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INTRODUCTION

Technology has once again overtaken the law. Ever since the United States Supreme Court concluded in 1980 that anything under the sun that was made by man could be patented,¹ and especially since the United States Patent and Trademark Office ("USPTO") announced in 1987 that it considered nonnaturally occurring nonhuman animals to be patentable subject matter,² legislative bodies in both the United States and the European Economic Community ("EEC") have been debating to what extent living matter should be patentable. Not only have animal patents³ been granted,⁴ but appli-
cations for patents for human gene fragments\(^5\) have been filed both in the United States by the U.S. National Institutes of Health ("NIH")\(^6\) and in the United Kingdom.\(^7\) The USPTO has rejected the human gene fragment applications submitted by NIH for failure to meet minimum U.S. patent law requirements of usefulness and non-obviousness.\(^8\) However, NIH is confident it can answer the USPTO's concerns.\(^9\)


The so-called "Harvard mouse" U.S. patent claim is actually for any species of "transgenic nonhuman mammal, all of whose germ cells [reproductive cells] and somatic cells [cells that become tissues, organs, etc.] contain a recombinant activated oncogene sequence [genetic information that makes the animal susceptible to cancerous tumors] introduced into said mammal, or an ancestor of said mammal, at an embryonic stage." U.S. Patent No. 4,736,866, 1089 OFFICIAL GAZ. PAT. OFF. 703 (Apr. 12, 1988). In January 1993, a second animal patent was issued to researchers at Ohio State University for a strain of mice carrying a human gene that makes them resistant to viral infection. Virus-Resistant Mouse to Receive a Patent, N.Y. TIMES, Dec. 28, 1992, at D2.

5. As part of the work on the Human Genome Project, an international effort to map and sequence all of the human genes, a researcher at the U.S. National Institutes of Health developed a technique of identifying genes on the basis of DNA sequences. See Gina Kolata, Biologist's Speedy Gene Method Scares Peers But Gains Backer, N.Y. TIMES, July 28, 1992, at C1.


7. In July 1992, the U.K. Medical Research Council filed its own applications with the U.K. Patent Office for about 1,100 human gene fragments in retaliation for NIH's filing and to secure its bargaining position should the NIH applications succeed. Celia Hampton & Simon Cohen, A Patent for Dr. Frankenstein, FIN. TIMES, Aug. 14, 1992, at 8; see also Gladwell, supra note 6.

8. Warren E. Leary, Health Counsel Opposes New Gene Patents, N.Y. TIMES, Oct. 8, 1992, at B26. In testimony to Congress on September 22, 1992, Dr. Bernadine Healy, then Director of the NIH, told Congress that the USPTO, in rejecting an application by NIH to patent thousands of gene fragments that NIH researchers had identified, questioned granting patent protection to gene fragments whose uses are unknown and concluded that the application did not meet the requirement for nonobviousness. Id.

9. It is unclear to what extent the NIH claims will be prosecuted. The then general counsel of the United States Department of Health and Human Services ("HHS") had advised NIH not to pursue the patent applications. However, the final decision to pursue the claim is up to the Secretary of HHS. Dr. Bernadine Healy asked Congress to take action on the issue of the patenting of human genes. Id. Since then, Bill Clinton has been elected President and Dr. Donna E. Shalala has been named Secretary of HHS. Dr. Healy resigned from NIH on June 30, 1993. Reynolds Holding, Nobel Prize Winner from
In the wake of the debate over the patentability of living organisms, the Commission of the European Communities ("Commission") has proposed to the Council of Ministers ("Council") a Directive on the Legal Protection of Biotechnological Inventions ("Proposed Directive"). On October 29, 1992, the European Parliament ("Parliament") voted to approve the Proposed Directive subject to its amendments. On December 16, 1992, the Commission submitted to the Council its amended proposal for a directive ("Amended Proposed Directive").

This Article examines the patentability of living organisms, including human material, under Chapter 1 of the Proposed Directive. Part I reviews the economic issues that were the impetus for the Proposed Directive and the legal context that framed the Directive's scope, including international agreements and the European Patent Office decision on patenting animals. Part II examines eco-

San Francisco in Running for Top NIH Post, S.F. CHRON., June 17, 1993, at A13. As of this writing, the policy of the current administration on this issue has not been announced.

12. Amended Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions O.J. C 44/36 (1993) [hereinafter Amended Proposed Directive]. The Council must now reach a "common position," by qualified majority, to submit to Parliament for a second reading. Parliament has three months in which to accept, amend, or reject the Council's common position. If Parliament accepts or takes no action, the Council adopts the proposal as found in its common position. If Parliament amends, the Commission has one month in which it may again amend the proposal, thereafter called the "re-examined proposal." Within the next three months, the Council must adopt the Directive or else it lapses. There must be a qualified majority if it adopts the Commission's re-examined proposal without changes. It must act with unanimity if it amends the Commission's re-examined proposal. If Parliament rejects the Council's common position at the second reading, then the Council can only adopt the proposal by unanimous vote. See generally AUDREY WINTER ET AL., EUROPE WITHOUT FRONTIERS: A LAWYER'S GUIDE (1989).

nomic and ethical issues that concerned Parliament when it pro-
posed amendments with respect to the patentability of living matter un-
der the Proposed Directive. Part III analyzes the attempt in the
Amended Proposed Directive to reconcile Parliament’s concerns
with the goal of achieving competitive parity with the United
States. This Part also explores the Amended Proposed Directive’s
failure to adequately address the reservations about patenting hu-
man materials. Some such reservations are based on economic
concerns that the patent system may permit monopolistic powers
derived from broad patent claims to choke off the flow of develop-
ments. Accordingly, the Article suggests that, given the uncertain-
ties in this area in both the United States and the EEC, an interna-
tional agreement would be the most effective way to satisfy eco-
nomic concerns. This Article concludes that the Amended Pro-
posed Directive’s specific definitions and minimum standards will
provide greater certainty in determining what is patentable and thus
help to strengthen the EEC’s domestic biotechnology industry.

