms which derived from earlier conventions, dating as far back as 1961, see *supra* notes 108-09 and accompanying text, "without seriously reconsidering developments which in the meantime had taken place in various areas of biotechnology." Commission Proposal of 1988, *supra* note 6, at 10. The belief inherited in the EPC that biological inventions were patentable only in rare cases. See *id.* at 10-12. The Directive expressly departs from this view, however, providing that "Member States shall protect biotechnological inventions under national patent law," Directive, *supra* note 3, art. 1.1, at 18, and "inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used." *Id.* art. 3.1, at 18.

opment of the “public abhorrence” test under Article 53(a) of the EPC. This test remains viable,¹⁶⁰ and is likely to be applied in some of the cases brought under Article 6 of the Directive.

The EPO’s Opposition Division rejected any contention that the *Lubrizol* patent contravened morality. First, they held that because known subject matter is not patentable under the EPC,¹⁶¹ and only known plant genetic resources can be considered a part of a common heritage, the patented invention at issue must contain unknown genetic resources and therefore could not be part of a common heritage. Second, with respect to genetic diversity, the Opposition Division concluded that biotechnology inventions involving plants normally give rise to a new combination of genes and that the patent system therefore facilitated an increase in the amount of available genetic material. Furthermore, biotechnology did not pose the only potential threat to biodiversity, since a decrease in the number of plant varieties could arise simply from traditional breeding techniques. Finally, the Opposition Division rejected the argument that plant patents conflicted with European religious sensibilities, because many European nations already provided patent protection for plants, as did the U.S., which is similarly influenced by Christian ethical thought.¹⁶²

The *Lubrizol* case is significant in that, in 1992, at the same time that the European Parliament was debating the inclusion of a morality provision in the Directive, the EPO held that “patent law is not an appropriate instrument for regulating the development of new technologies and that the legislature should determine whether a certain technology is so dangerous and unacceptable to the public that it should be suppressed.”¹⁶³ Furthermore, the Opposition Division emphasized that exclusions from patentability generally are to be interpreted narrowly,¹⁶⁴ relying on past decisions of the Technical Boards of Appeal.¹⁶⁵

Most importantly, the Opposition Division in *Lubrizol* adopted the “public abhorrence” test to determine whether an invention violated Article 53(a) of the EPC. According to this test, an invention will be excluded from patent protection only where the public in general would regard the invention as so abhorrent that the grant of a patent would be inconceivable.¹⁶⁶

b. Hormone Relaxin

In 1994, two years after its decision in *Lubrizol*, the Opposition Division of the EPO again applied the “public abhorrence” test, this time in the case of

160. Indeed, the “public abhorrence” test was again employed by the EPO in the 1994 *Hormone Relaxin* action. See *infra* Part III.B.1.b.

161. See *supra* notes 96-97 and accompanying text regarding the novelty requirement under European patent law.

162. See Jaenichen & Schrell, *supra* note 155, at 467.

163. *Id.*

164. See *id.*

165. See *supra* note 139 for a discussion of EPO procedure, including the role of the Technical Board of Appeal.

166. See Jaenichen & Schrell, *supra* note 155, at 467.

Hormone Relaxin (Relaxin).¹⁶⁷ In the *Relaxin* case, the Opposition Division approved the grant of a patent for a DNA fragment encoding a human protein, produced by pregnant women, that had useful applications during the childbirth process.¹⁶⁸

The patent at issue in *Relaxin* had originally been granted in 1991,¹⁶⁹ and the Green Party¹⁷⁰ filed an opposition in 1992 on the grounds that, *inter alia*, the invention offended against *ordre public* and morality.¹⁷¹ Opponents of the relaxin patent invoked powerful language in calling for its revocation. First, they claimed that the patent instructs that tissue be taken from pregnant women in order to replicate the invention. The Greens' argument, as paraphrased by the EPO, was that "[t]he isolation of the DNA relaxin gene from tissue taken from a pregnant woman is immoral, in that it constitutes an offence against human dignity to make use of a particular female condition (pregnancy) for a technical process oriented towards profit."¹⁷² Second, opponents of the patent asserted that patenting human genes amounted to "a form of modern slavery since it involves the dismemberment of women and their piecemeal sale to commercial enterprises throughout the world."¹⁷³ Third, they contended that the patenting of human genes is equivalent to the patenting of human life, which is inherently immoral.¹⁷⁴

In evaluating these arguments against the relaxin patent, the Opposition Division noted that the provisions of Article 53(a) of the EPC, which "have only very seldom been invoked," must "be seen as a measure to ensure that patents would not be granted for inventions that would universally be regarded as outrageous."¹⁷⁵ In light of this standard, the Opposition Division rejected the arguments of the patent opponents on several grounds.¹⁷⁶

First, regarding the isolation of tissue taken from pregnant women, the patent holder stated that the women who donated the tissue consented to do so during the course of necessary gynecological procedures. The Opposition Division noted that human tissue and other materials such as blood and bone had served for years as a source for products such as proteins, RNA and DNA. Numerous life-saving substances, such as blood clotting factors, had been isolated

167. See *supra* note 150.

168. See *Relaxin*, *supra* note 150. See also Stephen Crespi, *Biotechnology Patenting: The Wicked Animal Must Defend Itself*, 17 EUR. INTELL. PROP. REV. 431, 434 (1995).

169. See *Relaxin*, *supra* note 150, Facts and Submissions, ¶ I.

170. See *supra* note 62.

171. See *Relaxin*, *supra* note 150, Facts and Submissions, ¶ II.1.

172. *Id.* ¶ 6.1(a).

173. *Id.* ¶ 6.1(b).

174. *Id.* ¶ 6.1(c). Similarly, the Directive provides that human life generally cannot be patented. See *supra* notes 100-03, 113-15 and accompanying text.

175. *Relaxin*, *supra* note 150, ¶ 6.2.1. The Opposition Division referred to the EPO GUIDELINES FOR EXAMINATION, *supra* note 136, in stating that Article 53(a) of the EPC "is likely to be invoked only in rare and extreme cases, for example that of a letter bomb." *Id.* ¶ 6.2.1. The Opposition Division further noted that "[t]he boards of appeal have repeatedly found that such exceptions [under Article 53(a)] are to be narrowly construed." *Id.* ¶ 6.2.2 (citations omitted).

176. *Id.* ¶ 6.3.

in this way and many had been patented.¹⁷⁷ According to the Opposition Division, “[e]very evidence indicates that this practice is perfectly acceptable to and even welcomed by the vast majority of the public.”¹⁷⁸ Moreover, the Opposition Division observed that, contrary to the opponents’ assertions concerning the repeatability of the invention, the isolation procedure need not be repeated in order to carry out the invention since a DNA fragment encoding relaxin can be chemically synthesized.¹⁷⁹

Second, as for the opponents’ assertions concerning slavery and the dismemberment of women, the Opposition Division admonished that such arguments “betray a fundamental misunderstanding of the effects of a patent.”¹⁸⁰ A patent does not confer on its holder any rights whatsoever in individual human beings, but merely allows the holder to preclude third parties from commercially exploiting the patented invention for a designated period of time.¹⁸¹ Thus, “[n]o woman is affected in any way by the present patent – she is free to live her life as she wishes and has exactly the same right to self-determination as she had before the patent was granted.”¹⁸² Nor does the exploitation of the invention involve dismemberment and the piecemeal sale of women, according to the Opposition Division. Indeed, the very aim of the patent, as with other types of gene cloning, is that the protein encoded by the cloned gene – in this case human H2-relaxin – is produced in unicellular organisms containing the corresponding DNA, thereby obviating the need to use human beings as a source of the protein. The only stage at which a woman was involved was at the beginning, as a voluntary source for the relaxin mRNA.¹⁸³

Third, the Opposition Division rejected the allegation that human life was being patented, since DNA is not itself “life,” but rather a chemical substance that carries genetic information and can be used to produce proteins with medical applications. According to the Opposition Division, the patent opponents “apparently do not object to the patenting and exploitation for medical purposes of other human substances such as proteins (even the H2-relaxin protein).” The Opposition Division found “no moral distinction . . . in principle between the patenting of genes on the one hand and other human substances on the other, especially in view of the fact that only through gene cloning have many important human proteins . . . become available in sufficient amounts to be medically applied.”¹⁸⁴

In addition to addressing the specific arguments made by the opponents of the relaxin patent, the Opposition Division also responded to the opponents’ general arguments that patenting human genes is inherently immoral. The Opposition Division alluded to the contemporaneous debate regarding whether the

177. *Id.* ¶ 6.3.1.

