Notes

BUILDING A BETTER MOUSETRAP: PATENTING BIOTECHNOLOGY IN THE EUROPEAN COMMUNITY

I. INTRODUCTION

The Onco-mouse is a mouse that is genetically engineered to be susceptible to human cancer.[1] As such, the animal is a valuable tool for researchers studying the origins of human cancer and pursuing a treatment for the disease. For six years, however, the Onco-mouse was trapped in the flawed European Community (EC) patent system while a debate raged on the ethics of patenting a life form. It is apparent that the real victim of the inadequate EC patent system in this case was not the Onco-mouse or its inventor. Rather, the EC was the real victim as the Community goals of a common market and of global competitiveness in biotechnology atrophied while the ethical debate continued. Indeed, the EC was caught in a mousetrap of its own device.

Biotechnology is a global industry[2] that is well suited to the

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1. *See* U.S. Patent No. 4,736,866, 1089 Off. Gaz. Pat. Off. 703 (April 12, 1988) [hereinafter Onco-mouse patent]. The Onco-mouse patent covers "a transgenic nonhuman eukaryotic animal (preferably a rodent such as a mouse) whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal . . . which . . . increases the probability of the development of neoplasms (particularly malignant tumors) in the animal." *Id.* The mouse was a product of modern biotechnology produced using recombinant DNA techniques. Recombinant DNA technology allows direct manipulation of the genetic material of individual cells to control production of biological material. This technology is used to develop new organisms with special uses or to make existing products more efficient. *See, e.g.*, U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 4 (1984) [hereinafter COMMERCIAL BIOTECHNOLOGY]. For a more detailed discussion of the scientific techniques used in recombinant DNA, see Sean Johnston, Comment, *Patent Protection for the Protein Products of Recombinant DNA*, 4 HIGH TECH. L.J. 249, 251–54 (1989).

2. *See, e.g.*, TREVOR COOK ET AL., PHARMACEUTICALS, BIOTECHNOLOGY AND THE LAW 5 (1991). The main applications of biotechnology are in industries as diverse as health care, pharmaceutical, medical research, pesticides, fertilizers, and chemicals. *See id.*; *see also* U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 7–12 (1991) [hereinafter BIOTECHNOLOGY GLOBAL] (discussing the role of biotechnology in the

resources of the EC. The EC has strong research capacities in fields such as pharmaceuticals, which are typically commercialized by biotechnology.[3] However, research alone does not translate directly into marketable and profitable industrial applications.[4] A patent protection system is needed to shepherd innovation into application. Patent protection is a crucial link between research and commercial success because it stimulates innovation with the promise of reward.[5] The Commission of the European Communities (Commission) has said that "[t]he economic and social prosperity of the European Economic Community depends heavily on the growth and success of activities leading to innovation . . . closely allied with the use of the patents system."[6] Therefore, the goals of the EC of creating a common

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pharmaceutical, agricultural, chemical, and environmental protection industries); Joan O'C. Hamilton et al., *Biotech: America's Dream Machine*, BUS. WK., Mar. 2, 1992, at 66–73 [hereinafter *Dream Machine*] (discussing the economic growth potential of biotechnology in the pharmaceutical, agriculture, and chemical industries).

3. *See, e.g.*, Biotechnology in the Community: Communication from the Commission to the Council, COM(83)672 final/2-Annex at 12–13 (discussing "strategic significance" of biotechnology to the EC). For example, the European pharmaceutical industry provides one-third of worldwide pharmaceutical production. COOK ET AL., *supra* note 2, at 7. Europe represents over a quarter of the world market for such products, and it employs over 500,000 people in the industry, including 75,000 in research and development. *Id.* ("Europe's strengths in pharmaceutical and agriculture lend themselves to the adoption of biotechnology.").

4. *See generally* Biotechnology in the Community, COM(83)672 final (discussing fragmented Community efforts in biotechnology and the need for a more systematic approach to tap the benefits of biotechnology). A striking example of research that did not directly translate into commercial marketability involves patent protection for penicillin in the United Kingdom (UK). Although the UK led in scientific research, United States industry benefited because of more favorable patent protection. Joseph Straus, *The Development and Status of European Law*, *in* ANIMAL PATENTS: THE LEGAL, ECONOMIC & SOCIAL ISSUES 16, 17 (William H. Lesser ed., 1989). The United States was the victim of a similar experience involving Japanese commercialization of United States research in the areas of semiconductors and computers. *See, e.g.*, Peter G. Gosselin, *For Japan and the U.S., a Reversal of Fortune*, BOSTON GLOBE, Nov. 26, 1991, at 1, 8; *U.S. Industry Could Lose Ground to Japan by 2000 Unless Changes Made, Study Says*, Daily Rep. for Executives (BNA) at 95, May 15, 1992, *available in* LEXIS, Nexis Library, Omni File [hereinafter *Biotechnology 2000*]. Some commentators fear that the United States biotechnology industry could suffer a similar fate. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 39; BIOTECHNOLOGY 2000, *supra*. However, the EC is currently the most at risk of lagging behind permanently on the global level. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 19–21; COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 21.

5. *See* SHELDON KRIMSKY, BIOTECHNICS & SOCIETY: THE RISE OF INDUSTRIAL GENETICS 51 (1991) ("Patent law is built on a philosophy that patent protection must nourish innovation and not stifle it."); Alan R. Geraldi, Comment, *In His Image: On Patenting Human-Based Bioproducts*, 25 U.S.F. L. REV. 583, 592 (1991); *see also infra* note 48 and accompanying text (discussing the special importance of patents for biotechnology).

6. COMMISSION OF THE EUROPEAN COMMUNITIES, PATINNOVA '90: STRATEGIES FOR THE PROTECTION OF INNOVATION: PROCEEDINGS OF THE FIRST EUROPEAN CONGRESS ON INDUSTRIAL PROPERTY RIGHTS AND INNOVATION 217 (U. Tager & A. von Witzleben eds., 1991)

European market and of increasing international competitiveness[7] would be furthered by enhancing patent protection for the products of biotechnology in the Community. The Onco-mouse will serve as an example for the following discussion on how the EC can harness the potential of the rapidly growing European biotechnology industry[8] while managing the ethical concerns about patenting biotechnology.

The Onco-mouse first stimulated discussion in the scientific and legal communities[9] when the United States awarded a patent[10] on the mouse to a researcher at Harvard University in 1988.[11] That was the first patent ever granted on an animal.[12] Recently, Harvard was

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(comments of Jose Mota Maia, President of INPI, Ministry of Industry and Energy of Portugal). The Commission has stressed the "importance of modern biotechnology for the future of . . . the Community" and the "absence in the Community of a context supportive and encouraging for biotechnology." Biotechnology in the Community, COM(83)672 final at E2.

7. An essential goal of the EC was to create a common market among member states as well as a unified economic unit to compete on an international level. *See* TREATY ESTABLISHING THE EUROPEAN ECONOMIC COMMUNITY [EEC TREATY] art. 2.

8. Biotechnology is a set of biological techniques applied to existing industries. BIOTECHNOLOGY GLOBAL, *supra* note 2, at 3, 39. The biotechnology industry refers to an aggregate of many commercial applications of biotechnology. *Id.* at 31, 39. The economic promise of biotechnology has already been demonstrated in the United States. *See, e.g., Dream Machine, supra* note 2, at 66. For a discussion of the economic importance of patents analyzed from the American perspective, see Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 22–25 (1991); Donald F. Turner, *The Patent System and Competitive Policy*, 44 N.Y.U. L. REV. 450, 450–53 (1969).

9. *See infra* notes 68–72 and accompanying text (discussing the legislative reaction to the Onco-mouse patent and other applications of the scientific principles underlying the Onco-mouse); *see also* ANIMAL PATENTS: THE LEGAL, ECONOMIC AND SOCIAL ISSUES *passim* (William H. Lesser ed., 1989) (containing a collection of articles on the legal, economic, and social implications of animal patents); David Manspeizer, Note, *The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland*, 43 RUTGERS L. REV. 417 (1991) (reviewing the issues relating to animal patents both in the United States and in Europe); Marsha L. Montgomery, Note, *Building a Better Mouse—and Patenting It: Altering the Patent Law to Accommodate Multicellular Organisms*, 41 CASE W. RES. L. REV. 231 (1990) (discussing the legal response to the Onco-mouse in the United States).

10. A United States patent confers upon the patentee the right to exclude others from making, using, or selling the patented invention for seventeen years. *See* 35 U.S.C. § 154 (1988). After the limited monopoly is over, the public is free to use the invention. The United States Supreme Court has noted that without the patent system the inventor would "keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, the patent is granted." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) (citing United States v. Dubilier Condenser Corp., 289 U.S. 178, 186–87 (1933)). The principle of exclusion as a reward and incentive is the universal premise behind patent systems worldwide. *See, e.g.*, PAUL DEMARET, PATENTS, TERRITORIAL RESTRICTIONS, AND EEC LAW 3–8 (1978).