I. PATENT PROTECTION AS AN ELEMENT OF ECONOMIC POLICY

The granting of a patent for an invention is regarded as an
incentive to invest in and carry out research and development.13 At
the same time, granting a patent promotes early disclosure of new
advances in technology and makes an invention part of the general
information system of society upon which further industrial devel-
opment can be based.14

According to at least one commentator, biotechnology15 is con-

Friedrich-Karl Beier & Joseph Straus, Patents in a Time of Rapid Scientific and Techno-
logical Change: Inventions in Biotechnology, in BIOTECHNOLOGY AND PATENT PROTEC-
14. Id.
15. For purposes of the Proposed Directive, biotechnology 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.
Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions,
COM(88)496 final—SYN 159 at 7-8 [hereinafter Commission Memorandum]. It includes
the techniques of recombinant DNA, gene transfer, embryo manipulation and transfer,
sidered the third technological revolution of this century, preceded only by nuclear energy and information technology.\textsuperscript{16} Perhaps its earliest and greatest impact has been in the pharmaceutical and health care industry, with the production of human insulin, interferons for the treatment of cancer, tissue plasminogen activators for the dissolution of blood clots, and hundreds of diagnostic tests capable of detecting diseases.\textsuperscript{17} In plant and animal agriculture, biotechnology is expected to improve food production by increasing the growth rates and growth efficiency of animals and by creating plants resistant to diseases, insects, and herbicides.\textsuperscript{18} Patent protection and public acceptance are conditions critical to the diffusion of biotechnology throughout society.\textsuperscript{19} Both of these topics are at the center of the debate in Europe at the present time.

In 1985, when the Commission presented its program for completing a single, integrated Common Market for the European Community by 1992,\textsuperscript{20} its recommendations for the removal of technical barriers to trade in goods included measures for the patent protection of biotechnological inventions.\textsuperscript{21} Differences in intellectual property laws were seen as having a direct and negative impact on intra-Community trade and on the ability of businesses to treat the common market as a single environment for their activities.\textsuperscript{22}

In 1988, the Commission sought to establish clear and improved standards for the protection of biotechnological inventions by issuing the Proposed Directive.\textsuperscript{23} The Commission intended to


\textsuperscript{17} \textit{Id.} at 23.

\textsuperscript{18} \textit{Id.} at 24-25.

\textsuperscript{19} \textit{Id.} at 57; \textit{see, e.g., BIOTECHNOLOGY AND CHANGING ROLE OF GOVERNMENT (OECD 1988); 1992—PLANNING FOR CHEMICALS, PHARMACEUTICAIALS, AND BIOTECHNOLOGY} (Int'l Bus. Intelligence 1989).

\textsuperscript{20} Commission of the European Communities, Completing the Internal Market: White Paper from the Commission to the European Council, COM(85)310 final.

\textsuperscript{21} \textit{Id.} at 37.

\textsuperscript{22} \textit{Id.}

\textsuperscript{23} Commission Memorandum, \textit{supra} note 15, at 6.
facilitate the development of the EEC's biotechnology industry and trade in biotechnological products, as well as enable the EEC's industries to keep pace with leading nations in biotechnology and to close or narrow existing gaps with a harmonized system of patent law.\textsuperscript{24}

Eliminating barriers to the exchange of knowledge and technology transfers between Member States, and to trade in the EEC by providing harmonized protection of biotechnological inventions would be an incentive for investments throughout the EEC.\textsuperscript{25} In addition, the Proposed Directive would contribute to trade among Member States hampered (without the Directive) "by the fact that export of self-reproducible biotechnological products into areas with uncertain, weak or even non-existent protection is less than attractive."\textsuperscript{26} Furthermore, EEC industries would be more likely to repatriate their funds, previously invested overseas, in research and development.\textsuperscript{27} Finally, investors from other countries "would be more inclined to invest in the EEC."\textsuperscript{28}

The importance of biotechnology patent protection to the economy of the EEC was emphasized in a Commission communication on April 18, 1991.\textsuperscript{29} The Commission identified three problem areas to be addressed in order to improve the competitiveness of the EEC's biotechnology industry: (1) inadequate patent protection; (2) a fragmented market; and (3) public concern with ethical

\textsuperscript{24} Id. The United States and Japan were perceived as having been able to adapt their patent protection according to the latest needs of industry. Id. at 22. The Commission was not alone in viewing intellectual property protection as a key factor in fostering competitive industries. See, e.g., U.S. CONGRESS, OFFICE OF TECH. ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 203 (1991).

\textsuperscript{25} Commission Memorandum, supra note 15, at 22.

\textsuperscript{26} Id.

\textsuperscript{27} Id.

\textsuperscript{28} Id.

\textsuperscript{29} Commission proposes programme to strengthen European biotechnology, New Developments, [1991-1993 Transfer Binder] Common Mkt. Rep. (CCH) ¶ 95,877 (1991). The communication noted the impact of biotechnology on various sectors of society, including food production, health, and environmental protection. It also pointed out the volume of world-wide sales (European Currency Unit 7,500m in 1985) and the number of persons presently employed in the EEC in the sector (fifteen million). Id.
issues. Emphasizing that enterprises will only invest in high-risk, long-term projects if intellectual property law guarantees adequate protection for the results of research, the Commission set a high priority on its proposals to ensure that biotechnology products fall within the scope of patent protection.

II. LEGISLATIVE FRAMEWORK OF THE PROPOSED DIRECTIVE

A. The Strasbourg and European Patent Conventions

The 1963 Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions ("Strasbourg Convention") was aimed at unifying substantive patent law in Europe. It set out the basic requirements for the patentability of an invention; that is, it must have industrial application, must be new, and must involve an inventive step. The Strasbourg Convention also provided that contracting states did not have to grant patents for inventions which would be contrary to public order or morality or "plant or animal varieties or essentially biological processes for the production of plants or animals," although this last provision did not apply to microbiological processes and products. Thus, the Strasbourg Convention allowed contracting states to exclude from patent protection inventions that were contrary to public order or morality, plant and animal varieties, or "essentially biological processes for the production of plants or animals," but not to exclude microbiological processes and products.

The background documents to the Strasbourg Convention do not provide much information on the reasons for the exclusions from the patent harmonization effort for inventions in animal breeding; however, neither economic arguments nor ethical consid-

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30. Id.  
31. Id.  
33. Id. art. 1.  
34. Id. art. 2(a).  
35. Id. art. 2(b).
erations seem to have played any major role.\textsuperscript{36} Although certain writers justify the exclusion of animal varieties and "essentially biological" inventions as corollary to the exclusion of inventions contrary to public order or morality, most argue against the exclusion with respect to animal breeding.\textsuperscript{37} The exclusion of animal varieties and "essentially biological processes" for breeding animals has been attributed to the fact that the conventional forms of patent protection were not considered suitable for biological processes and products.\textsuperscript{38} Thus, the provision may have been influenced by the concept that special protection schemes, along the lines of the plant variety protection system established two years earlier under the International Union for the Protection of New Varieties of Plants,\textsuperscript{39} were more appropriate.\textsuperscript{40}

Further legal uncertainty is caused by the difficulty in drawing an exact borderline between patentable microbiological processes and unpatentable "essentially biological processes."\textsuperscript{37}\textsuperscript{41} For instance, with regard to the effect of this provision on patents for genetic engineering, it has been argued: (1) that the whole field of genetics is biological and that all genetic processes and methods are essentially biological processes, and thus unpatentable;\textsuperscript{42} (2) that a genetic invention is not essentially biological if an "important part" of the process relies on physical or chemical means, and thus a case-