178. *Id.*

179. *Id.* ¶ 6.3.2.

180. *Id.* ¶ 6.3.3.

181. *Id.* See also *supra* note 42 and accompanying text.

182. *Relaxin*, *supra* note 150, ¶ 6.3.3.

183. *Id.* ¶ 6.3.3.

184. *Id.* ¶ 6.3.4.

Directive would permit patenting of human genes (ultimately, it did¹⁸⁵) to prove that there was no consensus among the contracting states that the patenting of human genes is abhorrent and hence prohibited under Article 53(a).¹⁸⁶

Thus, the *Relaxin* case established that the EPO would apply the “abhorrent” standard even to patents involving human gene sequences. The Opposition Division held that:

there is no provision in the EPC that only those inventions actively approved of by the public should be patented. If such a provision existed, it is arguable that the number of patents granted would be decimated since there are plenty of fields other than biotechnology (which the opposition division, unlike the opponents, does not see as a special case) in which patents may well be objectionable to parts of the public. Only in those very limited cases in which there appears to be an **overwhelming consensus** that the exploitation or publication of an invention would be immoral may an invention be excluded from patentability under Article 53(a).¹⁸⁷

In *Relaxin*, the Opposition Division, which had applied the “public abhorrence” test to transgenic plants in the *Lubrizol* action two years earlier, employed that same standard in a case dealing with genetic data derived from human beings.

2. The Unacceptability Test

a. Harvard/Onco-mouse

In 1992, the EPO Examining Division¹⁸⁸ departed from the “public abhorrence” test articulated in the EPO Guidelines for Examination¹⁸⁹ and applied the more stringent “unacceptability” test in approving the first patent granted to a transgenic animal, the Harvard Onco-mouse. Scientists at Harvard University created the Harvard Onco-mouse in the 1980s by inserting into a mouse a human gene that renders the mouse highly susceptible to breast cancer.¹⁹⁰ The inventors applied for an U.S. patent on January 22, 1984, for the process of producing genetically-manipulated animals, as well as for the transgenic animal

185. See *supra* notes 100-03, 113-15 and accompanying text.

186. See *Relaxin*, *supra* note 150, ¶¶ 6.4.1 to 6.4.4.

187. *Id.* ¶ 6.5.

188. See *supra* note 139 for a discussion of EPO procedure, including the role of the Examining Division.

189. See *supra* note 150.

190. Carrie F. Walter, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1029 (1998). The Harvard researchers isolated a gene that causes cancer in many mammals, including humans. They then injected this gene into a fertilized mouse egg that developed into the Harvard mouse. See *id.*; Keith Schneider, *Harvard Gets Mouse Patent, a World First*, N.Y. TIMES, Apr. 13, 1988, at A1. The scientists developed the animal, which eventually became the property of the pharmaceutical company Du Pont, to serve as a more effective model for studying how genes contribute to various forms of cancer, particularly breast cancer, as well as for testing drugs for breast cancer. See Alun Anderson, *Oncomouse Released*, 336 NATURE 300, 300 (1988).

itself.¹⁹¹ The patent, granted on April 12, 1988, was the first patent the U.S. Patent and Trademark Office awarded for a new variety of animal.¹⁹²

In 1985, less than two years after they applied for a patent in the U.S., the inventors of the Harvard mouse sought a patent in Europe from the EPO.¹⁹³ In 1989, the Examining Division of the EPO denied the Harvard Onco-mouse patent application. This rejection was based largely upon EPC Article 53(b), which provides that European patents shall not be granted for "plant or animal varieties or essentially biological processes for the production of plants or animals."¹⁹⁴ The EPO interpreted the term "animal variety" in Article 53(b) of the EPC in a manner that excluded patent protection for all animals per se.¹⁹⁵ The Examining Division did not address the moral considerations implicit in the patent application, concluding that patent law was not the appropriate tool for regulating conflicts that arise from genetic engineering technology.¹⁹⁶

The inventors of the Harvard mouse appealed the decision of the Examining Division to the EPO Technical Board of Appeal.¹⁹⁷ In this proceeding, the Technical Board of Appeal held that the EPC does not exclude the patenting of

191. See 6 EUROPEAN PATENTS HANDBOOK 106:E-35 (2d ed. 1995). In distinguishing among patents upon processes used to make products, patents on the resultant products themselves, and patents on useful applications of such products, the Commission Proposal of 1988 explained as follows:

Inventions resulting from modern biotechnological techniques can be grouped according to the usual patent law distinction made between product, process and use or application inventions.

Inventions relating to products concern living entities of natural or artificial origin, such as plants, animals and microorganisms, biological material, such as plasmids, viruses and replicons, and parts thereof (e.g., organs, tissues, cells and organelles). They may also relate to naturally occurring substances from living entities, biological materials and parts thereof. The invention itself may be the plant, animal, microorganism or a specific biological material (e.g., a plasmid) per se or the plant, animal, etc. produced by a particular process.

The second category (process inventions) concerns processes for the creation of plants, animals, microorganisms or any biological material and parts thereof. It includes also such processes as cultivation, isolation, and purification, and also of bioconversion.

The third category of biotechnological inventions (application inventions) comprises specific uses of plants, animals, microorganisms or biological material.

Commission Proposal of 1988, *supra* note 6, at 9-10.

192. See Walter, *supra* note 190, at 1029. See also U.S. Patent No. 4,736,866 (1988).

193. European patent application 85 304 490.7 was filed on June 24, 1985. See *Harvard/Onco-mouse*, 1989 O.J. E.P.O. 451 (Examining Div.), reprinted in 1990 EUR. PAT. OFF. REP. 4, 5 [hereinafter *Harvard/Onco-mouse Decision of 14 July 1989*].

194. See *supra* note 109.

195. See *Harvard/Onco-mouse Decision of 14 July 1989*, *supra* note 193, at 8. Although Article 53(b) of the EPC, see *supra* note 109, was formerly interpreted to preclude patents on plants and animals per se, see *supra* notes 104-12 and accompanying text, this provision is now understood to mean that, at least with respect to plants, an invention is patentable provided that it is not confined to a particular variety. See *infra* note 222.

196. See *Harvard/Onco-mouse Decision of 14 July 1989*, *supra* note 193, at 11.

197. See *Harvard/Onco-mouse*, 1990 O.J. E.P.O. 476, reprinted in 1990 EUR. PAT. OFF. REP. 501 [hereinafter *Harvard/Onco-mouse Decision of 3 October 1990*].

animals as a per se category.¹⁹⁸ The EPO Board interpreted Article 53(b),¹⁹⁹ which purports to exclude plant and animal varieties from patentability, to bar only existing varieties, not new and distinct plants or animals engineered by biotechnology.²⁰⁰ With this decision, the EPO Technical Board of Appeal expanded the scope of patentable subject matter, moving in the direction of the U.S., which first recognized the right to patent living organisms in the 1980 case of *Diamond v. Chakrabarty*.²⁰¹

The Technical Board of Appeal stopped short of granting a patent for the Harvard mouse, however. It remanded the case to the Examining Division for further inquiry on the issue of whether the exploitation of the invention would be contrary to morality and *ordre public* as those terms are used in Article 53(a).²⁰² The Board's concern was two-fold. First, the genetic manipulation described in the claim caused the animal to be inordinately sensitive to carcinogenic substances and predisposed to develop tumors, which caused suffering. Moreover, the release of genetically-manipulated animals into the environment could have unintended and irremediable adverse effects.²⁰³ The Technical Board of Appeal also disagreed with the Examining Division's conclusion that patent law was not an appropriate means of dealing with moral concerns.²⁰⁴ In remanding the question of whether the patent should be barred by Article 53(a), the EPO Board articulated a test for "unacceptability" that involved "a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other."²⁰⁵

On remand, in determining whether a patent grant for the *Harvard/Onco-mouse* would violate Article 53(a) of the EPC, the Examining Division invoked this "unacceptability" test, weighing the interest of humankind in treating diseases against the need to protect the environment against the uncontrolled dissemination of unwanted genes and the need to avoid cruelty to animals.²⁰⁶ In

198. *Id.* at 510-11. The Board stressed that "the Examining Division was wrong in refusing the present application on the ground that Article 53(b) EPC excludes the patenting of animals as such." *Id.* at 511.