11. Onco-mouse patent, *supra* note 1, at 703.

12. *See, e.g.*, BIOTECHNOLOGY GLOBAL, *supra* note 2, at 214.

granted a patent in Europe[13] for the same Onco-mouse, prompting a debate in Europe[14] and the European Community.[15] That patent was granted after considerable debate and discussion in the European Patent Office (EPO).[16] Proponents of biotechnological patents see the Onco-mouse patent as a modest step toward achieving patent protection for beneficial biotechnology products, while opponents view this type of patent as an inappropriate and unethical encouragement of genetic engineering.[17]

This Note discusses the importance of enhancing legal protection for biotechnological patents in the EC and urges the enactment a Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions (Proposed Directive).[18] Part II outlines the reasons that reform of the EC patent system is necessary in the field of biotechnology. Part III introduces the Proposed Directive, which would enhance protection of biotechnological inventions, but which has been delayed by concerns over bioethics. Finally, Part IV urges enactment of the Proposed Directive, arguing that the ethical issues arising in conjunction with the Proposed Directive are misplaced in the patent system and are adequately addressed both by the EC regulatory system and by the Proposed Directive itself. In the end, it is clear that

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13. Patents are enforceable contracts only with the nation that grants the patent. *See* COOK ET AL., *supra* note 2, at 59. Therefore, to have a valid patent in multiple nations, the inventor must apply and get the patent approved in each nation. *See id.* This was the procedure that Harvard University followed to obtain a European patent for the Onco-mouse.

14. *See, e.g.*, Suzanne Perry, *Frankenstein and Hitler Loom Large as Europe Debates "Bioethics"*, Reuters, May 18, 1992, *available in* LEXIS, Nexis Library, Reuters File.

15. *See, e.g., Success for "Inventor" of a Mouse*, BUS. L. BRIEF, Jan. 1992, *available in* LEXIS, Nexis Library, Omni File; Suzanne Perry, *Decision to Grant Patent on "Harvard Mouse" Won't Stop EC Debate*, Reuters, Oct. 16, 1991, *available in* LEXIS, Nexis Library, Reuters File [hereinafter *EC Debate*]; *Genetically Engineered Mouse May be Patentable in Europe*, 40 Pat. Trademark & Copyright J. (BNA) 535 (Oct. 25, 1990).

16. *See* HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525 (Examining Div.), *acq.*, 1990 Eur. Pat. Off. Rep. 501 (Tech. Bd. App.), *rev'g & remand'g*, 1990 Eur. Pat. Off. Rep. 4 (Examining Div.); *Patenting the Harvard Mouse*, BUS. L. BRIEF, May 1991, *available in* LEXIS, Nexis Library, Omni file; *see infra* notes 75–85 and accompanying text (discussing the decisions of the Examining Division and the Technical Board of Appeal of the EPO regarding the patentability of the Onco-mouse).

17. *See generally* HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525, 526 (stating the position of the ECJ on the ethical questions involved, in view of the "extraordinary attention the present case has attracted from the public"); *EC Debate*, *supra* note 15 (discussing the effect of the European Patent Office decision to grant a patent on the Onco-mouse on efforts to afford animal inventions legal protection and on the ensuing public ethical debate).

18. Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, 1989 O.J. (C 10) 3 [hereinafter Proposed Directive].

passage of the Proposed Directive is a crucial step if the EC is to become competitive in the emerging global market of biotechnology.

II. THE NEED FOR REFORM OF BIOTECHNOLOGY IN THE EC

Enhanced biotechnology patent protection in the EC requires uniform protection for products throughout the member states.[19] Currently, differences exist in the legal protection afforded to biotechnological inventions in the respective member states which create barriers to trade and an effective internal market.[20] Unless these differences are minimized, free trade could be hampered as member states adopt conflicting legislation and policies.[21] The EC has already recognized that uniform protection of intellectual property is important for a unified common market.[22] Nevertheless, the EC must implement further intellectual property protection for biotechnological inventions in order to achieve the goal of a common market.

A. The Existing European Patent System

The EC currently operates under what is known as the European Patent Convention (EPC),[23] an agreement that has been signed by all EC member states except Portugal.[24] Article 52 of the EPC defines patentability in the European Community.[25] Specifically, Article 52(1) states that "European patents shall be granted for any inventions

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19. *See, e.g., id.* at 3–4.

20. *See id.*; *Legal Protection: Biotechnological Inventions*, INFO–92, Aug. 18, 1992, *available in* LEXIS, Europe Library, Alleur file.

21. *See* Proposed Directive, *supra* note 18, at 3.

22. Recognizing the importance of intellectual property to the biotechnology area, the EC recently strengthened patent protection for pharmaceutical products by extending the terms of such patents. *See* Council Regulation 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products, 1992 O.J. (L 182) 1, 1; *see also* Alan K. Palmer & Thomas C. Vinje, *The EC Directive on the Legal Protection of Computer Software: New Law Governing Software Development*, 2 DUKE J. COMP. & INT'L L. 65 (1992) (discussing recent EC software directive and intellectual property protection for high technology products).

23. Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 270 [hereinafter EPC]. The EPC is a procedural agreement that allows applicants to apply through the EPO to receive multiple national patents for each member state of the EPC. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 208.

24. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 208. The EPC also covers Austria, Liechtenstein, Norway, Sweden and Switzerland. *Id.*

25. EPC, *supra* note 23, art. 52, 13 I.L.M. at 285.

which are susceptible of industrial application, which are new, and which involve an inventive step."[26]

Subsequent provisions of the EPC narrow the broad language of potential patentability declared in Article 52(1). First, the EPC details with some clarity matter which does not have a sufficient "inventive step" to be patentable. Such materials include mathematical models, aesthetic creations, and presentations of information.[27] Next, categorical exclusions from the general rule of patentability are listed under Article 53.[28] Particularly relevant to this discussion, Article 53(b) excludes "plant or animal varieties" and "essentially biological processes" from patentability.[29] However, in contrast to the foregoing explanation of matter not rising to the level of an invention under Article 52, the terms "varieties" or "essentially biological" are not defined under Article 53 or elsewhere in the EPC.[30] While the Guidelines for Examination of Patents (Guidelines) issued by the EPO attempt to define these terms,[31] the Guidelines are not binding on the member states.[32] Thus, a lack of uniformity in patent protection

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26. *Id.* This is analogous to the patentability requirements in the United States, which require that an invention be a process, machine, manufacture, or composition of matter that is new, useful, and nonobvious. *See* 35 U.S.C. §§ 101–03 (1988).

27. EPC, *supra* note 23, art. 52(2), 13 I.L.M. at 285.

28. *Id.*, art. 53, 13 I.L.M. at 286.

29. *Id.* Article 53(b) of the EPC states: "European patents shall not be granted in respect of . . . (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof." *Id.*, art. 53(b), 13 I.L.M. at 286.

30. *See, e.g.*, Straus, *supra* note 4, at 24. *See generally* EPC, *supra* note 23, arts. 52–53, 13 I.L.M. at 285-86 (lacking definition of terms). These terms, however, are defined or interpreted outside the scope of the EPC. The drafters of the International Convention for the Protection of New Varieties of Plants defined "plant variety" as referring to a generic category of plants with a common characteristic to satisfy homogeneity and stability in their essential characteristics. International Convention for the Protection of New Varieties of Plants, Oct. 23, 1978, arts. 6(1)(a), 6(1)(c)–6(1)(d), 33 U.S.T. 2703, 2711–12 [hereinafter UPOV]. The EPO has previously interpreted "essentially biological" narrowly to grant protection for biological processes where human intervention plays a substantial role. *See* LUBRIZOL/Hybrid Plants, 1990 Eur. Pat. Off. Rep. 173, 178; *see also* Kevin W. O'Connor, *Patenting Animals and Other Living Things*, 65 S. CAL. L. REV. 597, 617 (1991) (human intervention must be greater than biological forces).

31. Chapter IV, Part C of the Guidelines for Examination at the European Patent Office regarding Article 53(b) states:

> The question whether a process is "*essentially biological*" is one of degree depending on the extent to which there is technical intervention by man in the process; if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded.

EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, ch. IV, ¶ 3.4 (1992) [hereinafter EPO GUIDELINES].

32. *See, e.g.*, EXXON/Alumina Spine, 1988 Eur. Pat. Off. Rep. 387, 391 ("The *Guidelines* . . . do not have the binding authority of a legal text."). In addition, the patent granted through

among member states is distinctly possible under the existing definitional system.[33]

B. The Exclusions Under the EPC Are Problematic

In addition to the ambiguities surrounding the key definitions discussed above, the Article 53 exclusions from patentability are problematic with regard to biotechnological patents for several reasons. First, as noted by the European Parliament (Parliament), "the patent system, when applied to living matter, must be adapted to the problems linked to the special nature of such matter."[34] In light of changing technology, the EC's international competitors have explicitly declared living matter and even animals to be patentable and have enacted special rules to deal with problems unique to patenting living matter.[35] However, under Article 53 of the EPC, only microbiological inventions[36] can be patented.[37] Some member states have responded to the inadequacies of the outdated EPC provisions in this area by enacting national laws to deal specifically with biotechnology.[38]

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the EPC offers limited protection to the applicant. *See* EPC, *supra* note 23, art. 138, 13 I.L.M. at 302. As stated in the Commission of the European Communities Memo on the Draft Directive, "A European Patent is granted, defined and revoked in applying rules of the EPC. . . . For all other purposes, such as the scope of protection, European patents represent patents with national effects, subject to national laws . . . ." Straus, *supra* note 4, at 20, *quoting* Commission of the European Communities Memo on the Draft Directive.

33. *See* Andrew J.A. Parkes, *The Significance of the European Patent Convention and the Community Patent Convention, in* INTELLECTUAL PROPERTY: PAPERS FROM THE I.C.E.L. CONFERENCE, APRIL 1989, at 51, 55 (Mary Robinson, ed. 1989). *But see* Straus, *supra* note 4, at 20 (national courts of Germany, Sweden, and the United Kingdom have followed the EPO practice).

34. Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions Approved with the Following Amendments, 1992 O.J. (C 125) 183, 183 (Amendment No. 3) [hereinafter Amended Proposal].

35. *See infra* notes 62–74, 100 and accompanying text.