\textsuperscript{37} Id. at 831.
\textsuperscript{40} Moufang, supra note 36, at 830 n.40.
\textsuperscript{41} Id. at 836.
\textsuperscript{42} Id. at 837.
by-case analysis is required to determine if the biological parts of the process outweigh the physical or chemical steps and the invention is unpatentable;\(^43\) and (3) that there is a distinction between a technical process in which human intervention occurs and a biological process which is essentially natural and uncontrollable (without human intervention) and thus “essentially biological” means “essentially without human intervention.”\(^44\)

Despite these uncertainties, the same Strasbourg Convention provisions, with one major modification, were picked up in the 1973 European Patent Convention (“EPC”) and signed by fourteen European countries.\(^45\) Like the Strasbourg Convention, the EPC defines patentable subject matter as inventions which are susceptible to industrial application, are new, and involve an inventive step.\(^46\) Unlike the Strasbourg Convention, however, the EPC explicitly excludes patents for certain inventions:

European patents shall not be granted in respect of: (a)

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43. Id.

44. Id. at 837-38.


46. EPC, *supra* note 45, art. 52(1), 13 I.L.M. at 285. However, the EPC adds that the following are not inventions: “(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information.” *Id.* art. 52(2), 13 I.L.M. at 285. It further adds that “[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application.” *Id.* art. 52(4), 13 I.L.M. at 285-86.
inventions, the publication or exploitation of which would be contrary to "ordre public" [public policy] or morality [and] (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 products thereof.\(^4\)

Since most of the Member States had signed the EPC,\(^48\) the Commission chose to build on the harmonization process begun under the Strasbourg Convention and the EPC rather than develop a sui generis system for protecting biotechnological inventions.\(^49\) When the Commission proposed the directive in 1988, the U.S. Patent Office had already issued a patent on the Harvard mouse,\(^50\) and the same application was pending in the European Patent Office. The Commission was concerned that the existing legal framework for protecting biotechnological inventions in the Member States could not satisfy the needs of the patent authorities and the courts because the underlying assumptions were outdated by scientific and technological developments.\(^51\) In particular, the distinction between microbiology and macrobiology as the dividing line between patentable and non-patentable inventions was seen as artificial and no longer tenable.\(^52\) The Commission addresses these issues in Chapter 1 of the Amended Proposed Directive.\(^53\)

**B. EPO Ruling on Patenting the Harvard Mouse**

While the Parliament was considering the Proposed Directive, the European Patent Office ("EPO") ruled on the Harvard mouse patent application. In 1989, the Examining Division of the EPO
("Examining Division") denied the Harvard mouse patent application on the grounds that Article 53(b) of the EPC excludes patent protection for animals per se, and does not merely exclude a patent relating to a particular variety of animal.\textsuperscript{54} It also ruled that where the essence of the process invention is the introduction of an oncogene into an animal by technical means (micro-injection), the process is clearly not "essentially biological."\textsuperscript{55} However, it held that if the product-by-process is a plant or animal variety excludable by the first part of Article 53(b), then the exception for microbiological processes and products in the second part of the provision cannot be interpreted as setting aside the exclusion with respect to that product.\textsuperscript{56}

In October 1990, the EPO Board of Technical Appeals ("Board of Appeals") ruled that the language of Article 53(b) excluded only animal varieties as such from patent protection.\textsuperscript{57} Thus, if the subject matter of a patent claim is not an animal variety, Article 53(b) is not a bar to patentability.\textsuperscript{58}

The Board of Appeals confirmed that the process claim for the introduction of the oncogene by technical means was not an "essentially biological process."\textsuperscript{59} However, it ruled that a product-by-process claim is still a product claim, irrespective of the process to which it refers.\textsuperscript{60} Since Article 53(b) excludes only "essentially biological processes" for the production of animals, it is not a bar to patenting the product of the process.\textsuperscript{61}

Further, the Board of Appeals ruled that the provision in the second part of Article 53(b) that microbiological processes were not excluded from patent protection was an exception to the origi-
nal exclusion from patent protection of "essentially biological processes" in the first part of Article 53(b). Thus, "the general patentability under Article 52(1) is restored for inventions involving microbiological processes and the products of such processes." Consequently, according to the Board of Appeals, animals produced by microbiological processes are patentable.

Finally, the Board of Appeals remanded the question of whether the invention was contrary to public policy or morality. The concern was two-fold. The genetic manipulation described in the claim caused the animal to be abnormally sensitive to carcinogenic stimuli and prone to develop tumors and thus caused suffering. There was also consideration of the danger that genetically-manipulated animals, if released into the environment, might have unforeseeable and irreversible adverse effects.

On remand, the Examining Division concluded that an animal variety is a sub-unit of a species, and therefore of even lower ranking than a species, and that rodents or even mammals are a higher classification unit than species. Accordingly, the subject-matter of claims for patents to animals per se is not covered by the term "animal variety," and the Harvard mouse claim is not excluded by the Article 53(b) exclusion of animal varieties from patent protection.

62. Id. at T 19/90-11.
63. Id.; see supra text accompanying notes 46-47 for general rule for patentable inventions.
64. Onco-mouse/Harvard, Case T-19/90, [1990] O.J.E.P.O. 12/476 (Tech. Bd. App. 1990), reprinted in 5 Eur. Pat. Handbook (MB), ch. 103, T 19/90-11. Although the issue of whether the claimed processes were microbiological processes was remanded to the Examining Division, that division did not decide the question.
65. Id.
66. Id.
67. Id.
68. Onco-mouse/Harvard, Decision of 3 April 1992, [1992] O.J.E.P.O. 568 (Examining Div.), reprinted in 5 Eur. Pat. Handbook (MB), ch. 106, E-35, E-37; see also Moufang, supra note 36, at 833 (noting that according to Webster’s Dictionary, there is a tendency to abandon the word "variety" on account of its indefiniteness and quoting its definition of “variety” as narrower in scope and lower in rank than a species, i.e., a subspecies, race, breed, strain, stock).
69. Onco-mouse/Harvard, Decision of 3 April 1992, [1992] O.J.E.P.O. 568 (Examining Div., reprinted in 5 Eur. Pat. Handbook (MB), ch. 106, E-35, E-37; see also Moufang, supra note 36, at 833 (noting that according to Webster’s Dictionary, there is a tendency to abandon the word “variety” on account of its indefiniteness and quoting its definition of “variety” as narrower in scope and lower in rank than a species, i.e., a subspecies, race, breed, strain, stock).
exclusion of patents contrary to public policy or morality, the Examining Division balanced the interests of mankind in curing diseases, the need to protect the environment against the uncontrolled dissemination of unwanted genes, and the need to avoid cruelty to animals. It concluded the transgenic mouse was not an invention that was immoral or contrary to public policy since it was useful in cancer research and thus beneficial to mankind.