199. See *supra* note 109.

200. See *Harvard/Onco-mouse Decision of 3 October 1990*, *supra* note 197, at 510-11. The patent actually covered any non-human mammal with an inserted oncogene. See Tom Wilkie, 'Onco-Mouse' Spreads Confusion in Patent Office, INDEP. (London), Nov. 25, 1995, at 8.

201. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). At issue in *Chakrabarty* was whether a human-made, genetically engineered multicellular organism capable of breaking down crude oil qualified as patentable subject matter under U.S. law. *Id.* at 309. The organism, which was useful for controlling oil spills, was a bacterium developed by a microbiologist through cross-breeding of four different strains of oil-eating bacteria into one microorganism. *Id.* at 305 n.1. No naturally-occurring bacteria was capable of breaking down the components of crude oil. *Id.* at 305. The U.S. Supreme Court concluded that patentable subject matter was to "include anything under the sun that is made by man." *Id.* at 309 (quoting S. Rep. No. 1979, 82nd Cong., 2d Sess. at 5 (1952); H.R. Rep. No. 1923, 82nd Cong., 2d Sess. at 6 (1952)).

202. *Harvard/Onco-mouse Decision of 3 October 1990*, *supra* note 197, at 513.

203. *Id.*

204. *Id.*

205. *Id.* Although this balancing test appears to be incorporated into Article 6.2(d) of the Directive, see *supra* note 19, it is not evident that the Directive actually employs this same standard, see *infra* notes 267-70 and accompanying text.

206. See *Harvard/Onco-mouse Decision of 3 April 1992*, *supra* note 151, at 527-28.

1992, the Examining Division finally granted Harvard a patent on the Onco-mouse, holding that the transgenic mouse was not immoral or contrary to public policy, since the invention's usefulness in cancer research outweighed the actual harm suffered by animal research subjects and the potential harm to the environment.²⁰⁷ The Examining Division gave clear priority to curing the disease, stating that "[a]ny contribution to the development of new and improved human anti-cancer treatments is . . . a benefit to mankind and must be regarded as valuable and highly welcome by everybody."²⁰⁸ Moreover, the use of patented animals for conducting cancer research was likely to necessitate a smaller number of animals being needed for testing overall.²⁰⁹ With respect to possible risks to the environment, the Examining Division concluded that, since no release of the animals was planned, the only possible risk was that a malevolent scientist would bring about such a release intentionally or an inept scientist would do so inadvertently.²¹⁰ According to the Examining Division, "[t]he mere fact that such uncontrollable acts are conceivable cannot be a major determinant for deciding whether a patent should be granted or not."²¹¹ Thus, "in the overall balance," the Examining Division determined that the patented invention could not be considered immoral or contrary to *ordre public*.²¹²

Legal challenges to the Harvard mouse patent continue to the present day in the E.U. When the EPO announced in 1992 that it intended to approve the Onco-mouse patent application, protests arose throughout Europe. More than two hundred organizations, whose members include animal welfare activists, environmentalists and religious adherents, combined to support seventeen oppositions. Most of these oppositions rely on the argument that the patent is inconsistent with Article 53(a) of the EPC.²¹³ In February 1993, under pressure from these groups, the European Parliament revoked the patent and banned further animal patenting until a formal policy could be researched and established.²¹⁴ In deference to national law, this revocation was non-binding, resulting in diverging national laws.²¹⁵ At this writing, the outcome of the opposition pro-

207. See *id.* at 528. Notably, in *Harvard/Onco-mouse Decision of 3 April 1992*, see *id.*, the Examining Division declined to consider the general objection made by opponents to the patent that transgenic animals represent per se an unethical interference with evolution. The refusal of the Examining Division to examine this question presaged the enactment of the Directive, which expressly provides for patenting of transgenic animals in Article 3.2, see *supra* notes 98-99, 159 and accompanying text. The fact that the Directive does not permit per se objections to patenting plants and animals represents a significant limitation of the Directive, in the view of those opposed to such patents. See *infra* notes 273-80 and accompanying text.

208. *Harvard/Onco-mouse Decision of 3 April 1992*, *supra* note 151, at 527. The Examining Division also pointed out that legislation was in place in the contracting states to regulate animal testing. See *id.*

209. *Id.*

210. *Id.* at 528.

211. *Id.* The Technical Board of Appeal stated that such issues should be regulated by specialized government authorities, not the European Patent Office. See *id.*

212. *Id.*

213. See van de Kamp, *supra* note 68, at 236; Charles Arthur & Tom Wilkie, *Is This the Work of Man or Nature?*, INDEP. (London), Nov. 20, 1995, at 2.

214. Estelle J. Tsevdos et al., *Law and Nature Collide*, NAT'L L.J., June 16, 1998, at C1, C27.

215. *Id.*

ceedings has not yet been decided, and it is expected to be affected by the recent Directive.²¹⁶

b. Greenpeace Ltd. v. Plant Genetic Systems N.V.

In *Greenpeace Ltd. v. Plant Genetic Systems N.V.* ("PGS"),²¹⁷ the Technical Board of Appeal of the EPO clearly established that the "unacceptability" standard employed in the *Harvard/Onco-mouse* action could also apply to plant patents. The case arose from the EPO's 1990 grant of a patent to Plant Genetic Systems N.V. for a method of developing plants and seeds resistant to a particular class of herbicides. The method involved inserting into the cell genome a gene coding for an enzyme that protects the cells when they come into contact with the herbicide.²¹⁸ The patent was granted for genetically engineered plant cells and for all subsequent seeds and plants derived from the genetically altered cells. Greenpeace, an international nongovernmental organization concerned with environmental issues, filed an opposition to the patent in 1992 on the grounds that, *inter alia*, it violated Article 53(a) of the EPC.²¹⁹ The Opposition Division heard the action in 1992, and upheld the patent.²²⁰ Greenpeace immediately lodged an appeal, which the Technical Board of Appeal decided in February 1995.²²¹ After applying the "unacceptability" test, the Technical Board of Appeal held that none of the claims in the patent violated Article 53(a) of the EPC.²²² The "unacceptability" test in *PGS* is particularly significant because the Technical Board of Appeal used it to reverse the Opposition Division's 1993 decision, which had employed the "public abhorrence" test.²²³

216. Gavaghan, *supra* note 133, at 1188. According to Gavaghan, although "not officially acknowledged, it is widely believed" that the *Harvard/Onco-mouse* decision has been "on hold until the directive was passed." *Id.*

217. T 356/93 - 3.3.3, 1995 O.J. E.P.O. 545 (Technical Bd. of App.) [hereinafter *PGS*].

218. See Ingeborg Voelker, *Europe Won't Reverse Controversial EPO Ruling*, IP WORLDWIDE, July-Aug. 1997, LEXIS, General News Library, Magazines & Journals File.

219. See *supra* notes 132-37 and accompanying text.

220. See *Greenpeace Ltd. v. Plant Genetic Systems N.V.* (Opp. Div. 1992), reprinted in 24 INT'L REV. INDUS. PROP. & COPYRIGHT L. 618 (1993).

221. See Margaret Llewelyn, *Article 53 Revisited: Greenpeace v. Plant Genetic Systems NV*, 17 EUR. INTELL. PROP. REV. 506, 506 (1995); Voelker, *supra* note 218.