36. *See* EPC, *supra* note 23, art. 53, 13 I.L.M. at 286. Patentable microbiological inventions include the following: (1) micro-organism, (2) process to make a micro-organism, (3) process using a micro-organism, (4) products obtained from microbiological process, (5) DNA/RNA molecules or subcellular units. EPO GUIDELINES, *supra* note 31, ch. IV, ¶ 3.5–3.6.

37. EPC, *supra* note 23, art. 53, 13 I.L.M. at 286. The EPC adopted the prevailing intellectual property conventions, such as the Strasbourg Convention, when the EPC was ratified. *See* Straus, *supra* note 4, at 18. The Strasbourg Convention made it mandatory to protect microbiological processes and their resulting products. *See* Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, Nov. 27, 1963, art. 2(b), Europ. T.S. No. 47. Therefore, there was no consideration of new scientific developments such as the distinction between microbiology and macrobiology. *See* Straus, *supra* note 4, at 18.

38. "New legislation specific to the regulation of biotechnology [has been] enacted in Denmark, Germany, and the United Kingdom." BIOTECHNOLOGY GLOBAL, *supra* note 2, at 174.

Second, the interpretation of the plant and animal varieties exclusion may be problematic. The basis of this exclusion was that, under the International Convention for the Protection of New Varieties of Plants (UPOV), another method exists besides patenting through which to obtain legal protection for plant varieties. The Convention declared that plant varieties were entitled either to a special title of protection or to a patent, but not both.[39] Unlike plants, however, animals do not have protection outside the scope of the EC patent system, under the UPOV or any other convention. Nonetheless, this exclusionary provision was invoked in the *HARVARD/Onco-mouse* decision by the Examining Division, which considered the Onco-mouse to be a type of animal variety.[40]

C. Inconsistency Under the Current EPC System

The member states of the EC also have inadequate guidance on patenting biotechnological inventions because of inconsistent EPO decisions. Two prior decisions by the EPO Technical Board of Appeal indicate a propatent protection attitude[41] and seem initially to forecast fundamental change to the patent system.[42]

In the *Hybrid Plants/LUBRIZOL* decision, the Technical Board of Appeal narrowly construed one of the stated exceptions to the general rule of patentability.[43] Also, in the *CIBA-*

In addition, where possible, existing legislation has been amended, such as in The Netherlands. *See* John Hodgson, *Dutch Regulations Now in Force*, BIO/TECHNOLOGY, Apr. 1990, at 284.

39. *See* UPOV, *supra* note 30, art. 2(1), 33 U.S.T. at 2708.

40. *See infra* note 77 and accompanying text.

41. *See* LUBRIZOL/Hybrid plants, 1990 Eur. Pat. Off. Rep. 173; CIBA-GEIGY/Propagating material, [1979–85] Eur. Pat. Off. Rep. Vol. C. 758.

42. Fundamental changes in patent law have been previously sparked by court decisions, at least in the United States. *See Ex parte Allen*, 2 U.S.P.Q.2d 1425 (PTO Bd. Pat. App. & Int. 1987) (genetically engineered oysters are potentially patentable, even though they are living matter); *In re Bergy*, 596 F.2d 952, 972, 976 (manmade, biologically pure culture of microorganism is patentable because it only occurs in an impure form in nature). These decisions foreshadowed the PTO announcement, although it was most immediately prompted by the ruling in Allen. *See* Donald J. Quigg, Animals—Patentability, Statement of April 7, 1989, *reprinted in* ANIMAL PATENTS, *supra* note 9, at 159 (outlining the holding of *Allen* and the rationale behind it, as well as the scope of patentability under 35 U.S.C. § 101). For a more detailed discussion of case law preceding and foreshadowing the PTO decision, see Bradford Chaucer, Note, *Life, The Patent Office and Everything: Patentability of Lifeforms Created Through Bioengineering Techniques*, 9 BRIDGEPORT L. REV. 413 (1988).

43. The Board held that the question of whether or not a nonmicrobiological process could be considered "essentially biological" and hence, unpatentable, should be narrowly construed based on the essence of the invention and the totality of human intervention. LUBRIZOL/Hybrid plants, 1990 Eur. Pat. Off. Rep. 173, 177.

GEIGY/Propagating Material decision, the Board narrowly construed the Article 53(b) exclusion clause and held that "no general exclusion of inventions in the sphere of animate nature could be inferred from the EPC."[44]

In *HARVARD/Onco-mouse*, however, the Examining Division initially refused to construe Article 53(b) narrowly and thus broke with the preceding opinions on the basis that there was different legislative intent behind the provision for plant and animal varieties.[45] The Appeals Board disagreed and noted that "[a]ny such exception must, as repeatedly pointed out by the Boards of Appeal, be narrowly construed."[46] Because of *HARVARD/Onco-mouse*, the interpretation of Article 53(b) is unsettled.[47] In addition, by introducing Article 53(a) as a consideration in its patentability decision, the Examining Division thus set forth another consideration for member states to apply when determining patentability without any guidance other than the dicta from the *HARVARD/Onco-mouse* decision itself.

This environment of inconsistent EPO case law may have a chilling effect on commercial biotechnology—a field where the economic incentive of the patent system is necessary to stimulate biotechnology research and development. This is true because biotechnology research is very expensive.[48] Inventors who cannot predict whether their inventions will be granted protection will be

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44. CIBA-GEIGY/Propagating material, [1979–85] Eur. Pat. Off. Rep. Vol. C. 758, 759; *see also* BRUKER/Non-invasive measurement, 1988 Eur. Pat. Off. Rep. 357, 360 (narrowly construing the exclusionary clause of Article 52(4), regarding medicinal products).

45. The Examining Division found that "[t]he restrictive interpretation of the exclusion of plant varieties is . . . justified by the limited purpose of the [UPOV Convention] provision to exclude from patent protection only such subject-matter which is eligible for plant variety protection," thus avoiding double protection. HARVARD/Onco-mouse, 1990 Eur. Pat. Off. Rep. 4, 7.

46. HARVARD/Onco-mouse, 1990 Eur. Pat. Off. Rep. 501, 510 (citation omitted).

47. *See Success for "Inventor" of a Mouse*, *supra* note 15 (EPO decision in *HARVARD/Onco-mouse* still leaves future patentability questions up in the air and subject to EPO review on an individual basis).

48. The Commission has stated that "the investments required in research and development particularly for genetic engineering are especially high and especially risky and the possibility for recouping that investment can only effectively be guaranteed through adequate legal protection." Proposed Directive, *supra* note 18, at 3; *see also* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 19 (discussing the vast funding and patent protection received by United States biotechnology companies and how instrumental such protection is to innovation); IRA H. CARMEN, CLONING AND THE CONSTITUTION: AN INQUIRY INTO GOVERNMENTAL POLICYMAKING AND GENETIC EXPERIMENTATION 23, 26 (1985) (discussing the National Institute of Health's financial assistance to recombinant life form projects and United States courts' interpretation of these gene-splicing exercises as falling within the patent statutes).

dissuaded from investing in the EC.[49] In fact, Martin Bangemann, vice-president of the Commission, noted in a recent debate on the Proposed Directive that the Directive affects the competitiveness of the EC and that "[e]ven now entire research sections of the industries . . . are leaving the Community because the legal position is unclear, causing us to lose not only the researchers, who were employed there, but technological capacity."[50]

D. International Pressure

Reform in the EC is also increasingly necessary as the United States, Japan, and other nations develop and protect biotechnological innovation.[51] International investment is lured by strong and effective patent protection,[52] and there seems to be a correlation between flexible laws that protect biotechnology and economic prosperity.[53] The Commission has acknowledged that the EC lags behind its international competitors in the area of biotechnology.[54] This discrepancy can be explained by the insufficient and inconsistent legal protection afforded by EC law in this area.[55]

International competition has become even stronger since the current regulatory atmosphere in the United States favors biotechnology. For example, the United States Food & Drug Administration (FDA) recently decided that it would not regulate food products

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49. The Director of the Senior Advocacy Group on Biotechnology (SAGB), a Brussels-based committee of major chemical companies, noted that "[i]f our companies can't use their innovations on a par with their competitors in the United States or Japan, they will either decline or move their investments elsewhere." David Buchan, *Biotech Groups Find Bright New World Slow to Dawn: Europe's Patent Legislation and Regulations Have Caused Frustration in the Sector*, FIN. TIMES, Apr. 27, 1992, at 2.

50. 1992 O.J. (Annex 3-417) 17, 23 (Apr. 6, 1991) (Debates of the European Parliament) [hereinafter Debates].

51. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 205–13 (outlining sources of international intellectual property protection and international property rights in biotechnology).

52. *See* K.F. BEIR, R.S. CRESPI, & J. STRAUS, BIOTECHNOLOGY AND PATENT PROTECTION: AN INTERNATIONAL REVIEW 88 (1985).

53. The United States and Japan have the most liberal legal protection in this area and are at the forefront of the competition. *See id.*; BIOTECHNOLOGY GLOBAL, *supra* note 2, at 17–21.

54. *See, e.g.*, Proposed Directive, *supra* note 18, at 3; Biotechnology in the Community, COM(83)672 final at E3, E5 (noting the necessity of taking actions designed to "stimulate biotechnology in the Community and to increase competitiveness in Europe's bio-industries"). More recently, the EPO has also noted that further steps need to be taken to improve the European patent system in order to lay the foundation for a "common internal and technological market in Europe." 1990 EPO ANN. REP. 8; *see also* Buchan, *supra* note 49, at 2 (Biotechnology investment is shifting to the United States where the climate is more favorable to patents).