In summary, the EPO's position with respect to Article 53 is to construe the exceptions and limitations very narrowly. Patents can be obtained for a wide range of genetically modified organisms. It has been suggested that EPC product protection should be available for most results of modern animal biotechnology, beginning with animal biological material of all kinds, such as genes, transfer vectors, cell lines modified cells, and ending with transgenic animals.

The Examining Division's announcement in October 1991 that it would grant the animal patent caused an uproar in the Parliament. One member of Parliament suggested the apparent preemption of the Parliament's discussion might lead to the Proposed Directive's rejection. Various interest groups—including animal welfare groups, farmers, and the Patent Concern Coalition (some thirty organizations opposed to the patenting of animals and plants)—voiced objections to the EPO's decision.

C. Parliament's Concerns

The Parliamentary committees that examined the Proposed


70. \textit{Id. at E-38.}
71. \textit{Id. at E-39.}
74. \textit{Id.}
75. \textit{Id.}
76. The Committee on Legal Affairs and Citizens' Rights was primarily responsible for suggesting amendments to the Proposed Directive. The Committee on Economic and Monetary Affairs and Industrial Policy, the Committee on Energy, Research and Technology, and the Committee on Agriculture, Fisheries and Rural Development also gave their
Directive suggested amendments that reflected the economic and ethical concerns of a number of groups, including animal rights activists, the "Greens," and farmers. One of the ethical concerns was the pain and suffering of transgenic animals created by genetic manipulation to be susceptible to disease, which was also an issue addressed in granting the Harvard mouse patent.

Parliament's concern about industrial competitiveness seems to have been less acute than the Commission's. The Third Report of the Committee on Legal Affairs and Citizens Rights ("Third Report") concluded that easier patentability of biotechnological inventions is just one factor in the restructuring of the biotechnology industry. It acknowledged the problems of access to biotechnological inventions and monopolistic powers of patent holders. It noted that the Commission and the Court of Justice have responsibilities in combating efforts to secure market dominance and market carve-ups. With respect to the major economic conflict of interest between the agro-chemical industry and seed producers on one side and user/farmers on the other, the Third Report concluded those problems would not be solved by special provisions in the Directive.

The Committee on Economic and Monetary Affairs and Industrial Policy was particularly concerned with the economic power invested in patent holders. It identified three major concerns linked to the development of biotechnology: (1) to ensure that

opinions.

77. Third Report of the Committee on Legal Affairs and Citizens' Rights, EUR. PARL. DOC. (PE 201.664/fin) 1, 3 (1992) [hereinafter Third Report].

78. Id. at 31-33. The rapporteur (author of the document) also noted the arguments that it was indefensible to reduce animals to mere units of production and that living creatures should not be the objects of title to property, but rejected those statements as going too far. Id. at 32.

79. The rapporteur's reaction to the Commission's goal of maintaining international competitiveness was that legal policy in the EEC should be more than a set of arrangements for bringing about favorable conditions of competition. Id. at 27.

80. Id. at 35.
81. Id. at 35-36.
82. Id. at 36.
83. Id.
84. Id. at 47-49.
patent protection does not mean that users are unable to exploit new discoveries without long delay and without the cost being prohibitive, in other words, that the patent system does not result in market monopolies; (2) to prevent the creation of a cultural monopoly favoring those who first obtain a patent; and (3) to ensure that patent regulations do not prevent action by public authorities to exploit new technical possibilities if this will expedite some of their programs. It also considered the ethical issue of patenting human beings. It recommended that the Proposed Directive clearly exclude inventions relating to the human being as such and which could modify the genetic identity of the individual as a whole.

In its examination of the issues raised by the Proposed Directive, the Committee on Energy, Research and Technology concluded that patent law was not the proper method of handling ethical issues. It suggested that the ethical limits of research on animals should be addressed outside of patent law. It concluded that living matter should not be excluded from patent protection. However, it recommended that human beings and their “constituent parts,” including human genes, cell lines, organs, and tissues, should not be patentable. This exclusion would not extend to inventions involving genetic change in human beings in order to treat or cure disease, so long as they do not violate public policy or human dignity.

The Committee on Economic and Monetary Affairs and Industrial Property examined objections to patent protection for living matter because of concerns about potentially adverse effects on users. In particular, the Committee was presented with concerns that: (1) farmers would lose their independence since they could not use patented seeds or subsequent generations bred from them

85. Id. at 49.
86. Id. at 50.
87. Id.
88. Id. at 58.
89. Id. at 61.
90. Id. at 60.
91. Id.
92. Id. at 60-61.
for their private use;\footnote{Id. at 57.} (2) independent plant breeders would have to pay fees for each patented gene or breeding process, leading to a small number of genetic engineering firms rather than many breeders;\footnote{Id.} (3) consumers would have to pay higher prices for more sophisticated food;\footnote{Id.} (4) researchers would have to keep their material secret until large genetic engineering firms filed their patent applications, thus narrowing access to scientific information;\footnote{Id.} and (5) that concentration among firms would be encouraged since fewer firms would be able to stand up to multinational businesses' mass market power.\footnote{Id. at 58.} The Committee concluded that the economic benefits of patent protection for living matter outweigh the drawbacks.\footnote{Id. at 59.} It found no evidence to bear out the assumption that only large firms benefit from patent protection and that, on the contrary, the absence of patent protection encourages secretiveness and denies small firms access to technical advances.\footnote{Id.}

On the other hand, the Committee on Agriculture, Fisheries and Rural Development opposed the Proposed Directive. It concluded that the economic costs of patenting living matter and processes outweigh the benefits.\footnote{Id. at 65.} It feared that such patents would introduce secrecy into the research world because of restricted communication of scientific advances while corporations applied for patent rights.\footnote{Id. at 64.} This committee was concerned that not only would the payment of royalties for every generation of plant or livestock during the life of the patent be an added burden to farmers, but also that farmers would be faced with the problem of “patent stacking,” where one plant or animal could be covered by multiple patents with their separate components, each of which would give rise to royalty payments.\footnote{Id.} Breeders and farmers would be increasingly dependent on major chemical, pharmaceutical and food processing
firms which would own the genes and genetic information. 103

III. PATENTABILITY OF LIVING MATTER UNDER THE AMENDED PROPOSED DIRECTIVE

A. The Proposed Directive and Parliament's Amendments

Under the Proposed Directive, Article 2 simply read, "subject matter of an invention shall not be considered unpatentable for the reason only that it is composed of living matter." 104 The Commission intended to negate the argument that living matter is not patentable only because it is a natural product. 105 Living matter is no less patentable than non-living matter, if the required novelty, inventive activity, and industrial applicability are present. 106 Further, technology that makes use of plants, animals, and microorganisms is patentable. 107 Moreover, the Commission concluded that inventive activity in the area of human beings was excludable from patent protection on public policy grounds and thus did not need to be mentioned specifically. 108