222. See *PGS*, *supra* note 217, ¶ 19. The Technical Board of Appeal did, however, reject two of the patent claims, those directed to the transgenic plants obtained by regenerating mature plants from the genetically modified plant cells, and the seeds derived from the plants, on the grounds that these claims embraced new plant varieties, which, along with animal varieties, were explicitly excluded from plant protection by Article 53(b) of the EPC. See Voelker, *supra* note 218. However, in light of a December 1999 EPO decision, an invention that is not confined to a particular plant variety is patentable under the EPC. See *European Patent Office*, at http://www.european-patent-office.org/news/pressrel/991220_e.htm (last modified October 13, 2000). With this decision, the EPO has tracked the language of the Directive with respect to plant varieties. See *supra* notes 104-12 and accompanying text.

223. See *Greenpeace Ltd. v. Plant Genetic Systems N.V.* (Opp. Div. 1992), *supra* note 220, ¶ 3.16. The Opposition Division in *PGS* had invoked the EPO GUIDELINES FOR EXAMINATION, see *supra* notes 136 and 150, stating in 1992 that, in most cases, it was not necessary to consider the question of morality, and that morality should be considered only where there was an application that would "universally be regarded as outrageous" that is, "only in rare and extreme cases." See *Greenpeace Ltd. v. Plant Genetic Systems N.V.*, *supra* note 220, ¶ 3.5.

In *PGS*, Greenpeace contended that the patent at issue violated the Article 53(a) morality provision of the EPC in several ways. First, because plant material is the common heritage of mankind, it would be immoral to allow any entity a monopoly over such material.²²⁴ Second, as paraphrased by the EPO, Greenpeace contended that the patent was immoral in that it sought to exercise “dominion . . . over the natural world.”²²⁵ Third, patenting of plant material could have disastrous environmental effects.²²⁶ Greenpeace based these arguments in part upon opinion polls in which a significant majority of those surveyed opposed the patenting of genetically engineered, herbicide-resistant plants as technical inventions.²²⁷ Fourth, Greenpeace argued that the Examining and Opposition Divisions that had considered *PGS* had failed to follow the “unacceptability” standard established in the *Harvard/Onco-mouse* case.²²⁸ In light of that case, Greenpeace demanded that, in deciding whether a patent grant violated Article 53(a) of the EPC, the Technical Board of Appeal must weigh the benefits to be gained from herbicide-resistant plant material against any environmental harm that might result from such an invention.²²⁹

In response to Greenpeace, *PGS* contended that the patent grant was proper for several reasons. First, although Greenpeace feared that the patent at issue would foster a monopoly, the negative character of the patent right²³⁰ meant that the patentee did not have an unfettered right to exploit the claimed invention, and was subject to all applicable government regulation.²³¹ Second, since no governmental regulation proscribed the invention, it followed that the patent was not universally disfavored, survey evidence notwithstanding. As noted by the patentee, many scientists believe that biotechnology is a useful tool for ensuring sufficient food supplies for the growing world population.²³² Third, with respect to environmental harm, appellants had not furnished sufficient evidence regarding alleged potential risks, such as the spreading of the herbicide-resistant gene to other plants or the transformation of crops into weeds.²³³ *PGS* asserted that, rather than reducing biological diversity, the patent grant would instead foster greater genetic variability by furnishing new genetic material.²³⁴ Finally,

224. See *PGS*, *supra* note 217, Summary of Facts and Submissions, ¶ IX(a). As set forth previously, such an argument would likely fail under the Directive. See *supra* note 159.

225. *PGS*, *supra* note 217, Summary of Facts and Submissions, ¶ IX(a).

226. Specifically, Greenpeace asserted that the invention at issue in *PGS* posed the following environmental risks: (1) the plants could themselves become weeds or pests and pass their genes on to other plants which, in turn, might become herbicide-resistant; (2) the release of the plants could disrupt the ecostructure and lead to a reduction in biodiversity; and (3) the patent could increase the use of herbicides, and lead to the creation of more genetically engineered plants. See *PGS*, *supra* note 217, Summary of Facts and Submissions, ¶ IX(c).

227. *Id.* ¶ 15.

228. The Examining and Opposition Divisions in *PGS* had applied the “public abhorrence” standard. See *id.* ¶ III(b). See also note 223 *supra*.

229. See *PGS*, *supra* note 217, ¶ IX(c) (stating that Greenpeace called for the application of a “balancing exercise” pursuant to “the guidance given” in the *Harvard/Onco-mouse* case).

230. See *supra* note 42.

231. Llewelyn, *supra* note 221, at 507.

232. *PGS*, *supra* note 217, Summary of Facts and Submissions, ¶ X(a).

233. *Id.* ¶ X(b).

234. Llewelyn, *supra* note 221, at 507.

with respect to the test to be applied in deciding whether the invention contravened morality, PGS referred to the EPO's Guidelines for Examination,²³⁵ which state that only inventions that can be regarded as "abhorrent" would be excluded under Article 53(a). PGS contended that the *Harvard/Onco-mouse* case had not established the "unacceptability" test as precedent to be applied in every biotechnology patent case, and in no way mandated the weighing of benefits and detriments for every invention. Rather, the result of such a balancing test was merely one factor to be considered with respect to a patent application. Furthermore, according to PGS, even under the "unacceptability" test, any risks posed by their invention would be handily outweighed by the potential benefits.²³⁶ As for the governmental organization that should conduct such a balancing test, PGS asserted that the regulatory institutions that determine whether genetically modified material can be exploited commercially were better suited than the EPO to weigh the risks of an invention against its advantages.²³⁷

In its February 1995 decision in the *PGS* case, the EPO Technical Board of Appeal implicitly denied PGS's assertion that the EPO was not well-situated to interpret terms such as morality and *ordre public*, by agreeing with Greenpeace's assertion that "patent offices are placed at the crossroads between science and public policy"²³⁸ and by proceeding to consider the morality of the *PGS* invention. The EPO stated that, since there was no pan-European definition of morality or *ordre public*,²³⁹ it would examine each particular invention on its own merits in order to assess whether it constituted an exception to patentability under Article 53(a) of the EPC.²⁴⁰ The Technical Board of Appeal also criticized the survey evidence submitted by Greenpeace, stating that it was not representative of attitudes prevalent in society. Indeed, the results of the survey undertaken in Sweden were skewed, because the only participating group, farmers, was the one most likely to be harmed by the patent grant.²⁴¹

After declaring itself competent to evaluate the morality of an invention, the Technical Board of Appeal then considered the transgenic plant at issue, treating separately the questions of morality and *ordre public*.²⁴² With respect to the morality of the invention, the Technical Board of Appeal held that "plant biotechnology per se cannot be regarded as being more contrary to morality than traditional selective breeding" since "both traditional breeders and molecular biologists are guided by the same motivation, namely to change the property of a plant by introducing novel genetic material into it in order to obtain a new and,

235. See *supra* note 150.

236. *PGS*, *supra* note 217, ¶ X(b); Llewelyn, *supra* note 221, at 507-08. Although PGS also asserted that a regulatory government organization, rather than the EPO, ought to engage in such a weighing process, the EPO implicitly recognized its own authority to consider morality and *ordre public* when evaluating a patent grant. See *PGS*, *supra* note 217, ¶ 13.

237. *PGS*, *supra* note 217, ¶ X(b); Llewelyn, *supra* note 221, at 507-08.

238. *PGS*, *supra* note 217, ¶ 18.3. The EPO recognized that it shared this authority with "an increasing number of other authorities and bodies." *Id.*

239. *Id.* ¶ 4.

240. *Id.* ¶ 13.

241. *Id.* ¶ 15.

242. *Id.* ¶ 16.

possibly, improved plant.”²⁴³ The main difference between genetic engineering techniques and traditional breeding is that the former allows “a more powerful and accurate control of genetic modifications.”²⁴⁴ The Board then held that the patented invention would violate Article 53(a) only if used for destructive purposes.²⁴⁵ In the view of the Technical Board of Appeal, none of the claims of the patent, which related to the process of producing plants and seeds that are protected from weeds or fungal diseases, as well as products such as plant cells, plants, and seeds themselves, was tantamount to an actual misuse or destructive use of plant biotechnology, in light of “conventionally accepted standards of conduct of European culture.”²⁴⁶ Thus, the invention at issue in *PGS* was not barred by the morality prong of the EPC’s Article 53(a).