55. *See supra* notes 34–47 and accompanying text.

derived from genetic engineering[56] any differently than other food products.[57] Since no additional requirements are imposed on genetically engineered food, the FDA decision may stimulate the development of new genetically engineered food and the patents to protect such products. International competition was a significant factor in this decision: "[t]he United States is already the world leader in biotechnology and we want to keep it that way."[58] This decision allows the United States' biotechnology industry to establish an early lead in the biotechnology food market and to remain at the forefront of biotechnological development[59] until its competitors make similar accommodations.

E. The Problems Encountered by the Onco-Mouse Are Illustrative of the Inadequacy of Biotechnology Protection

The problems that the EC will face without the enactment of the Proposed Directive are highlighted by an examination of the issues raised in *HARVARD/Onco-mouse*.[60] That case illustrates how the United States patent system is currently more efficient than the EPC system under which the EC operates. Similar patent applications for the Onco-mouse were filed in the United States and Europe, although the patent was granted much faster in the United States.[61] This is a

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56. The regulations concern genetically engineered food—vegetables or fruits that contain traces of genes from other plants or organisms. For a discussion of possible new foods appearing in the marketplace, see Sibella Kraus, *Big Business Pursues the Foods of the Future*, S.F. CHRON., July 8, 1992, at 4.

57. *See Gene-Altered Food Called Safe*, Facts on File World News Digest, May 28, 1992, at 392 E2, *available in* LEXIS, Nexis Library, Omni file; Ben Hirschler, *Biotech Moves Into Food, But Will Consumers Bite*, Reuters, June 24, 1992, *available in* LEXIS, Nexis Library, Reuters file; Oppenheimer makes $10 million investment in PGS, Business Wire, July 7, 1992, *available in* LEXIS, Nexis Library, Wires file. The FDA will not require premarket review for foods which have been genetically altered as long as the constituents are substantially the same as substances currently found in other foods. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (1992); *FDA to Regulate Biotech Food Products Under Same Rules Used for All Other Foods*, Wash. Insider (BNA), May 27, 1992, *available in* LEXIS, Nexis Library, Omni File.

58. *FDA to Regulate Biotech Food Products Under Same Rules Used for All Other Foods*, *supra* note 57 (comments of Vice-President Dan Quayle). Vice-President Quayle noted that "[i]n 1991 alone [biotechnology] was a $4 billion industry. It should reach at least $50 billion by the year 2000 as long as we resist the spread of unnecessary regulation." *Id.*

59. *See* Hirschler, *supra* note 57.

60. *See* HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525, 526–28.

61. The total time from application date to grant of patent lasted four years in the United States versus six years in Europe. *Compare* Onco-mouse patent, *supra* note 1, at 703 (four years from application date to patent grant) *with* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 217 (European patent application filed June 24, 1985) and *EC Debate*, *supra* note 15 (European

result of the increased receptiveness by the United States' patent system to the Onco-mouse patent application—a response that can be explained by a series of events which enhanced protection of biotechnology in the United States.

The Onco-mouse patent received a warm reception in the United States relative to that in the EC due to fundamental advances in the United States' patent system. First, in *Diamond v. Chakrabarty*, the United States Supreme Court (Court) declared that living matter could be patented if it satisfied the normal criteria for patentability under the United States' federal patent statute.[62] Thus, when the Court allowed a patent to be issued for a genetically engineered strain of bacteria that could disintegrate oil spills,[63] the development of the biotechnology industry was stimulated.[64] Second, in 1987 the United States Patent and Trademark Office (PTO) announced that nonhuman, multicellular organisms that did not occur naturally could be patented.[65] Subsequently, the Onco-mouse became the first such organism to be patented.[66]

However, the grant of the Onco-mouse patent did not occur without controversy in the United States. Legislative and public debate was stimulated on the ethical implications of patenting living matter. Most claims were based on bioethical concerns lying outside of the patent system.[67] While legislation was introduced in Congress to reverse the PTO decision,[68] it was ultimately decided that a patent

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Onco-mouse patent granted in October, 1991).

62. Diamond v. Chakrabarty, 447 U.S. 303, 308–10 (1980).

63. *Id.* at 305, 318.

64. *See, e.g.*, BIOTECHNOLOGY GLOBAL, *supra* note 2, at 209. The flood of biotechnological patent applications was a factor in the creation of a new examining unit in the PTO. *See id.* Between 1980 and 1991, the PTO received nearly 20,000 biotechnology patent applications. *See* Sandra Sugawara, *Drug Patent Race Heads to the Bench*, WASH. POST, Sept. 15, 1991, at H7.

65. Quigg, *supra* note 42, at 159 (announcing the United States Patent Office position on patenting higher animal life).

66. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 214; 134 CONG. REC. H7436 (daily ed. Sept. 13, 1988) (statement of Representative Kastenmeier).

67. The most commonly discussed ethical dilemmas in this area are that the patents will interfere with the natural world, devalue human life, increase animal suffering, reduce genetic diversity, accelerate commercialization of academic research, and undermine the family farm. *See* Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 410–24 (1988) (containing an in-depth discussion of ethical dilemmas).

68. Legislation was introduced in the 100th and 101st Sessions of Congress to regulate animal patents. *See, e.g.*, H.R. 3247, 101st Cong., 1st Sess. § 1 (1989); H.R. 3119, 100th Cong., 1st Sess. § 2 (1987). Proposed legislation included an outright prohibition of animal patents. *See, e.g.*, S. 2111, 100th Cong., 2d Sess. (1988); *see also* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 216 (box 12-C summarizes legislative efforts to reverse the PTO decision). For further discussion of proposed legislation, see Robert L. Baechtold et al., *Property Rights In Living Matter: Is New*

does not materially increase the potential uses of an invention, and that ethical considerations were unaffected by the issuance of such a monopoly.[69] As a result, no congressional proposals were passed.[70] Because the scientific principles underlying the Onco-mouse[71] could be applied to genetically altered animals with other research applications,[72] biotechnological patent applications flooded the PTO[73] and the biotechnology industry flourished.[74]

In contrast to the experience of the Onco-mouse application in the United States, the history of the Onco-mouse in Europe highlights the inadequate patent protection afforded to biotechnology in the EC system. Initially, the claims[75] for the Onco-mouse patent were refused[76] on the grounds that animals were excluded *per se* from patentability under Article 53(b) of the EPC.[77] On appeal that

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Law Required?, 68 DENV. U. L. REV. 141, 150–52, 162–63 (1991); David Beier & Robert H. Benson, *Biotechnology Patent Protection Act*, 68 DENV. U. L. REV. 173, 183–90 (1991) (the PTO decision "opened the floodgates" of biotechnological investment).

69. *See* Stephen A. Bent, *Issues and Prospects in the USA*, *in* ANIMAL PATENTS, *supra* note 9, at 8.

70. Some of the bills were approved in one chamber but not by both the House and the Senate. *See, e.g.*, H.R. 4970, 100th Cong., 2d Sess. §§ 2, 4 (1988) (creating farmer's exemption and statutory exclusion of humans from patentability); *see also* SECTION OF PATENT, TRADEMARK & COPYRIGHT LAW, 1990–91 ANNUAL REPORT 376 (Michael O. Sutton, ed. 1992) (summary of Congressional activities).

71. For detail on the techniques used in creating transgenic animals such as the Onco-mouse, see O'Connor, *supra* note 30, at 608.

72. *See, e.g.*, Barnaby J. Feder, *The 'Pharmers' Who Breed Cows That Can Make Drugs*, N.Y. TIMES, Feb. 9, 1992, § 3, at 9; *Genpharm Should Get Transgenic Animal Patent Within a Few Months*, 12 GENETIC TECH. NEWS 2 (1992).

73. The flood of biotechnology applications caused a processing backlog despite the fact that the PTO created a new department to deal specifically with biotechnological patent applications. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 213.

74. *See* L. Christopher Plein, *Biotechnology: Issue Development and Evolution*, *in* BIOTECHNOLOGY: ASSESSING SOCIAL IMPACTS AND POLICY IMPLICATIONS 158 (David J. Webber, ed. 1990) (the PTO decision "opened the floodgates" of biotechnological investment).

75. A claim defines the scope of a patent. *See* DONALD S. CHISUM, 2 PATENTS § 8.01 (1992).

76. The claims at issue in this proceeding related to a method for producing a "transgenic non-human mammalian animal having an increased probability of developing neoplasms" (tumors), the resulting animal, and a resulting animal rodent. HARVARD/Onco-mouse, 1990 Eur. Pat. Off. Rep. 4, 6 (claims 1, 17, and 18).

77. The Examining Division considered the Onco-mouse to be an animal variety and thus *per se* unpatentable under Article 53(b) based on several facts. First, the Examining Division found that unlike plant varieties, the animal varieties exclusion should not be narrowly interpreted because when the EPC was ratified, nations had the opportunity to patent animal varieties but elected not to do so. *See id.* at 7. Second, the Examining Division found legislative intent to exclude animals in general based on the fact that the three official languages of the EPC used different terms for "animal varieties." *Id.* at 8.

decision was reversed.[78] The Technical Board of Appeals concluded that Article 53(b) did not exclude animal patents *per se*.[79] The case was remanded to the Examining Division of the EPO to determine whether the Onco-mouse was an animal variety under Article 53(b), and whether it violated the ethical exclusion of Article 53(a)[80] after weighing the risks and benefits of the invention.[81] The Examining Division subsequently determined that the Onco-mouse was not an animal variety.[82] In addition, the Examining Division believed that the Onco-mouse's contribution to human welfare outweighed potential environmental risks and animal suffering[83] and thus determined that it did not violate the ethical exclusion of Article 53(a).[84] In particular, the Examining Division noted:

> The development of new technologies is normally afflicted with new risks .... The experience has also shown that these risks should not generally lead to a negative attitude *vis-a-vis* new technologies but rather to a careful weighing up of the risks on the one hand and the positive aspects on the other and that the result of this consideration should be the determining factor in whether a new technology should be used or not. ... [B]iotechnological inventions and particularly inventions relating to genetic engineering are not in general excluded from patent protection.[85]

The Examining Division also rejected the patent under Article 83 of the EPC on the grounds of insufficient disclosure because the patent covered all nonhuman animals but the background experiments only involved mice. *Id.* at 11–13.