Parliament offered ten amendments ("Amendments") to Article 2 that, while accepting the essential premise that living matter is patentable, limited the Commission's broad proposal. 109 The Amendments agree that an invention is not unpatentable only because it is "composed of, uses or is applied to biological material." 110 Biological material is defined in the Amendments to mean "any self-replicating living matter and any living matter capable of being replicated through a biological system." 111

However, Parliament did not leave the issue of inventions with respect to the human body to public policy provisions. The

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103. Id. at 65-66.
106. Id. at 33.
107. Id.
108. Id.
110. Id. amend. 13.
111. Id. amend. 14.
Amendments specify that "[t]he human body or parts of the human body shall not be patentable." With respect to the treatment of diseases, the Amendments require that "[p]rocedures for surgical or therapeutic treatment of the human or animal body and diagnostic procedures carried out on the human or animal body not be patentable." Specifically, the Amendments state that procedures for the genetic modification of human beings are not patentable, although products used in such procedures are patentable. Furthermore, under the Amendments, the genetic modification of human beings in connection with the treatment of diseases is patentable, unless it offends public policy or affects the dignity of human beings.

In the Amendments, Parliament defined certain inventions that it deemed to offend public policy. In language similar to Article 53(a) of the EPC, Parliament provided that inventions would not be patentable if their publication or exploitation would offend public policy or common decency. In addition, just as the Board of Appeals directed the Examining Division to weigh the suffering of animals and possible risks to the environment against the usefulness of the invention in its remand of the Harvard mouse patent claim, Parliament would amend the Proposed Directive to require that whether an invention offends public policy be determined on an individual basis. Specifically, "in each particular case on the basis of 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, be taken into consideration."

In response to concerns over the treatment of animals, Parliamentary Amendments, supra note 109, amend. 16.

112. Id. amend. 15.
113. Id. amend. 20.
114. Id.
115. See supra text accompanying note 47.
116. Parliamentary Amendments, supra note 109, amend. 16.
118. Parliamentary Amendments, supra note 109, amend. 17.
119. The Third Report described the suffering of the "notorious Beltsville pig," which was the subject of a patent application. The pigs were given a gene originating from human genetic material which caused them to grow faster, carry less fat, and pass
ment further specified that inventions "which involve unnatural processes for the production or modification of animals or cause unnecessary suffering or unnecessary physical harm to the animals concerned" be deemed incompatible with public policy and unpatentable. Furthermore, inventions of animals which, "owing to the phenotype or their genetic constitution, cannot be kept without adverse effects on their health or which are unnaturally interspecific," be deemed incompatible with public policy and unpatentable.

If an invention is not patentable under the Amendments to Proposed Directive Article 2, then "a temporary universal ban on copying the invention" is required. Thus, not only would Parliament not allow patent protection for certain inventions, it would also limit their use.

the new gene on to their offspring. However, they also suffered from arthritis and were more susceptible to infections. Third Report, supra note 77, at 33.

120. Parliamentary Amendments, supra note 109, amend. 18. The denial of patent protection for inventions involving "unnatural processes for the production or modification of animals" could end all patenting of genetically modified animals. That clause does not, strictly speaking, provide for any balancing of interests. The denial of patent protection to inventions which cause unnecessary suffering or harm, while implying some degree of balancing to determine what is "unnecessary" suffering, certainly invites litigation and opposition to patent claims involving genetically modified animals.

121. Id. amend. 19. Proposed amendment 19 in the Second Report of the Committee on Legal Affairs and Citizens' Rights included the term "chimera" in parentheses following the term "interspecific" to explain the phrase. EUR. PARL. DOC. (PE 156.257/fin.2) 8 (1992). A chimera is made by substituting embryonic cells of one organism for some cells in another organism's blastocyst (the last stage of embryonic development before an embryo implants on the wall of the uterus). The technique has been used to transfer the embryonic cells of one variety of mouse into another variety and to mix two closely related species, i.e., a goat and a sheep, to create a geep. HOUSE COMMITTEE OF THE JUDICIARY, TRANSGENIC ANIMAL PATENT REFORM ACT, H.R. REP. NO. 888, 100th Cong., 2d Sess. 34 (1988). By using the phrase "unnaturally interspecific," the rapporteur apparently did not intend to go as far as those who would deny patent protection to any biotechnological invention that breaches species barriers or violates species integrity, but only those inventions that would cause "unnecessary" suffering. See supra note 120.

122. Parliamentary Amendments, supra note 109, amend. 21(1). This Temporary ban shall remain in force until it is definitely ascertained whether exploitation is inadmissible on the grounds of general public order considerations or for reasons relating to the safety and protection of human beings, animals or the environment. Id. amend. 21(2).
B. The Amended Proposed Directive

In the Amended Proposed Directive, the Commission substantially revised Article 2.\(^\text{123}\) It accepted Parliament’s amendment that an invention would not be unpatentable “for the reason only that it is composed of, uses or is applied to biological material.”\(^\text{124}\) It modified slightly Parliament’s definition of biological material\(^\text{125}\) to mean “any self-replicating living matter and any matter capable of being replicated through a biological system or by any indirect means.”\(^\text{126}\) Presumably, the addition of the last five words is intended to assure that replication by genetic engineering techniques would be patentable.

In its Explanatory Memorandum accompanying the Amended Proposed Directive (“Explanatory Memorandum”),\(^\text{127}\) the Commission reversed itself on the need to include a public policy requirement for patentable subject matter. Acknowledging the public controversy and Parliament’s concerns since the original proposal was published, the Commission found it essential that patent law contain certain impassable barriers as a guide for those interpreting the concepts of public policy and morality.\(^\text{128}\) Similar to Article 53(a) of the EPC\(^\text{129}\) and Parliament’s amendment number 16,\(^\text{130}\) the Amended Proposed Directive provides that “[i]nventions shall be considered unpatentable where publication or exploitation thereof would be contrary to public policy or morality.”\(^\text{131}\) However, the Commission attempted to limit the scope of the public policy prohibition with the proviso 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 Member States.”\(^\text{132}\)

\(^{123}\) Amended Proposed Directive, supra note 12.

\(^{124}\) id. art. 2(1).

\(^{125}\) See Parliamentary Amendments, supra note 109, amend. 14.

\(^{126}\) Amended Proposed Directive, supra note 12, art. 2(2).


\(^{128}\) id. at 4.