The Technical Board of Appeal next considered the question of public policy, stating that the patent at issue would indeed be contrary to *ordre public* if its exploitation would be likely to “seriously prejudice the environment.”²⁴⁷ According to the Board, evidence that the exploitation of the invention would seriously prejudice the environment must be “sufficiently substantiated at the time the decision to revoke the patent is taken,”²⁴⁸ and that “[i]t would be unjustified to deny a patent under Article 53(a) [of the] EPC merely on the basis of **possible, not yet conclusively-documented hazards**.”²⁴⁹ The Board then held that since Greenpeace had not proved conclusively²⁵⁰ that any harm would result from exploitation of the subject matter at issue, the *ordre public* prong of Article 53(a) of the EPC did not preclude the Board from granting *PGS* a patent for its invention.²⁵¹ Thus, Article 53(a) of the EPC did not bar patentability, since none of the claims of the patent at issue contravened *ordre public* or morality.²⁵²

While the Board in *PGS* applied the more stringent “unacceptability” test as opposed to the “public abhorrence” standard set forth in *Lubrizol* and *Relaxin*, in *PGS* the Board deviated somewhat from the balancing test applied in *Harvard/Onco-mouse*. In *PGS*, the Board decided that “since no sufficient evidence of actual disadvantages has been adduced, the assessment of patentability with regard to Article 53(a) EPC may not be based on the so-called ‘balancing exercise’ of benefits and disadvantages,” as had been done in the *Harvard/Onco-mouse* action.²⁵³ The Board emphasized that the “balancing exercise” performed in that decision was “not the only way of assessing patentability with

243. *Id.* ¶ 17.1.

244. *Id.*

245. *Id.*

246. *Id.* ¶ 17.3. See *supra* note 191 regarding the distinction among patents on processes, products and the useful application of such products.

247. *PGS*, *supra* note 217, ¶ 18.

248. *Id.* ¶ 18.5. The Board stated that “[t]his view is consistent with the requirement that the exceptions to patentability under Article 53(a) [of the] EPC have to be narrowly construed.” *Id.* See *supra* note 150.

249. *Id.* ¶ 18.7.

250. The Board made it evident that Greenpeace bore the burden of proof as to environmental harm. See Llewellyn, *supra* note 221, at 509.

251. See *PGS*, *supra* note 217, ¶ 18.7.

252. See *id.* ¶ 18.8.

253. *Id.*

regard to Article 53(a) EPC, but just one possible way, perhaps useful in situations in which an actual damage and/or disadvantage (eg [sic] suffering of animals as in [the *Harvard/Onco-mouse* case]) exists.”²⁵⁴ Thus, in the most recent case decided under Article 53(a) of the EPC, the Technical Board of Appeal applied the “unacceptability” test, while proclaiming that this test was just one possible, but by no means exclusive, vehicle for assessing patentability.

c. Analysis of the Case Law Under Article 53(a) of the EPC Highlights the Difficulty of Harmonization Under the Directive

As the foregoing review of EPO decisions under Article 53(a) of the EPC demonstrates, the analogous Article 6 morality provision will hamper harmonization, the Directive’s primary goal. Strikingly, harmonization will remain elusive even though the Member States will have nearly identical morality provisions in their respective patent laws, as a result of their membership in the EPC. As mentioned previously, all of the E.U. Member States, as signatories to the EPC, have already enacted legislation modeled after Article 53(a) of that convention.²⁵⁵ Because Article 6 of the Directive derives nearly verbatim from Article 53(a) of the EPC,²⁵⁶ most Member States will not need to change the morality provisions in their national laws in order to comply with the Directive’s requirement²⁵⁷ that their patent laws be in accordance with the Directive.²⁵⁸ Thus, the conflicting interpretations under Article 53(a) of the EPC are likely to hound the Directive as well.

The major barrier to harmonization under Article 6 of the Directive is that the conflicting case law leaves in doubt whether the “public abhorrence” or the “unacceptability” test will apply.²⁵⁹ In two cases decided by the EPO in 1992, the Opposition Division applied the more lenient “public abhorrence” test for plants in *Lubrizol*,²⁶⁰ while the Technical Board of Appeal employed the stricter “unacceptability” standard for mice that had been bred to be susceptible to cancer in *Harvard/Onco-mouse*.²⁶¹ Based on this, one might assume that a more lenient test might be applied to plants, and a stricter one to situations where animals would be subject to pain. In fact, the Opposition Division’s suggestion in *PGS* that the tests would be applied this way²⁶² was roundly criticized by scholars²⁶³ until it was reversed by the Board two years later.

254. *Id.*

255. See *supra* notes 146-49 and accompanying text.

256. See *supra* text accompanying notes 116-17 and 132-37.

257. See *supra* note 124 and accompanying text.

258. See *supra* notes 146-49 and accompanying text.

259. See *supra* Part III.B.

260. See *supra* Part III.B.1.a.

261. See *supra* Part III.B.2.a.

262. *Greenpeace Ltd. v. Plant Genetic Systems N.V.* (Opp Div. 1993), *supra* note 220, ¶ 3.7.

263. See Lionel Bently, *Sowing Seeds of Doubt on Onco Mouse: Morality and Patentability*, 5 KING’S COLLEGE L.J. 188, 188 (“The distinction developed by the Opposition Division [in *PGS*], that the *Onco Mouse* case is confined to situations involving animals which will inevitably be subject to pain . . . is supported neither by the *Onco Mouse* decision itself nor the structure of the E.P.C. . . . [T]here is no reason therefore to suppose that [Article 53(a)’s] relevance is confined to inventions concerning animals.”).

To further confuse matters, the EPO Opposition Division in 1994 applied the more lenient “public abhorrence” test with regard to patenting a DNA fragment encoding a human protein in the *Relaxin* case,²⁶⁴ while in 1995 the Technical Board of Appeal in *PGS* employed for transgenic plants the stricter “unacceptability” test.²⁶⁵ Although one might construe from these cases that the Examining and Opposition Divisions will apply the more lenient “abhorrence” test, while the Technical Board of Appeal will implement the stricter “unacceptability” test, there is no logic to such a system.²⁶⁶ In truth, it is nearly impossible to determine at this point which test will apply when assessing the patentability of biotech inventions.

The Directive does not resolve the confusion as to whether the “public abhorrence” or “unacceptability” standard will be applied, even though, at first glance, a particular provision might seem to settle this question. Article 6.2(d) of the Directive denies patent protection on moral grounds for “processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”²⁶⁷ While this language might seem to indicate that the *Harvard/Onco-mouse* balancing test should be applied,²⁶⁸ at least in cases challenging the patentability of genetically modified animals on moral grounds, it is not clear whether the Directive does indeed advocate the use of this test. As noted by one European scholar, the phrase “likely to cause . . . suffering” introduces ambiguity. It could mean that any pain caused to a research animal will instantly render an invention abhorrent, or, alternatively, that the level of pain incurred by the animal is weighed against the expected medical benefit in order to assess whether the invention is publicly acceptable.²⁶⁹ Increasing the ambiguity inherent in the Directive’s language is the removal from the Directive of a Recital that had appeared in an earlier version, and which pointed to the adoption of the *Harvard/Onco-mouse* “unacceptability” test.²⁷⁰

Thus, it is unclear which of the morality standards emerging from the EPO case law, the “public abhorrence” or the “unacceptability” test, is supported by the Directive. This failure of the Directive to provide any further guidance re-

264. See *supra* Part III.B.1.b.

265. See *supra* Part III.B.2.b.

266. See Bently, *supra* note 263, at 189 (stating that “Article 53(a) is a criterion of patentability and therefore equally applicable at the examination (at the E.P.O. or in national offices), opposition (at the E.P.O.) and revocation (at national offices or in court) stages”).