78. HARVARD/Onco-mouse, 1990 Eur. Pat. Off. Rep. 501, 507.

79. *Id.* at 510–11.

80. The EPC excludes from patentability inventions which are contrary to public order or morality under article 53(a). EPC, *supra* note 23, art. 53(a), 13 I.L.M. at 286. Originally, Article 53(a) was not a factor in rejecting the application since the Examining Division considered patent law an inappropriate "legislative tool" for resolving the ethical questions raised by the patent. *See* HARVARD/Onco-mouse, 1990 Eur. Pat. Off. Rep. 4, 11; *see also Patenting The Harvard Mouse*, *supra* note 16 (discussing the decisions of the Appeals Board and the Examining Division).

81. The Examining Division examined these provisions at the request of the Appeals Board. *See* HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525, 526.

82. *Id.* at 526.

83. The Examining Division found that the "invention's usefulness to mankind cannot be denied" and that overall animal suffering would actually be reduced since fewer animals would be needed in comparison to conventional testing. *Id.* at 527. Also, the probability of an unintended release of the genetically altered mouse into the environment is small. *Id.* at 528. With respect to the possibility of intentional misuse of the mouse, "[t]he mere fact that ... uncontrollable acts are conceivable cannot be a major determinant for deciding whether a patent should be granted or not." *Id.* at 528. For a discussion of the action taken by the Examining Division on remand, see *EC Debate*, *supra* note 15.

84. HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525, 528.

85. *Id.* at 527.

Although the Onco-mouse eventually was granted a patent in Europe,[86] it spent six years in the cumbersome EPC system before the patent was approved.[87] In the EC the limited commercial monopoly granted by a patent retroactively applies to cover the time elapsed since the date of the application.[88] As a result, the longer the gap between the application date and patent grant, the more vulnerable an inventor is to competitors who may appropriate the inventor's ideas.[89] Furthermore, the time that the application sits in the EPC system is deducted from the length of the resulting patent grant. Thus, the longer the application process, the shorter the patent life.[90] The lengthy time period for obtaining a biotechnological patent in the EC results in a backlog of biotechnology applications and hinders the international competitiveness of the Community.[91]

F. Implications of the *HARVARD/Onco-mouse* Decision

The applicability of the *HARVARD/Onco-mouse* decision to future EC biotechnological patents is limited because the decision is very fact-specific.[92] Although some of the language of the decision was phrased broadly,[93] the Examining Division specifically stated that the "considerations apply *solely* to the present case and . . . other cases of transgenic animals are conceivable for which a different conclusion

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86. The patent was finally granted in October, 1991. *See* HARVARD/Onco-mouse, 1991 Eur. Pat. Off., *passim* (decision to allow Onco-mouse patent); *EC Debate*, *supra* note 15.

87. *Id.* The patent was filed with the European Patent Office on June 24, 1985. BIOTECHNOLOGY GLOBAL, *supra* note 2, at 217.

88. EPC, *supra* note 23, art. 63(1), 13 I.L.M. at 287 (term of patent is 20 years from the date the application is filed).

89. European patent applications are published approximately 18 months after their filing dates, which may require disclosure of proposed patents before they are granted. *Id.* art. 93(1), 13 I.L.M. at 293.

90. In contrast, the laws of the United States are more favorable to inventors, who receive a patent grant only from the date the patent issues. 35 U.S.C. § 151 (1988) (issue of patent); 35 U.S.C. § 154 (Supp. 1992) (term of patent grant).

91. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 212; U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE—SPECIAL REPORT 23 (1989) (Box 1-A summarizes backlog of animal patent applications in Europe as of 1988); *cf.* Geraldi, *supra* note 5, at 591 (discussing the patent backlog at PTO, which was exacerbated by constitutional policy concerns and interpretation of the United States Patent Act).

92. *Contra Chakrabarty*, 447 U.S. at 309 ("anything under the sun that is made by man" is patentable).

93. The decision notes that exclusions to the general principle of patentability contained in Article 52(1) EPC are to be "interpreted narrowly." HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525, 527.

might be reached in applying Article 53(a) EPC."[94] In this case, the patent was granted on the basis of the fundamental medical utility of the Onco-mouse.[95] The EPO underscored the narrow scope of the decision when it recently opposed a similar mouse patent designed to study hair growth because the study was not deemed to be sufficiently important to outweigh animal suffering.[96] Furthermore, the scope of the Onco-mouse patent specifically precludes the patenting of human beings.[97] Thus, inventions involving human cells may have insufficient precedent to be granted patent protection.[98]

HARVARD/Onco-mouse illustrates potential problems with patenting biotechnological inventions in the EC under the current system because of the ethical prohibition of Article 53(a) of the EPC. The narrow reading of the ethics provision of Article 53(a) in this case is economically troublesome for the EC. This provision could be invoked to thwart almost any biotechnological invention because genetic engineering, a major technique used to create biotechnological inventions, is a controversial process.[99] The problem is especially pronounced in the international marketplace because the provision is unique to the EC.[100] Unless Article 53(a) is interpreted leniently and uniformly, the EPO could further undermine the European biotechnol-

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94. *Id.* at 528.

95. The Examining Division determined that the possibility of remedying widespread and dangerous diseases combined with reduction of overall suffering of laboratory animals outweighed considerations that might otherwise constitute an unpatentable invention based on moral concerns. *Id.* at 527.

96. *See* Debates, *supra* note 50, at 17; *EC Debate*, *supra* note 15.

97. HARVARD/Onco-mouse, 1990 Eur. Pat. Off. Rep. 4, 6. During the application process, the applicants modified the patent to claim only nonhuman mammals. *Id.* at 5–6.

98. The problem with insufficient protection of human cells is especially enhanced by the recent amendments to the Proposed Directive. For example, Amendment No. 15 limits the general rule set forth in Article 2 of the Proposed Directive allowing patentability of biological matter that self-replicates by stating that the "human body or parts of the human body . . . shall not be patentable." Amended Proposal, *supra* note 34, at 185; *see also* Geraldi, *supra* note 5, at 592–93 (discussing the potential negative economic effect of the failure to provide an incentive for patent protection on the development of beneficial human-based products).

99. *See, e.g.*, Dennis S. Karjala, *A Legal Research Agenda for the Human Genome Initiative*, 32 JURIMETRICS J. 121, 152–53 (1992). Moreover, even if the EPO grants a biotechnological patent, such protection can be revoked under national laws in certain circumstances. EPC, *supra* note 23, art. 138, 13 I.L.M. at 302.

100. The EPO Examining Division has noted that "[n]o article analogous to Article 53(b) EPC exists in the Patent Laws of the USA, Japan and Australia" which would allow granting of patents on animals as long as the standard patentability requirements are satisfied. HARVARD/Onco-mouse, 1990 Eur. Pat. Off. Rep. 4, 10.

ogy industry, which is already hampered by relatively stringent regulations.[101]

The Onco-mouse decision indicates that the EPO may prevent the patenting of biotechnological inventions, perhaps contrary to the intent of the drafters of the EPO Guidelines. The text of the Guidelines indicates that Article 53(a) was meant to safeguard the public,[102] but that it should be invoked "only in rare and extreme cases."[103] The Guidelines note that a consideration of "whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable" is the proper test to apply.[104] The Appeals Board determined that the Onco-mouse was such a case, even though it had fundamental utility as a medical research tool.[105] While the public perceptions in the United States should not be grafted onto the European public, the fact that the United States had already issued a similar patent and prospered from such a decision[106] indicates that a patent in this case is not entirely inconceivable. Also, the fact that not all members of the Parliament are opposed to the Proposed Directive,[107] a measure that would permit such patents to issue routinely, indicates that the Onco-mouse concept is not so abhorrent as to be inconceivable to the European public. This is buttressed by the fact that the Parliament is the most democratic institution of the EC[108] and therefore probably most accurately reflects the opinions among the citizens of the member states.

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101. *See, e.g.*, BIOTECHNOLOGY GLOBAL, *supra* note 2, at 186–96; Buchan, *supra* note 49, at 2. Further evidence of the problem is that investors and companies, including Europeans, are turning to the United States to take advantage of lenient regulations and liberal patent protection. *See, e.g.*, Buchan, *supra*.

102. *See* EPO GUIDELINES, *supra* note 31, ch. IV, ¶ 3.1.

103. *Id.*

104. *Id.* The example given in the EPO guidelines of an unpatentable inventions based on Article 53(a) is a letter bomb. *Id.* The Appeals Board considered three interests: curing a dangerous disease, protection of the environment, and avoiding cruelty to animals. HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525, 527.

105. *Id.*

106. *See supra* notes 66–74 and accompanying text (discussing the grant of the Onco-mouse patent in the United States and the subsequent development of the biotechnology industry).

107. Debates, *supra* note 50, *passim*.

108. *See* EEC TREATY art. 137 (European Parliament consists of representatives of the member states).