\(^{129}\) See EPC, supra note 45, art. 53(a).

\(^{130}\) See supra note 116 and accompanying text.

\(^{131}\) Amended Proposed Directive, supra note 12, art. 2(3).

\(^{132}\) Id. (emphasis added).
The Commission specified three categories of inventions that would be unpatentable because they are contrary to public policy or morality:

(a) the human body or parts of the human body per se;

(b) processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man;

(c) processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal.\footnote{133}

In its Explanatory Memorandum accompanying the Amended Proposed Directive, the Commission said that the exclusion from patentability of “parts of the human body per se” in Article 2(3)(a) is intended to apply to “parts of the human body as found inside the human body.”\footnote{134} The language is intended to remove all ambiguity with respect to patents already granted, for example: patents for a human cell line; recombinant DNA molecules; molecular cloning and characterization of gene sequence coding processes; and particular processes for producing human antibody and human protein.\footnote{135} The Explanatory Memorandum’s statement that “a mere part of the ‘human body’ \textit{per se}, e.g., a human gene neither the function of which nor the protein for which it codes is known,” is excluded from patentability,\footnote{136} appears to be a statement that would block NIH’s attempt to patent human gene fragments,\footnote{137} not on the basis of the lack of usefulness, but rather because they were parts of the human body per se.\footnote{138}

In Article 2(3)(b),\footnote{139} the Commission revised Parliament’s
Amendments\textsuperscript{140} to ensure that inventions that modify the genetic identity of human beings and that improve the lives of persons suffering from serious illness would be patentable.\textsuperscript{141} Thus, the requirement that a process for modifying the genetic identity of human beings conform to the principle of the "dignity of man" was coupled with the requirement that the process be therapeutic so that processes for eugenics would not be patentable.\textsuperscript{142}

In Amended Proposed Directive Article 8, the Commission added the language found in Article 52(4) of the EPC,\textsuperscript{143} that "[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be patentable," although it specified that this prohibition would "not apply to products, in particular substances or compositions, for use in any of these methods."\textsuperscript{144} The prohibition is in a separate article from the public policy provisions of Article 2 because the Commission intended to distinguish biotechnological processes meeting the ethical requirement of having a therapeutic purpose in keeping with the dignity of man from methods of treatment which are not patentable under the EPC.\textsuperscript{145} An invention which meets the ethical test of having a therapeutic purpose in keeping with the dignity of man would nonetheless not be patentable if it were a method of treatment.\textsuperscript{146} Conversely, an invention of a product that was not excluded by Article 8, might still be unpatentable if it violated the ethical requirements of Article 2(3)(b).\textsuperscript{147}

\begin{footnotes}
\item[140. See supra notes 113-114 and accompanying text.]
\item[141. Explanatory Memorandum, supra note 127, at 8.]
\item[142. Amended Proposed Directive supra note 12, 2(3)(b); see also Explanatory Memorandum, supra note 127, at 9.]
\item[143. See EPC, supra note 45, art. 52(4). Similar language was also included in the Parliamentary Amendments. See supra text accompanying notes 113-114.]
\item[144. Amended Proposed Directive, supra note 12, art. 8.]
\item[145. Explanatory Memorandum, supra note 127, at 9; see also Thurston, supra note 138, at 188 (critical analysis of Proposed Amended Directive and Explanatory Memorandum in which author suggests that qualifying language "contrary to the dignity of man," seems to apply whether or not purpose is non-therapeutic).]
\item[146. Explanatory Memorandum, supra note 127, at 9.]
\item[147. Id.]
\end{footnotes}
While the Commission accepted, in part, Parliament's Amendments with respects to patents relating to humans, it rejected the numerous amendments limiting animal patents.148 Instead, in Article 2(3)(c) it provided a minimal balancing test, along the lines of the test used in EPO's Harvard mouse decision,149 where processes modifying the genetic identity of an animal may cause suffering.150 The Commission pointed to other laws that regulate the treatment of research animals.151 The Commission further emphasized that the patent directive was not the place to regulate biotechnology research by including in the Amended Proposed Directive a provi-
sion that the Directive would "not affect national and Community
laws on the monitoring of the applications of research and of the
use or commercialization of its results."152

One of the Commission's original goals was to provide clear and improved standards of patentability.153 Thus, under the original Proposed Directive, it set out specific definitions of what would be patentable:

Micro-organisms, biological classifications other than plant or animal varieties as well as parts of plant and animal varieties other than propagating material . . . protectable under plant variety protection law shall be considered patentable subject matter. Claims for classifications higher than varieties shall not be affected by any rights granted in respect of plant and animal varieties.154

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148. See supra notes 119-121 and accompanying text.
150. Amended Proposed Directive, supra note 12, art. 2(3).
151. Explanatory Memorandum, supra note 127, at 10-12.
152. Amended Proposed Directive, supra note 12, art. 2(4).
153. See supra text accompanying note 23.
154. Proposed Directive, supra note 10, art. 3(1). Article 3 also clarifies the distinc-
tion between the rights protected under the plant varieties protection system, UPOV
Treaty, supra note 39, and patent claims. Patent protection for plant material which is
not a variety is enforceable, even with respect to finished varieties incorporating patented
inventions. Thus, patents on new plant characteristics, such as insect, disease, and herbici-
cide resistance, are allowed. Plants, parts of plants such as genetic sequences, and classi-
fications other than varieties are protected by patent. Where a patented genetic sequence
is incorporated into an existing variety to produce a new variety with a new characteristic,
Essentially, under the Proposed Directive, patents were prohibited only for animals, plants, and plant propagating material in the genetically fixed form of a plant or animal variety. According to the Commission, the Proposed Directive provides no justification for not permitting a patent for an invention concerning plant or animal matter which is not a variety, such as plant or animal cells, cell lines, tissue cultures, and larger parts. In its Amendments to the Proposed Directive, however, Parliament had only gone so far as to say that “[b]iological material, including plants and animals, as well as parts of plants and animals, except plant and animal varieties as such” would be patentable to the extent allowed by the patent law in the Member States. Ultimately, the Commission chose to forego the benefits of specificity and accepted Parliament’s amendment, but without the reference to Member State law.

The Commission rejected Parliament’s amendment to Article 4, which would have provided patent protection for the “[u]ses of plant or animal varieties or of processes for their production, other than essentially biological processes.” According to the Commission’s analysis, the three types of inventions traditionally protected by patents—product, process, and application (or use) inventions—correspond to biotechnological inventions relating to an organism or material as such, a process for the creation of a living organism, and the use of an organism or other biological material. Thus, while plant and animal varieties as such are not patentable, the other two types of biotechnological inventions may be patented if they relate: (a) to a process that is not essentially biological; or

the patent rights in the genetic sequence are not extinguished. In short, the patent system is not hindered by the plant varieties protection system. Commission Memorandum, supra note 15, at 36.