267. Directive, *supra* note 3, art. 6.2(d), at 19.

268. See *supra* note 205 and accompanying text.

269. See Amanda Warren, *A Mouse in Sheep’s Clothing: The Challenge to the Patent Morality Criterion Posed by ‘Dolly’*, 20 EUR. INTELL. PROP. REV. 445, 445-46 (1998).

270. See 1992 Committee Report, *supra* note 45, at 9 (proposing insertion of language into the Directive requiring “a comparative assessment in which the usefulness of the invention on the one hand and any risks arising from it on the other, together with any objections arising in terms of fundamental legal principles shall be taken into consideration” and providing that “[i]nventions whose subject matter is animals which, owing to the phenotype or their genetic constitution, cannot be kept under adverse effects on their health or which are unnaturally interspecific, shall at all events be deemed incompatible with public order and consequently unpatentable”) (emphasis added).

garding the interpretation of the Article 6 morality provision impedes its goal of harmonization.

IV.

THE DIRECTIVE HAS LIMITED UTILITY FOR PRESERVING THE RIGHTS OF MEMBER STATES TO CONSIDER MORALITY WHEN GRANTING A PATENT

Another stated goal of the Directive is to preserve the ability of the Member States to consider morality when determining whether to grant a patent.²⁷¹ Article 6 embodies the compromise reached between supporters of the biotech industry, who opposed the inclusion of a morality provision in patent law, and the Greens, who battled for the insertion of Article 6 in the Directive. However, examination of Article 6 leads to the conclusion that the Directive does not provide a significant method of protecting morality, a point upon which, ironically, both opponents and proponents of patents on life forms agree.²⁷²

271. See *supra* notes 9-10 and accompanying text.

272. It should be noted that these two groups cite different reasons for deeming the Article 6 morality/*ordre public* provision ineffective. Opponents of patents on life forms decry the Directive for failing to protect morality sufficiently. See *infra* Part IV.A. Conversely, those in favor of broad patent protection for biotech inventions cite the arguments of scholars who contend that the inclusion of any morality provision in patent law, no matter how carefully drafted, is by definition superfluous, since the grant of a patent by an E.U. Member State does not authorize the patent holder to implement his or her invention, but simply allows the holder to prohibit third parties from exploiting that invention for industrial and commercial purposes. See, e.g., ARMITAGE & DAVIS, *supra* note 150; Crespi, *supra* note 168, at 434-35; Schatz, *supra* note 25, at 11-16. Even the EPO has in the past espoused the view that patent law is not the proper vehicle for assessing morality, although this decision has been reversed. See, e.g., *Harvard/Onco-mouse Decision of 14 July 1989*, *supra* note 193, at 11 (stating that "the patent law is not the right legislative tool for regulating problems which may arise" with respect to the morality of an invention). Every invention, whether patented or not, is of course subject in each Member State to a broad array of existing legislation and regulations that determine directly whether scientific, technical or medical practice should be prohibited in the interests of public health and safety, environmental protection, animal welfare, the preservation of genetic diversity, and compliance with ethical standards. Indeed, this view is explicitly recognized in Recital 14 of the Directive, which provides that "[w]hereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes," therefore:

substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards.

Directive, *supra* note 3, ¶ 14, at 14. Since such legislation already restricts or prohibits the use of certain inventions and controls the way research is conducted in the Member States, these scholars contend that it is inappropriate for those opposed to the biotechnology industry to use patent law as a way to achieve their political ends, via the inclusion of an ethical provision in the Directive. See ARMITAGE & DAVIS, *supra* note 150; Crespi, *supra* note 168, at 434-35; Schatz, *supra* note 25, at 11-16. By the same token, the refusal of a patent application on moral grounds does not mean that the invention cannot be exploited. Instead, the invention is merely in the public domain, and, as such, can be used by anyone. Thus, according to this view, patent law is entirely superfluous in preventing any abuses or risks that a given biotechnological invention would incur. Rather, the concepts of *ordre public* and morality will be rooted in already existing legal and moral codes, which will vary among the Member States. For this reason, Article 53(a) of the EPC and the corresponding national provisions are hardly ever used in practice. See Schatz, *supra* note 25, at 12.

A. Limited Efficacy of the Directive With Respect to Protecting Morality

First, the morality provision of the Directive excludes entirely objections in principle, under either the stricter “unacceptability” test or the more lenient “public abhorrence” test. For example, opponents of patents on life forms cannot object to such patents per se, in light of Article 3.1 of the Directive, which provides that “inventions which are new, which involve an inventive step, and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.”²⁷³ Accordingly, Article 6 does not ensure a comprehensive moral assessment, since it excludes the consideration of the moral and ethical beliefs of those vehemently opposed to patents on life forms generally. Certainly, there is something incongruous about granting E.U. citizens legal standing under the Directive to challenge biotech patents on the grounds of morality and/or *ordre public*,²⁷⁴ while at

In response, other scholars have declared that the principle function of a morality provision in patent law is to deny the imprimatur of the state to “immoral” biotechnological inventions. A particularly compelling statement of this idea was articulated by Cornish, who declared that:

[t]he state, as granting authority, cannot disclaim responsibility for the inventions for which it grants protection. It cannot hide behind the negative character of the patent right in order to avoid deciding whether a particular idea is inherently too repellant or dangerous to deserve this form of incentive. The power to refuse a patent on grounds of morality or public policy may need to be used cautiously. It is an appropriate step only where all the significant uses of the information are objectionable, and not only where some are. But the objection is rightly contained in the law and courts should not interpret it out of existence.

See CORNISH, *supra* note 3, at 195. See also Bently, *supra* note 263, at 190 (stating that “to ignore the morality question is to provide incentives to direct investment towards immoral and dangerous inventions (and possibly away from positive ones)”). But cf. Schatz, *supra* note 25, at 12 (“The purpose of Art. 53(a) EPC is to prevent the impression being given that an invention whose exploitation would be contrary to legal fundamentals or offend the decency of any reasonable person bears the seal of state approval. More than that it will and can not do.”).

In this author’s view, with the passage of the Directive, the morality/*ordre public* provision in patent law can no longer be considered superfluous. Because the Directive requires Member States to provide more aggressive patent protection, see *supra* notes 89-91 and accompanying text, and *infra* notes 276-80 and accompanying text, Member States are likely to resort to the Directive’s Article 6 in order to preclude patents on certain life forms. For example, now that Article 5 of the Directive provides for the patenting of material of human origin, which is strongly opposed by many E.U. Member States, see *supra* note 20 and accompanying text, the morality provision is likely to be used to avoid the obligation to provide patent protection for such inventions. See Andrew Scott, *The Dutch Challenge to the Bio-Patenting Directive*, 21 EUR. INTEL. PROP. REV. 212, 215 (1999) (noting that the *ordre public* or morality doctrine might be invoked by Member States wishing to avoid patenting of material of human origin). Such is already the case in France, which amended its Intellectual Property Code by Law No. 94-653 on July 29, 1994 so as to declare unpatentable “the human body, its parts and products and the knowledge of the entire or partial structure of the human gene, as such, . . . as inventions, the publication or exploitation of which would be contrary to *ordre public* or morality.” Joseph Straus, *Patenting Human Genes in Europe - Past Developments and Prospects for the Future*, 26 INT’L REV. INDUS. PROP. & COPYRIGHT L. 920, 922 n.8 (1995).

273. Directive, *supra* note 3, Article 3.1, at 18. See also note 159, *supra*.

274. E.U. citizens, unlike their U.S. counterparts, possess legal standing to challenge the morality of biotech inventions, under both the Directive and the EPC. See Breffni Baggot, *Legislating a Transgenics Revolution*, INTEL. PROP. MAG., May 1998, LEXIS, General News Library, Magazines & Journals File. See also *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991) (denying a U.S. animal rights group standing to challenge the U.S. Patent and Trademark Office’s (PTO) Notice of April 7, 1987, regarding the PTO’s intent to recognize the patentability of animals).

the same time precluding such a proceeding if it is based on opposition to life patents per se. Indeed, those groups most likely to mobilize and finance such a legal action often oppose life patents on absolute terms.