III. THE PROPOSED DIRECTIVE TO ENHANCE THE PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

A. The Significance of the Proposed Directive

A study of the Onco-mouse experience reveals that the EC should reform patent protection for biotechnological inventions in order to enhance common market goals.[109] The EC has already recognized the importance of the biotechnology industry, as manifested by the allocation of special funding for biotechnology research and development.[110] This is consistent with the international promotion of biotechnology.[111]

However, the EC biotechnology programs are intended not only to mobilize research and development, but also to enhance the competitiveness of European industry.[112] Enhanced and uniform patent protection is still necessary to compete on an international

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109. *See supra* notes 60–101 and accompanying text; Buchan, *supra* note 49, at 2.

110. *See, e.g.*, Council Decision of 27 Nov. 1989 on a Specific Research and Technological Development Programme in the Field of Biotechnology (1990–1994) (Bridge), 1989 O.J. (L 360) 32, 32–34; Council Decision of 23 Feb. 1989 on a First Multiannual Programme (1988–1993) for Biotechnology-based Agro-industrial Research and Technology Development-Eclair (European Collaborative Linkage of Agriculture and Industry Through Research), 1989 O.J. (L 60) 48, 48–50; Council Decision of 7 Dec. 1981 Adopting a Multi-annual Research and Training Programme for the European Economic Community in the Field of Bimolecular Engineering, 1981 O.J. (L 375) 1, 1–4.

111. *See* R. Gerold, *Research Contracts in Execution of the European Science and Technology Community*, *in* ASSER INSTITUTE COLLOQUIM ON EUROPEAN LAW, TECHNOLOGICAL DEVELOPMENT AND COOPERATION IN EUROPE: LEGAL ASPECTS 39, 45–46 (1987) [hereinafter ASSER INSTITUTE COLLOQUIM]. For example, one multinational European program in technology is EUREKA, which aims to increase productivity and international competitiveness of Europe's industry and economies. *See Declaration of Principles relating to EUREKA*, *in* ASSER INSTITUTE COLLOQUIM, *supra*, at 105–08; R.-J.H.M. Smits, *Technology and European Cooperation: Introductory Remarks*, *in* ASSER INSTITUTE COLLOQUIM, *supra*, at 31, 36–37.

112. BIOTECHNOLOGY GLOBAL, *supra* note 2, at 161. However, the EC needs to move from promulgating isolated research programs to developing a comprehensive strategy in the area of biotechnology to take advantage of the commercial prospects of biotechnology. *See* Biotechnology in the Community, COM(83)672 final at E12; Mark Cantley, *Biotechnology in Europe: The Role of the Commission of the European Communities*, *in* BIOTECHNOLOGY IN FUTURE SOCIETY: SCENARIOS AND OPTIONS FOR EUROPE 9, 10 (Edward Yoxen & Vittorio Di Martino eds., 1989).

level.[113] An EC Directive improving the legal protection of biotechnology would address this problem directly.

B. The Proposed Directive[114]

The Commission has proposed a promising Directive to create uniform legal protection for biotechnological inventions.[115] First presented in 1988, the *Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions*, as amended, allows "biological material" to be patented[116] if it meets the traditional requirements for patentability set forth in Article 52(1) of the EPC.[117] The Amended Proposal defines biological matter as "self replicating living matter"[118] and further clarifies Article 2 of the Proposed Directive, which stated that "an invention shall not be considered unpatentable for the reason only that it is composed of living matter"[119] by delineating additional exclusions to the general rule of patentability for living matter.[120]

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113. *See, e.g.*, Opinion on the Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, 1989 O.J. (C 159) 10, 10–11 [hereinafter Opinion on the Proposed Directive]. The EC has the power to dictate results via directives since the directives mandate a common result but allow member nations to choose their own means of reaching the end results. *See* EEC TREATY art. 189.

114. The Proposed Directive covers procedural issues related to biotechnological patents beyond the scope of this Note which instead focuses on the patentability of biotechnology. *See* Proposed Directive, *supra* note 18, arts. 10, 14, 17 (infringement problems, licenses, and burden of proof issues particular to living matter). For a further discussion of these procedural issues see COOK ET. AL., *supra* note 2, at 134–35; Robin Whaite & Nigel Jones, *Biotechnological Patents in Europe—The Draft Directive*, 5 EUR. INTELL. PROP. REV. 145, 150–51 (1989).

115. Proposed Directive, *supra* note 18, at 3.

116. Amended Proposal, *supra* note 34, art. 2, at 185 (Amendment No. 13); *see also* Proposed Directive, *supra* note 18, art. 2 (stating that "living matter" is not *per se* unpatentable). If enacted, the Proposed Directive would have the same effect as the United States Supreme Court holding in *Diamond v. Chakrabarty* which explicitly allowed living matter to be patented. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980). This case made it clear that living matter was patentable as long as it satisfied the traditional requirements of patentability. *Id.* at 307–10; *see also supra* notes 62–66 and accompanying text (discussing *Chakrabarty* case as the beginning of biotechnology protection in the United States).

117. *See* EPC, *supra* note 23, art. 52(l), 13 I.L.M. at 285 (the traditional requirements for patentability are industrial applicability, novelty, and an inventive step).

118. Amended Proposal, *supra* note 34, art. 2(a), at 185 (Amendment No. 14); *see also* Proposed Directive, *supra* note 18, arts. 10–13 (extending protection to subsequent generations). The Onco-mouse patent, thus, would protect subsequent offspring of the mouse which had identical genetic material characteristic to the patented invention.

119. Proposed Directive, *supra* note 18, art. 2.

120. Amended Proposal, *supra* note 34, arts. 2(b)–2(j), at 185–86 (Amendment Nos. 7-20). The Proposed Directive also set forth examples of patentable subject matter on a smaller scale. Proposed Directive, *supra* note 18, arts. 3–7.

The Proposed Directive complements the EPO Guidelines by clarifying and mandating results similar to the EPO Guidelines and by addressing issues not discussed in the Guidelines. Recall that the EPO Guidelines, which attempted to define the EPC terms,[121] were not binding on the member states.[122] Thus, if enacted, the Proposed Directive would take the EPO Guidelines one step further by making the definition of terms binding on all EC members.[123] For example, the Amended Proposal explains that a microbiological process consists of a succession of steps in which "at least one essential step of the process is microbiological."[124] It also explains that whether a biotechnological invention is more than an "essentially biological" process[125] will be determined on the basis of the amount of human intervention and its impact on the result.[126]

C. The Potential of the Proposed Directive

The Proposed Directive is an important step that the EC must take in order to compete internationally.[127] Eight years ago the United States government recognized the growing importance of the biotechnology industry and conducted a study to determine the identity of its global competitors.[128] At that time the United States Office of Technology Assessment (OTA) determined that although European nations had inherent strengths in scientific research, the strengths were underutilized for commercial purposes due to insufficient biotechnology protection.[129] The Commission recognizes the

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121. EPO GUIDELINES, *supra* note 31, ch. IV, ¶ 3.4.

122. *See supra* note 32 and accompanying text.

123. *See* Proposed Directive, *supra* note 18, art. 1; *see also* EEC TREATY art. 189 (regulations made by the Council and Commission are binding on member states).

124. Amended Proposal, *supra* note 34, art. 5(a), at 187 (Amendment No. 24). The Proposed Directive defined microbiological process as one that is "carried out with the use of or performed upon or resulting in a micro-organism." Proposed Directive, *supra* note 18, art. 5.

125. *See* EPC, *supra* note 23, art. 53, 13 I.L.M. at 286; EPO GUIDELINES, *supra* note 31, ch. IV, ¶ 3.4.

126. *See* Amended Proposal, *supra* note 34, art. 7, at 187 (Amendment No. 25); Proposed Directive, *supra* note 18, art. 7; COOK ET AL., *supra* note 2, at 134.

127. *See* Opinion on the Proposed Directive, *supra* note 113, at 10–11 (Economic and Social Committee opinion affirming international competitiveness as a goal of the Proposed Directive).

128. *See* COMMERCIAL BIOTECHNOLOGY, *supra* note 1, *passim* (report assessing the United States' ability to compete in commercial development of new biotechnology).

129. *See generally id.* at 401 (stating types and degrees of biotechnology protection in various communities). The Commission noted this problem and referenced the U.S. OTA report specifically. Biotechnology in the Community, COM(83)672 final at E3. The Commission's response was to enact a series of biotechnology research and development programs. *See, e.g.*, Proposal for a Council Decision Adopting a Multiannual Research Action Programme of the

necessity of increasing patent protection for biotechnology[130] and has stated that the purpose of the Proposed Directive is "to establish harmonized, clear and improved standards for protecting biotechnological inventions in order to foster the overall innovatory potential and competitiveness of Community science and industry in [the] important field of modern technology."[131] Despite the fact that the Commission recognizes the necessity of increasing protection of biotechnology, it has not yet transformed this concern into action. Thus, while the EC continues to debate the ethical implications of biotechnology, the United States and other nations have already given increased protection to biotechnological inventions.[132]

The delay in enactment casts a negative light on the future of biotechnological patents in the EC. If the Proposed Directive continues to languish in the Parliament, the chances of passing a directive that remains true to the intent of the Commission is increasingly diminished. Amendments enacted by the Parliament that introduce ambiguous new terms into the Proposed Directive, such as "unnatural processes" for the production or modification of animals,[133] threaten to erode the Commission's intent as well as the effectiveness of the Proposed Directive. The ambiguity of this phrase diminishes the prospect of patenting biotechnological inventions as the interpretation of the term "unnatural" will be subject to the caprice of each member state.