155. Commission Memorandum, supra note 15, at 34.
156. Id.
157. Parliamentary Amendments, supra note 109, amend. 22. This amendment would allow the Member States to enact their own limits to the patentability of biological materials. It would also defeat the intent of the directive to remove any barriers to trade within the community, and would encourage cross-border investment by providing common rules for patent protection.
158. Amended Proposed Directive, supra note 12, art. 3.
159. Id. art. 4.
(b) to the use of the plant or animal variety.\textsuperscript{160}

Parliament, however, would not specifically permit a "use" patent for biological material. It would provide only that procedures for the production of biological material, except for essentially biological procedures for breeding plants or animals and for the production of plant or animal varieties, would be patentable to the extent allowed by the different Member States.\textsuperscript{161} The intent was to exclude processes for the production of plant or animal varieties from patentability, rather than to include them as provided by the Proposed Directive.\textsuperscript{162} In rejecting Parliament's amendment, the Commission pointed out that Article 4 would not deal with processes for the production of biological material, but only with the patentability of inventions using plant or animal varieties or of the processes for their production.\textsuperscript{163}

The laws of most Member States reflect the EPC's language, excluding "essentially biological processes" from patent protection but protecting microbiological processes.\textsuperscript{164} The Proposed Directive clarified the meaning of "microbiological processes"\textsuperscript{165} stating that "[m]icrobiological processes shall be considered patentable subject matter. For purposes of this Directive, this term shall be taken to mean and to include a process (or processes) carried out with the use of or performed upon or resulting in a micro-organism."\textsuperscript{166}

A microbiological process was defined as a process in which the essence of the invention is incorporated in one or more microbiological steps of the process.\textsuperscript{167} Thus, a multi-step process in which the essence of the invention is incorporated in a microbiological step was not denied patent protection simply because the

\begin{itemize}
\item \textsuperscript{160} Commission Memorandum, \textit{supra} note 15, at 37.
\item \textsuperscript{161} Parliamentary Amendments, \textit{supra} note 109, amend. 23.
\item \textsuperscript{162} Third Report, \textit{supra} note 77, at 39.
\item \textsuperscript{163} Explanatory Memorandum, \textit{supra} note 127, at 13.
\item \textsuperscript{164} Commission Memorandum, \textit{supra} note 15, at 37.
\item \textsuperscript{165} \textit{See supra} text accompanying notes 36-44. As originally drafted, the underlying motive behind the phrase was to exclude the results of traditional breeding processes using plants and animals from patent protection. Commission Memorandum, \textit{supra} note 15, at 38.
\item \textsuperscript{166} Proposed Directive, \textit{supra} note 10, art. 5.
\item \textsuperscript{167} \textit{Id.} art. 6.
\end{itemize}
process contains other, non-microbiological steps.168 Without this guideline, regeneration of a single genetically engineered cell to produce an entire plant might well have been considered an “essentially biological” process.169 Parliament would simply provide that if one step in a process were microbiological, the process would be treated as a microbiological process.170

In the Amended Proposed Directive, the Commission modified the definition of a microbiological process to mean “a process involving or performed upon or resulting in microbiological material.”171 It also adopted Parliament’s more specific requirement that “one essential step” be microbiological.172

Because “essentially biological processes” are not patentable, the extent to which human intervention is necessary to ensure that an invention is patentable was also described. As discussed, a major consideration here is the distinction between traditional breeding activities and other forms of human intervention in biological matter.173 Under the original Proposed Directive, where “human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions,” the process was patentable.174 Thus, the Commission specified that any human intervention other than selection would remove a process from the field of “essentially biological processes,” and make it patentable. This standard was in contrast with the EPO’s examination guidelines (“EPO Guidelines”), which require that human intervention must play a significant part in determining the result.175 Parliament would have the

170. Parliamentary Amendments, supra note 109, amend. 24. Both the Parliament’s amendment and the Commission’s proposal required a determination of what is essential to, or the essence of, the invention.
171. Amended Proposed Directive, supra note 12, art. 5(1).
172. Id. art. 5(2).
standard of human intervention that makes a procedure technical rather than biological closer to that of the EPO by requiring the nature of the intervention to be examined, having regard to its extent and its impact on the results.176

The Commission adopted the "facts and circumstances" approach of Parliament with respect to the nature and extent of human intervention that makes a process non-biological and thus patentable. However, it also specified that "[a] process which, taken as a whole, does not exist in nature and is more than a mere production process," would be patentable.177

Biotechnological techniques permit many natural substances to be selected and adapted for industrial, commercial, and medical uses. A biotechnological invention may also consist of the identification of a naturally occurring substance and its isolation in a usable form which does not exist in nature. The natural material is thus changed by human intervention, and the product claimed for patent purposes is not the same as that which exists in nature.178 The Proposed Directive would have provided that "an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered unpatentable for the reason that it formed part of said natural material;"179 nor would it "be considered as an unpatentable discovery or as lacking novelty for the reason only that it formed part of said natural material."180 The Commission intended to make clear that where a patent is claimed for a substance in a form which results from human intervention, it is more than mere discovery, irrespective of whether the intervention is simple or complex. A product is considered new if it does not form part of the "state of the art," that is, if the product was available to the public before the patent application was

176. Parliamentary Amendments, supra note 109, amend. 25.
178. Commission Memorandum, supra note 15, at 42. The products here are likely to be other than living organisms, e.g., plasmids, DNA segments, proteins, peptides, enzymes, etc. Id.
180. Id. art. 9.
filed.\textsuperscript{181} That a product may have existed in a mixture before its identification, isolation, purification, and usefulness have been established does not make it part of the state of the art for purposes of patent law.\textsuperscript{182} On this point, Parliament would provide in Article 2 that discoveries are not inventions, in spite of the fact that Parliament makes no distinction between "inventions" and "discoveries."\textsuperscript{183}

Again, in the Proposed Amended Directive, the Commission backed off from its more detailed definitions, but it attempted to limit the denial of patent claims on the grounds the invention is merely a discovery of an existing material. Article 7 of the Amended Proposed Directive would provide that an invention concerning a biological material "shall not be considered a discovery or lacking in novelty for the reason only that, although not known, it formed part of an existing material."\textsuperscript{184}

**CONCLUSION**

The issues relating to patenting living matter illustrate how economic and ethical concerns can become intertwined. When the Commission issued the Proposed Directive in 1988, controversy swirled around patenting animals, with implications for the growth and development of the pharmaceutical and agricultural industries. The primary goal was to provide for a single internal market so that industries could market and invest freely across European borders. By providing uniform guidelines for national laws throughout the EEC through specific definitions and minimum standards, the Proposed Directive provided the foundation for achieving that goal. However, by codifying additional ethical criteria for patentability, the Amended Proposed Directive introduces more uncertainty and ambiguity into patent law. Although the

\textsuperscript{181} Commission Memorandum, supra note 15, at 43.