As a consequence of this limitation of the Directive, the Netherlands, which strictly circumscribes the patenting of biological material,²⁷⁵ brought an action against the European Parliament demanding annulment of the Directive on several grounds.²⁷⁶ While the Netherlands has challenged the Directive on procedural grounds,²⁷⁷ the underlying purpose of this suit is to oppose the E.U.'s enactment of a Directive that prohibits the Netherlands from maintaining its traditional opposition to life patents per se,²⁷⁸ and instead creates substantive rights beyond those previously available in national law.²⁷⁹ Some European scholars agree that the Directive does indeed create new rights, and, as mentioned previously, one has suggested that, with the Directive, "E.U. institutions are pursuing the goal not only of harmonising intellectual property legislation, but also, and at least as vigorously, of strengthening it at the same time."²⁸⁰

A second shortcoming of Article 6 is that, even if the stricter "unacceptability" test is used, it can be argued that the public benefit to be gained by an invention is not an appropriate yardstick by which to determine the morality of an invention, especially when the subject matter of the invention is a living creature. As one scholar noted with respect to the application of the morality principle in the *Harvard/Onco-mouse* case:

[i]t is surely an indictment of the importance placed by the EPO on the assessment of the issue of morality that the only way it seems able to address the issue of morality is by looking at factors which would seem to be more relevant to one of the granting criteria and which do not address properly any true question of what is morally correct.²⁸¹

275. See Bostyn, *supra* note 59, at 14 n.61 (stating that the Dutch government has "often held, in contradiction to the text of the Dutch Patent Act . . . , that plants are not patentable"), at 24 n.18 (describing Article 3 of the Dutch Patent Act of 1995, which provides that "animals can only be patented in very specific circumstances, i.e. if a licence has been granted for specific types of research pursued on these animals").

276. Case C-377/98, *Netherlands v. Parliament*, 1998 O.J. (C378) 13, was brought before the European Court of Justice in October 1998. Italy has since joined the case as well. See *Netherlands Files Suit to Cancel EU Patenting of Plants and Animals*, AGENCE FRANCE PRESSE, Oct. 19, 1998, LEXIS, World News Library, European News Services File; Scott, *supra* note 272, at 212. The Netherlands had been the only Member State to vote against the Directive, although Belgium and Italy abstained. See Patrick Farrant & Vicki Salmon, *Netherlands Seeks End to EU Biotech Directive*, IP WORLDWIDE, July-Aug. 1999, LEXIS, General News Library, Magazines & Journals File.

277. See Case C-377/98, *Netherlands v. Parliament*, 1998 O.J. (C378) 13. See also Scott, *supra* note 272 (describing the grounds for the Netherlands's challenge to the Directive).

278. See *supra* note 275 and accompanying text.

279. See *supra* note 91 and accompanying text.

280. *Id.* It should be noted that, although the Directive does not explicitly establish a maximum limit on ethical review that Member States may not exceed, an individual Member State opposed to life patents, such as the Netherlands, will not be able to eviscerate entirely its obligations under the Directive to provide national patent protection for biotechnological inventions by simply declaring that all controversial biotechnological inventions are counter to *ordre public* and morality. See *supra* note 130 and accompanying text.

281. Margaret Llewellyn, *Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States*, 16 EUR. INTELL. PROP. REV. 473, 478 (1994). The

This scholar declared that the *Harvard/Onco-mouse* decision did not appear “to be addressing any issue of morality, but merely to be applying one expedient definition for the purposes of justifying giving one company the right to commercially exploit an animal,” while conceding that “[i]t is difficult to say how morality should be defined in relation to a system which has to be applied in a practical sense.”²⁸²

Third, even if opponents of patents on life forms were to embrace the *Harvard/Onco-mouse* “unacceptability” standard, which requires “a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention’s usefulness to mankind on the other,”²⁸³ the E.U. would have to confront further procedural and substantive issues in order to determine which inventions are a public benefit and which are not. With respect to the process of reaching such a decision, the question arises whether the balancing test should be performed at the time of the patent application. If so, the E.U. must determine whether such a showing is to be left solely to the inventor, or, if other interested parties are to be consulted, who they are and at what point they are to be involved. Alternatively, the weighing of the possible advantages of an invention against its potential for harm could instead be addressed only after the patent grant has taken place, when the opponents of the patent dispute its validity.²⁸⁴ As noted by one scholar, “[i]f this latter is the case then it is difficult to justify the argument of weighing benefit against suffering if the only time the issue is looked at is when objectors to the patent are able to finance an opposition.”²⁸⁵

Further complications of the “unacceptability” standard arise in the form of ambiguous substantive guidelines. Consensus has yet to be reached throughout the E.U. as to what sort of benefits flowing from an invention are weighty enough to tip the balance in favor of a finding of patentability. In the *Harvard/Onco-mouse* case, the Examining Division allowed the patent on the grounds that it would be tantamount to immorality to deny it,²⁸⁶ since to do so would discourage the patent holders from carrying out further research and marketing any resulting drugs useful for cancer treatment.²⁸⁷ The Examining Division’s decision comports with the prevailing view among E.U. citizens, who generally

granting criteria to which Llewelyn refers are novelty, nonobviousness and usefulness. See *supra* note 97 and accompanying text.

282. Llewelyn, *supra* note 281, at 478. This view fails to recognize, however, the competing ethical theory of utilitarianism, which, as expressed by Jeremy Bentham, one of its most influential proponents, states that a good or moral act is one that results in the greatest happiness for the greatest number. DAVID BAUMGARDT, *BENTHAM AND THE ETHICS OF TODAY* 171 (1952). Arguably, transgenic plants and animals that solve problems such as human hunger and disease could be considered moral and ethical under this theory.

283. See *supra* note 205 and accompanying text.

284. Llewelyn, *supra* note 281, at 479.

285. *Id.*

286. The Examining Division held that “[t]he provision of a type of test animal useful in cancer research and giving rise to a reduction in the amount of testing on animals together with a low risk connected with the handling of the animals by qualified staff can generally be regarded as beneficial to mankind.” See *Harvard/Onco-mouse Decision of 3 April 1992*, *supra* note 151, at 528.

287. See *supra* Part I.B.

favor biotechnological development of pharmaceuticals.²⁸⁸ However, another issue that arises under the *Harvard/Onco-mouse* balancing test is whether food production is a significant enough public benefit to outweigh harm to animals.²⁸⁹ Even though such a question is likely to be answered affirmatively by developing nations,²⁹⁰ one wonders whether increasing food production in developing nations will be the primary goal of biotechnology, or, rather, whether products such as meat with a lower amount of fat or cholesterol will instead be developed for wealthier nations. Moreover, given the resistance throughout the E.U. to genetically modified foods, such benefits may prove theoretical rather than actual, since there is no assurance that members of the public would indeed consume such food.²⁹¹

Thus, opponents of life patents fear that Article 6 of the Directive might prove inadequate to protect morality, even if the stricter “unacceptability” test suggested by the *Harvard/Onco-Mouse* case is implemented. Certainly, an examination of the four cases decided under Article 53(a) of the EPC,²⁹² on which Article 6 of the Directive is modeled nearly verbatim, suggests as much, since none of the inventions at issue was denied patent protection on moral grounds. In light of the Directive’s allusions to increasing patent protection,²⁹³ there is reason to believe that national patent offices will be just as likely as the EPO has been to favor strong patent protection for biotechnological inventions, leading to further schisms with Greens and other opponents of patents on life forms.

V.

PROPOSED REVISIONS TO THE E.U. DIRECTIVE ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

In its efforts to achieve harmonized patent protection while simultaneously preserving the ability of Member States to consider morality when evaluating a patent application, the Directive surpasses the EPC, in that it attempts to create and *enforce* a consistent level of biotechnology patent protection throughout the E.U. Nonetheless, the Directive cannot fully realize these dual goals until it overcomes obstacles presented by the Article 6 morality provision. First, Article 6 will impede harmonization until the E.U. clarifies whether the “public abhorrence” or the “unacceptability” test ought to be applied in the assessment of patent applications. Second, the citizenry will not embrace Article 6 as an adequate protection for morality unless certain changes are made either in the Directive or in the understanding of which vision of morality will prevail. Although the Directive was nearly ten years in the making, it nonetheless requires further revision before it will have its intended impact.