In turn, the future of biotechnological patents appears bleak because the patentability obstacles of the EPC and EPO Guidelines are reinforced by the Amended Proposal. The general rule proposed by the Commission that allowed living matter to be patented has since been amended to include a provision analogous to EPC Article 53(a).[134] The general rule has been eroded by other amendments,

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European Economic Community in the Field of Biotechnology, COM(84)230 final.

130. *See* Biotechnology in the Community, COM(83)672 final at E12.

131. Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, COM(88)496 final at 6.

132. *See, e.g.*, BIOTECHNOLOGY GLOBAL, *supra* note 2, at 193–94, 223.

133. Amended Proposal, *supra* note 34, art. 2(e), at 186 (Amendment No. 18). However, some of the amendments were foreseeable as analogous to proposals suggested in the United States Congress at a similar juncture in biotechnology development. In particular, the farmer's privilege under the Amended Proposal is similar to the farmer's exception which was drafted into the House Transgenic Animal Reform Act. *Compare* Amended Proposal, *supra* note 34, art. 12(a), at 189 *with* H.R. 4970, 100th Cong., 2d Sess. § 2 (1988).

134. Amended Proposal, *supra* note 34, art. 2(c), at 185 (Amendment No. 16).

as well. Interspecies animals are declared *per se* unpatentable,[135] and genetically engineered animals that involve unnatural processes, unnecessary suffering, or unnecessary physical harm are unpatentable.[136] It is doubtful that even the Onco-mouse, whose "usefulness to mankind can not be denied . . ."[137] could have succeeded in overcoming these obstacles to patentability.[138]

The Proposed Directive remains an important step that the EC needs to take. That is the case despite the fact that the Amended Proposal, if enacted in its current form, may take a smaller step toward enhancing international competitiveness than originally envisioned by the Commission. Nonetheless, without some legislative action, the biotechnology industry will lack the necessary incentive to invest in the EC,[139] and the common market concept will be weakened in this burgeoning field.[140]

D. The Status of the Proposed Directive

While the Proposed Directive was first presented in 1988, the passage of the measure has since been stalled by the Green Party[141] and animal rights groups who oppose the legislation.[142] Because of these pressures, the Parliament has twice tabled the Proposed Directive for reconsideration of ethical and moral problems.[143] Furthermore, passage of the Proposed Directive was delayed a third time in order to determine whether it conflicts with the biodiversity convention recently signed at the Earth Summit in Rio de Janerio, Brazil.[144] Despite these obstacles, the recent enactment of over forty

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135. *Id.* art. 2(f), at 186 (Amendment No. 19 declares "interspecific" animals to be unpatentable).

136. *Id.* art. 2(e), at 186 (Amendment No. 18).

137. HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525, 527.

138. *See supra* notes 75–91 (discussing the history of the Onco-mouse in the EPO).

139. *See* COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 21; notes 48–50 and accompanying text (discussing the importance of patent protection to stimulate biotechnology research and commercialization).

140. *See supra* notes 19–22 and accompanying text.

141. The Green Parties are an umbrella group for organizations with concerns not addressed by mainstream parties. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 187. They are typically skeptical of new technology. *Id.* Biotechnology is their newest target of criticism since nuclear energy is no longer in the spotlight. *Id.*

142. *See, e.g.*, Suzanne Perry, *EC Bio-Tech Patent Plan Stalled by Ethics Money*, Reuters, Mar. 6, 1992, *available in* LEXIS, Nexis Library, Reuters File.

143. *See European Parliament Blocks Bill by EC Commission on Biotech Patents*, Int'l Env't Daily (BNA), June 12, 1992, *available in* LEXIS, Nexis Library, Omni File.

144. The major concern was that "an agreement in the Rio biodiversity convention concerning royalty payments to Third World countries for patented material derived from the

amendments[145] indicates that the Parliament has a strong interest in the continued viability of the legislation and the passage of this sweeping measure.

IV. ETHICAL ISSUES SHOULD NOT THWART ENACTMENT

A. Ethical Issues Regarding Patents Are Misplaced

The ethical concerns currently raised in conjunction with biotechnology patents are misplaced because they stem from a lack of understanding of the patent system. A patent system is not a means of safeguarding the public interest. It is primarily a commercial and industrial tool that encourages innovation, divorced from social and ethical concerns.[146]

Because a patent grant affords a limited commercial monopoly to use only what is already in existence, the grant of a patent is not an ethical event.[147] Instead, it is the regulatory system of a given nation that monitors social concerns as it implements general legislation—concerns which frequently encompass ethics and morality.[148] Thus, a patent makes the existing research on genetic engineering open and available to the public, which, in turn, permits public monitoring of genetic engineering.[149] In the context of the FDA decision on genetically engineered foods,[150] it was noted that "[g]enetic technology is too promising . . . to dismiss it out of a free-floating mistrust. 'If

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genetic resources of [those] nations" would conflict with provisions in the Proposed Directive. *Id.*

145. Amended Proposal, *supra* note 34, at 183–95.

146. *See* Proposed Directive, *supra* note 18, at 4 ("the function of a patent is to reward the inventor with an exclusive but time-bound right for his creative efforts and thereby encourage inventive activities . . . ."); Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1067–68 (1988) (assessing technology and determining potential social consequences is not the function of patent law).

147. *See* Bent, *supra* note 69, at 7; Debates, *supra* note 50, at 18 (right of prohibition only).

148. *See* BIOTECHNOLOGY GLOBAL, *supra* note 2, at 203–04; Bent, *supra* note 69, at 7–8; Merges, *supra* note 146, at 1067–68.

149. Debates, *supra* note 50, at 18. Rapporteur Rothley stated that:

> [i]t is a common and mistaken assumption that the fact of being able to patent genetically modified plants or animals will prompt research into genetic engineering in the first place. But that research is taking place. The right of patent is just as likely to prompt it as it is to prevent it. The issue is whether the process takes place in secret or is transparent. The right of patent contributes to the transparency of genetic engineering, and that transparency guarantees increased safety.

Id.

150. *See supra* notes 57–59 and accompanying text (discussing genetically engineered food).

the public understood the technology, they would understand that part of their emotional reaction is irrational. . . .'"[151] It is evident, then, that ethical concerns raised about the patent system reflect concerns about biotechnology itself rather than the grant of the patent for that biotechnology. Ethical issues associated with patents are inappropriately channeled fears of insufficient regulation.[152] Nevertheless, the patent system has become another arena for the campaigns of the Green Party, environmental groups, and animal rights activists to try to regulate science and technology.[153] In fact, biological patents have been granted routinely since the 1800s,[154] but ethical concerns did not enter the realm of the patent system until genetic engineering blossomed. Public concern over patenting biotechnology may reflect a public reaction to the scope and sophistication of genetic engineering involved in biotechnology due to misperceptions and unfounded fear of genetic engineering. This is illustrated by a series of decisions in the United States and Europe.

In 1970, the German Supreme Court allowed a living organism to be patented in the *Red Dove* case.[155] That case preceded the development of genetic engineering and was not followed by any significant public controversy.[156] However, following the advent of genetic engineering the 1980 United States Supreme Court holding in *Chakrabarty*, which paralleled the *Red Dove* decision in principle by holding genetically engineered bacteria to be patentable, was followed

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151. Molly O'Neill, *Geneticists' Latest Discovery: Public Fear of 'Frankenfood,'* N.Y. TIMES, June 28, 1992 at A1, A14 (comments of Dr. Susan K. Harlander, researcher and professor of food science and nutrition at the University of Minnesota); *see also* Cantley, *supra* note 113, at 14–18 (observations on public confidence as an essential element to developing biotechnology); Jorgen Lindgaard Pedersen, *Public Debate on Biotechnology: The Case of Denmark, in* BIOTECHNOLOGY IN FUTURE SOCIETY: SCENARIOS AND OPTIONS FOR EUROPE 107–15 (Edward Yoxen & Vittorio Di Martino eds., 1989) (discussing the development of public regulation of biotechnology in Denmark).

152. *See generally* Cantley, *supra* note 112, at 14–15 (effective regulation takes into consideration deep-rooted political and cultural considerations).

153. *See, e.g.*, David Burke, Note, *Animal Legal Defense Fund v. Quigg: Renewed Challenge to Animal Patents*, 59 U. MO. KAN. CITY L. REV. 409, 410 (1991); Jae H. Kim, Note, *Patent Law: Patenting Animal Life: Another Scapegoat for Small Interest Groups*, 42 OKLA. L. REV. 131, *passim* (1989).

154. *See* Alex Barnum, *Biotech Labs Enraged by Bid to Patent Human Genes*, S.F. CHRON., Dec. 2, 1991, at B1 (patent grant given to Louis Pasteur).

155. Rote Taube (Red Dove), 1 INT'L REV. OF INDUS. PROP. & COPYRIGHT L. (IIC) 136 (1970) (English translation of excerpts of the Decision of the Bundesgerichtshof); Straus, *supra* note 4, at 17–18.

156. *See* Straus, *supra* note 4, at 17–18.

by a public debate over the morality of patenting living matter.[157] Then, in 1987 the United States Board of Patent Appeals and Interferences determined in *Ex Parte Allen* that higher life forms, such as oysters, were patentable.[158] That decision triggered significantly more controversy[159] than a typical Board decision.[160] Finally, the 1987 PTO decision to allow genetically engineered animals such as the Onco-mouse to be patented stimulated tremendous controversy.[161] This litany indicates that debate over patenting biotechnology has sharpened with the sophistication and use of biotechnology despite the fact that the underlying scientific principles and patent procedures remain the same.