\textsuperscript{182} Id.


\textsuperscript{184} Amended Proposed Directive, supra note 12, art. 7.
public policy provision in Article 53(a) of the EPC is part of the law of the Member States,\textsuperscript{185} as one author noted, the EPO Guidelines indicate the article was intended to apply only in rare and extreme situations,\textsuperscript{186} and the paucity of case law before the Harvard mouse decision indicated its limited relevance.\textsuperscript{187} Article 2(3) of the Amended Proposed Directive, however, expands on the categories of inventions that are contrary to public policy,\textsuperscript{188} and it clearly is not limited to rare situations. Importing ethical concepts into patent law increases the uncertainty of attaining patent protection for biotechnology inventions.\textsuperscript{189} The Commission gave as a reason for limiting the public policy provisions in the Amended Proposed Directive the fact that national laws already existed to regulate biotechnology research and included Article 2(4) to specifically acknowledge the primacy of national laws in regulating research and its products.\textsuperscript{190} Although perhaps politically necessary, these provisions severely compromise the goal of having a single internal market for the biotechnology industry in the EEC.

These provisions also undermine the goal of achieving parity in patent protection vis-à-vis the United States. Although the Commissioner of the USPTO has announced that only non-human animals are considered patentable,\textsuperscript{191} U.S. patent law itself does not contain public policy criteria and moral standards of patentability, nor are human and animal material mentioned.\textsuperscript{192} The lack of specificity in the American law has provided the flexibility to meet the challenges of new technology.\textsuperscript{193} By starting with the premise that an invention is not unpatentable only because it is composed of

\begin{enumerate}
\item[185.] See supra text accompanying notes 47-48.
\item[187.] Id. at 197.
\item[188.] See supra text accompanying notes 133-147.
\item[189.] See Thurston, supra note 138, at 188; Ho, supra note 186, at 195-199.
\item[190.] See supra text accompanying note 152.
\item[191.] See supra text accompanying note 2.
\end{enumerate}
living matter, broadly defining patentability microbiological processes and products, and strictly limiting exceptions to patentability that exist in the law, the Proposed Directive would have achieved a level of protection of biotechnological inventions comparable to that of the United States. However, in specifying that the human body and its parts are not patentable, the Proposed Amended Directive immediately raises the issue of what is a part of the human body. The Explanatory Memorandum does not clarify the matter. In the meantime, harmonization is becoming more difficult, politically speaking, as Member States enact laws and issue guidelines with respect to patenting human and animal materials.

It should be noted in connection with international parity that case law in a number of areas relating to patent protection for biotechnological inventions is unsettled in the United States. For example, the question of the degree of human intervention that takes a product out of the unpatentable category of product of nature is not answered in the United States. Furthermore, in the area of process patent protection, European law appears to provide greater protection to patent applicants than the United States. This is particularly significant since process patent protection is the sort of protection that is more likely to support the development of

194. See Straus, supra note 72, at 27.
195. Explanatory Memorandum, supra note 127; see, e.g., Thurston, supra note 138, at 187.
197. See Robin Herman, France Defines the Ethics of High-Tech Medicine Law Drafted by Female Jurist Covers Fertility Treatment, Organ Donation, Gene Therapy, WASH. POST, Apr. 20, 1993, at Z8 (specifying that human genes are not patentable and that genes cannot be manipulated to change the genetic blueprint, but only to improve health).
198. See Clive Cookson, Guidelines May Be Set Up For Human Genetics Research, FIN. TIMES, Nov. 19, 1992, at 8 (United Kingdom considering terms under which researchers could patent human genes and exploit them commercially).
199. See Crespi, supra note 183.
more biotechnological products.\textsuperscript{201}

As noted earlier, patent protection and public acceptance are two conditions critical to the development of the biotechnology industry.\textsuperscript{202} The applications for patents on human gene fragments have brought into sharper focus the economic and ethical issues relating to the patentability of living matter in both the United States\textsuperscript{203} and the EEC. For instance, Stephen Raines, vice president at Genentech, has suggested that privatization of the gene search could lead to a sort of toll system for the human genome.\textsuperscript{204} Dr. David Botstein, chairman of the genetics department at Stanford University, fears that companies owning a library of gene fragments would be able to lay claim to the work of scientists who do the hard work of finding out what the genes actually do.\textsuperscript{205} Dr. Richard Sykes, research director at Glaxo, notes that "[t]he only thing some biotechnology companies have is their intellectual property so they patent everything in sight. That inhibits research."\textsuperscript{206} Reports that the institution that patented the gene whose defect causes cystic fibrosis is seeking royalties from those using it in research to treat and cure the disease give credence to such fears.\textsuperscript{207} A few laboratories churning out gene fragments about whose function they know little could gain too much control over products to which they had contributed little, and thus defeat the purpose of the patent system to reward innovation.

Indeed, it has been reported that after the patent applications for human gene fragments were filed, some researchers in the Human Genome Project stopped sharing their data as they were supposed to do.\textsuperscript{208} Questions have been raised as to whether patent protec-

\textsuperscript{202} See supra text accompanying note 19.
\textsuperscript{204} Kolata, supra note 5.
\textsuperscript{205} Id.
\textsuperscript{207} Tom Wilkie, Royalties Demand Threatens Research into Cystic Fibrosis, THE INDEPENDENT, Jan. 14, 1993, at 8.
\textsuperscript{208} Declan Butler, Who Owns the Building Blocks of Life?, THE INDEPENDENT, Nov.
tion is in fact the best system creating incentives for creating valuable inventions or whether a sui generis form of protection should be created.209

In order to assure the availability of information and to encourage the development of biotechnological inventions that improve the health of mankind, the United States and EEC, as well as other governments, should heed the call of science210 and industry211 for an international agreement on the patentability of human material.

2, 1992, at 14. Charles Auffray, a leading French human genome researcher, handed over French research results on the human genome project to UNESCO in Paris in protest against American and British attempts to patent fragments of human genes. More than 200 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. *Id.*


210. *See* Butler, *supra* note 208 (describing the French hope that the declaration will lead to an international agreement); Amanda Husted, *Health Watch Combination of Blood Tests May Spot Down's Syndrome*, ATLANTA J. & CONST., Aug. 27, 1992, at D3 (citing an article by Dr. Bernadine Healy in the August issue of the *New England Journal of Medicine*).

211. Kolata, *supra* note 5 (citing Richard D. Godown, President of the Industrial Biotechnology Association, as saying there should be an international agreement that gene fragments cannot be patented).