288. See generally George Gaskell et al., *Worlds Apart? The Reception of Genetically Modified Foods in Europe and the U.S.*, 285 *SCIENCE* 384 (1999).

289. See *supra* note 81 and accompanying text.

290. See Declan Butler, *Biotech Industry Seeks ‘Honest Brokers,’* 398 *NATURE* 360, 360 (1999) (noting that some developing nations have “attacked opposition to gene technology as a northern luxury”).

291. See *id.* (noting that European consumers are generally wary of genetically modified foods).

292. See *supra* Part III.B.

293. See *supra* notes 89-91, 276-80 and accompanying text.

A. *Achieving Harmonization Through Clarification of the Morality Test*

Most important, the Directive must be altered so as to apply a consistent moral standard, "public abhorrence" or "unacceptability." Member States' national courts and patents offices, drawing upon the inconsistent case law applied by the EPO in the four cases assessing inventions on the grounds of morality and *ordre public*, will otherwise be confounded as to which test is appropriate. The E.U. ought not to wait for case law to interpret which test will be applied, as this will simply delay harmonization. Moreover, it is the role of the citizenry, acting through its elected legislative body, not the courts, to define how morality is to be assessed.

A close reading of the language of the Directive, specifically, Article 6.2(d), indicates that the Directive contemplates adoption of the *Harvard/Oncomouse* "unacceptability" test, at least for the highly controversial category of inventions involving transgenic animals. As stated, this standard calls for a balancing of the advantages of an invention against harm to the animal. There are several advantages to the implementation of such a test.

First, the "unacceptability" test acknowledges that an innovative technology's advantages are accompanied by a countervailing collection of dangers, not only to the well-being of any animals involved in experimentation, but also to society's moral and ethical standards, the environment, and public health and safety. Through the political debate surrounding the enactment of the Directive, citizens in the E.U. have demonstrated, if not an absolute consensus on such issues, an ardent desire to interject them into the public discourse and to carefully assess these potential risks, while simultaneously seeking to enhance the E.U.'s competitiveness in the biotechnology industry. In this way, the E.U. demonstrates a cultural approach fundamentally different from those of the U.S. and Japan, and E.U. law must reflect this viewpoint.

Second, as noted by several scholars, a state's denial of a patent to an invention deemed "unacceptable" functions to deny the state's imprimatur to an invention deemed to contravene morality or public policy. Just as in the U.S., where a court will refuse to enforce a racially discriminatory restrictive covenant burdening real property in order to deny the state's tacit acceptance of racial animus,²⁹⁴ so has the E.U. chosen to deny patent protection to certain biotech inventions in order to avoid the appearance of official governmental approval of such creations.

Finally, it is apparent from a review of past cases assessing the morality of biotechnological inventions that the EPO has felt pressure to declare such inventions morally acceptable. Of the four inventions opposed on moral grounds, none has ultimately been denied patent protection on this basis. Moreover, national courts and patent offices in the Member States have made virtually no use of the morality provisions incorporated in their own patent codes. Clearly, there is overwhelming pressure upon those charged with evaluating patents in the E.U. today not to thwart the struggling E.U. biotech industry as it races to keep

294. See *Shelley v. Kraemer*, 334 U.S. 1 (1948).

pace with its U.S. and Japanese counterparts. The morality criteria will not be interpreted in ways that interfere with patentability, regardless of what test is adopted. Therefore, the stricter "unacceptability" test should be applied to provide greater efficacy to the morality provision.

The "unacceptability" test is more difficult to administer than the alternative, however, since it is easier for a diverse group to agree on what is "abhorrent" than on what is merely "unacceptable." For this reason, the E.U. must further explicate the "unacceptability" test.

B. Attaining Adequate Protection of Morality Through Refinement of the "Unacceptability" Test

The "unacceptability" test used to administer the Directive's Article 6 morality provision requires some clarification in order for it to furnish proper guidance to the national courts and patents offices administering it. First, opponents of life patents per se may not be satisfied with the morality provision's efficacy in precluding such patents. Because the Directive employs language indicating that patent protection must be provided for biotechnological inventions under national patent law, it appears that a nation such as the Netherlands, which strictly circumscribes patents on life forms, cannot avoid the obligation to furnish patent protection for transgenic plants and animals. For this reason, as stated above, the Netherlands and Italy are presently pursuing a legal challenge to the Directive before the European Court of Justice. This case, commenced just after the Directive's enactment, challenges the extent to which the E.U. can require Member States to offer patent protection beyond that previously available under their national law. The Court has not indicated how or when it will decide this case, but the general opinion is that this suit will not diminish the patent protection instituted by the Directive. Thus, the Greens and others opposed to life patents may indeed be forced to accept that opposition to patent protection on life forms per se does not constitute a cognizable claim under the Directive.

Second, assuming that opposition to patents on life forms per se is not a tenable position under the Directive, the E.U. must clarify what types of inventions will be considered so "unacceptable" as to be unpatentable. In this vein, the Directive enumerates in Article 6.2 a representative sample of inventions that shall be considered unpatentable on the grounds of morality. Such lists should not inhere in legislation, however, because technology, and, to a lesser degree, cultural norms are constantly changing. The codification of rules in legislation which would attempt to establish categories of eternally immoral inventions is essentially impossible and impractical. Moreover, national courts do not possess particular expertise in assessing either the uses of technology or the moral and ethical views prevailing in society. The Commission's twelve-member European Group on Ethics in Science and New Technologies (EGEST), a supranational body created pursuant to the Directive, is more qualified to handle this task. The EGEST can then operate with flexibility, altering its assessments of morality and public policy to take account of technological innovations and

changes in social mores. The EGEST must be granted adequate resources to handle its broad mandate, which includes the review of a range of technological issues, including information technology and biotech.

Finally, although the EGEST is intended to be free from political and national interests, it ought to furnish E.U. citizens with the opportunity to make their views known during that body's deliberative process, possibly via a system of regional offices. Twelve individuals cannot render definitive decisions on ethics and morality without at least considering the conflicting views in society at large. At the present time, as stated previously, E.U. citizens cannot formally challenge, or lodge support for, a patent until it has been granted. Since the controversy concerning patenting living organisms shows no signs of abating, the Directive must encourage public dialogue, even if some constituencies remain opposed, either in whole or in part, to the Directive.

CONCLUSION

With the enactment of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, the E.U. has celebrated what it hoped would be the end of the arduous process of reconciliation between supporters of the E.U. biotech industry, on the one hand, and advocates of strict controls of patents on life forms, on the other. However, analysis of the Directive reveals that the Article 6 morality provision is likely to impede the Directive's dual goals. First, though the Directive mandates a minimum level of patent protection for biotech inventions, Article 6 is exceedingly vague as to the standard that will be applied in order to determine whether an invention ought to be denied patent protection on the grounds of immorality. Consequently, Article 6 will be subject to conflicting interpretations, thereby precluding its first stated goal: harmonization throughout the E.U. Member States. The Directive is also likely to prove inadequate with respect to its second stated goal, the preservation of the right of patent offices and courts in each Member State to deny patent protection to any invention deemed contrary to morality or public policy.

Thus, the enactment of the Directive is not the culmination of the debate over biotechnology patent law in the E.U., but is a starting point for future refinements and enhancements of the morality provision. The Directive must be amended so as to clarify which test of morality is to be applied by national courts and patent offices. In addition, language in the Directive enumerating particular inventions that must be considered immoral should be eliminated, so as to allow the EGEST, the supranational body charged with evaluating the ethics and morality of particular inventions, maximum flexibility in reaching its conclusions. Finally, E.U. citizens must be permitted to express their views to the EGEST as that body evaluates particular technologies. In this way, the Directive will at last achieve its twin goals of harmonizing E.U. patent law while protecting the uniquely European view of ethics and morality.