There is a distinct paucity of case law that discusses ethical issues as a preclusion to patentability. This is the case even in the EPO decisions despite the existence of Article 53(a), which explicitly allows a consideration of ethics for patentability. The EPO Guidelines indicate that Article 53(a) is to be invoked only in "rare and extreme cases"[162] and is aimed at preventing extreme situations such as riots and criminal behavior.[163] The lack of discussion prior to *HARVARD/Onco-mouse* may indicate that ethics were generally not considered in patenting decisions. In fact, the Examining Division initially stated in *HARVARD/Onco-mouse* that it does not consider patent law an appropriate legislative tool and therefore declined to rule under Article 53(a).[164]

To a limited extent, the EPO Guidelines on Article 53(a) and the United States' cases are illuminating on the role ethics should play in the area of patentability. Ethics have been considered regarding the usefulness requirement that all patentable inventions must meet in both the EC and the United States. The issue is whether ethical issues render an invention "useless" according to statutory requirements for patentability.[165] In the United States, courts historically have been

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157. *See generally id.* at 17–18 (indicating public concern about patenting higher organisms stems from the novelty of genetic engineering and a general lack of understanding of how the patent system functions).

158. *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (PTO Bd. Pat. App. & Int. 1987).

159. *See* Manspeizer, *supra* note 9, at 418–19; Merges, *supra* note 146, at 1052.

160. *See* Merges, *supra* note 146, at 1052.

161. *See supra* notes 68–70 and accompanying text (discussing legislative activity following the grant of the Onco-mouse patent).

162. EPO GUIDELINES, *supra* note 31, ch. IV, ¶ 3.1.

163. *Id.*

164. HARVARD/Onco-mouse, 1990 Eur. Pat. Off. Rep. 4, 11.

165. *See* Merges, *supra* note 146, at 1062–63.

reluctant to deny patents based solely on ethical concerns[166] and consider an invention patentable so long as it has some moral use.[167] The drafters of the EPO Guidelines seem to concur in this result. The Guidelines state that a patent may be granted if an invention has both an offensive and nonoffensive use.[168] The Guidelines set forth as an example a process for breaking open safes; that is a process that may be offensive if used by burglars, but which is potentially nonoffensive and very useful if used by a locksmith in an emergency.[169]

B. Ethical Issues Are Dealt with by Regulations

The patent system functions independently of the regulatory system[170] and therefore should not be used as a regulatory tool. This is buttressed by the fact that the Amended Directive recognizes that the patent system could be used to regulate ethical concerns but specifically directs member states to regulate bioethics before an invention reaches the stage of patentability.[171] As noted in the Parliamentary debates, patents are an inappropriate tool with which to regulate research.[172] Requiring the patent system to operate as a regulatory system would merely duplicate the work of the existing regulatory framework and would threaten inconsistent results.[173] Furthermore, EC biotechnology regulations take ethical issues into account by regulating risks associated with genetic engineering.[174] The EPO has

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166. *See, e.g., Ex parte* Murphy, 200 U.S.P.Q. 801, 802 (PTO Bd. Pat. App. & Int. 1977); Fuller v. Berger, 120 F. 274, 275–76 (7th Cir. 1903). The only cases in which United States courts considered the issue of ethics in denying patents appeared in the 1800s. *See, e.g.*, Lowell v. Lewis 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (stating in dicta that an invention must be "useful," as opposed to "mischievous" in order to receive a patent).

167. *See* Klein v. Russell, 86 U.S. 433, 467 (1873) (holding patent process void for want of utility if "injurious and pernicious").

168. EPO GUIDELINES, *supra* note 31, ch. IV, ¶ 3.3.

169. *Id.*

170. *See generally In re* Hartop, 311 F.2d 249, 259–60 (C.C.P.A. 1962) (scope of PTO duty limited to determining whether invention within parameters of patentability).

171. *See* Amended Proposal, *supra* note 34, at 184 (Amendment No. 6).

172. Debates, *supra* note 50, at 18.

173. *See, e.g.*, Carter-Wallace, Inc. v. Riverton Laboratories, Inc., 433 F.2d 1034, 1039 n.7 (2d Cir. 1970) ("to require the Patent Office to make an affirmative finding as to the safety of a drug for human use would work a serious overlapping of the respective jurisdictions of the Patent Office and the Food and Drug Administration").

174. For instance, the Contained Use Directive sets minimum standards for research and development for industrial operations based on the risk associated with the modified microorganism and the type of research. *See* Council Directive 90/219 of 23 April 1990 on the Contained Use of Genetically Modified Micro-organisms, 1990 O.J. (L 117) 1, 2–6; *see also* Council Directive 90/220 of 23 April 1990 on the Deliberate Release Into the Environment of

stated that "[t]he regulation of the handling of dangerous material is not the task of the European Patent Office but is rather the business of specialised governmental authorities."[175]

C. The Proposed Directive Also Acknowledges and Deals with Ethical Concerns

The Amended Proposal indicates that the Parliament has strived to attain a balance between necessary reform aimed at international competitiveness and accommodation of ethical issues. The Amended Proposal requires rules on patenting living matter to consider ethical repercussions, as well as global and EC strategies,[176] and it suggests that mechanisms should be developed to address concerns at the regulatory level.[177] The specific exclusion of human beings or parts of humans,[178] as well as detailed exclusions on patentability of animals,[179] should quell some anxiety over patenting living matter and enhance the possibility of enactment. The focus is on balancing concerns. This is illustrated by a comparative assessment introduced in the Amended Proposal that requires the usefulness of the invention, as well as possible risks and objections based on fundamental legal principles, to be considered in determining whether an invention is unpatentable because it violates public order and morality.[180]

Genetically Modified Organisms, 1990 O.J. (L 117) 15, 16–21; Claus-Joerg Ruetsch & Terry R. Broderick, *New Biotechnology Legislation in the European Community and Federal Republic of Germany*, INT'L BUS. LAW., Oct. 1990, at 408, 408–11 (discussing the new Directive and the response of Germany).

Similarly, in the United States the Food and Drug Administration (FDA) regulates biotechnologically altered food products and therefore courts have determined that it would be redundant for the PTO to examine possible ethical implications of proposed patents. *See, e.g.*, *In re* Anthony, 414 F.2d 1383, 1399–1400 (C.C.P.A. 1969) (refusing to invalidate patent for drug despite FDA suspension of drug for acute side effects); *In re* Hartop, 311 F.2d at 260 (refusing to invalidate patent because of potential dangerous side effects).

175. HARVARD/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525, 528.

176. Amended Proposal, *supra* note 34, at 183 (Amendment No. 4).

177. *Id.* at 184 (Amendment No. 6).

178. *Id.* art. 2(b), at 185 (Amendment No. 15).

179. *Id.* arts. 2(e)–2(f), at 186 (Amendment Nos. 18–19).

180. *Id.* art. 2(d), at 186 (Amendment No. 17). This appears to be a tacit acknowledgement of the test set forth by the EPO in *HARVARD/Onco-mouse*. *See supra* notes 81–85 and accompanying text (discussing test suggested by Appeals Board and used by the Examining Division in finding the Onco-mouse deserving of a patent).

V. CONCLUSION

Imposing barriers to biotechnological patents will not prevent the advance of genetic engineering or address the ethical issues raised by scientific advancement. These issues will persist regardless of whether patents are granted.[181] Furthermore, even if the EC ignores the field of biotechnology, its international competitors will not.[182] As the United States Supreme Court stated, "The grant or denial of patents on micro-organisms is not likely to put an end to genetic research . . . [however] [w]hether . . . claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives."[183] In Germany a special Commission of Inquiry on the Opportunities and Risks of Genetic Technology echoed these insights and stated that the types of "criticism of genetic engineering are often simultaneously or primarily criticisms of over-arching strategies which have developed independently of genetic engineering . . . involving basic problems of . . . industrialization."[184]

The Proposed Directive should be enacted by the EC because it recognizes the potential ethical concerns and the reality of scientific progress.[185] The international competitors of the EC are capitalizing on biotechnology and encouraging scientific innovation by allowing biotechnological patents to issue under systems more lenient than the EPC. The Proposed Directive begins to address the EC gap in protection for biotechnological inventions, which are crucial to the commercial and international competitiveness of the EC, by mandating uniform legal protection. Although the scope of protection for biotechnological inventions under the Amended Proposal is more limited than the Proposed Directive originally introduced by the Commission, passage of the Directive is still a necessary step to take in narrowing the gap between the EC and its international competitors. Whether the Proposed Directive will achieve its goals remains to be seen. However, the history of the European Onco-mouse has shown

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181. In addition, it is inefficient to try to accommodate ethical norms which may change. For example, the United Kingdom refused to claim contraceptives under the Royal Prerogative under the 1949 Act, but now allows condoms to be the subject of Government advertising. *See* COOK ET. AL., *supra* note 2, at 120.

182. *See supra* notes 51–59 and accompanying text.

183. *Chakrabarty*, 447 U.S. at 317.

184. Wolf-Michael Catenhusen, *Public Debate on Biotechnology: The Experience of the Bundestag Commission of Inquiry on the Opportunities and Risks of Genetic Engineering*, *in* BIOTECHNOLOGY IN FUTURE SOCIETY: SCENARIOS AND OPTIONS FOR EUROPE 117, 123 (Edward Yoxen & Vittorio Di Martino eds., 1989).

185. *See* Amended Proposal, *supra* note 34, at 183 (Amendment Nos. 2, 4).

that the current outlook for biotechnological innovations will remain bleak if no action is taken.

The Onco-mouse currently stands alone in an area of inadequate and murky protection for biotechnology innovations. Without immediate action on the part of the Commission and member states, the EC will stand alone in its ethical debate as other nations simultaneously commercialize biotechnology and manage ethical concerns associated with biotechnological inventions.

Cynthia M. Ho