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Abstract

This article attempts to disentangle the mire of European patent authority and provide some picture of how the ultimate resolution of the proposed EC Directive will appear. Part I contains introductory and background materials on the biotech industry and the importance of patent protection to the future proliferation of technological innovation. Part I exposes current issues in the scientific and political realms of biotech patent law as well as the standard justifications for recognizing inventors rights, considerations that are presently shaping the debate in Europe. Part II attempts to ground the reader in the fundamentals of biotechnology patent laws as developed in the United States in order to provide a basic conceptual foundation for comparing and evaluating the bodies of European law. This section begins by introducing the basic statutory terminology before turning to a discussion of the landmark United States Supreme Court opinion in Diamond v. Chakrabarty, where the Court held that genetically altered living matter may be patented.8 The remainder of the section traces the legal developments spawned by the Chakrabarty decision. Part III begins with an introduction of the various bodies purporting to govern patent rights in Europe and attempts to resolve the supremacy issues among them. Attention then shifts to the proposed Council Directive on biotech patents: the procedures for its adoption, the political forces shaping the debate of life patents in Europe, and the important proposals for amending the original draft. Finally, this article will speculate on the ultimate resolution of the Draft Directive as a united system of patent laws for the European Community Member States.

PATENTING LIVING MATTER IN THE EUROPEAN COMMUNITY: DIRIMENT OF THE DRAFT DIRECTIVE

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INTRODUCTION

By early 1985, Europe's biotechnology industry found itself at a competitive disadvantage vis-à-vis its international rivals in a deficit that was fast approaching perilous dimensions. Its predicament was attributable to the woefully deficient patent rights recognized by most European nations pertaining to the protection of industrial property. For many of Europe's biotechnology companies the solution was to relocate outside the European Community ("EC") into countries that fostered innovation with liberal patent laws.[1] Witnessing the premature demise of its biotech industry, which had been heralded as the technology and enterprise of the twenty-first century, the EC was compelled to act.

Resolved to reaffirm its position in the emerging biotech industry the Commission of the EC (the "Commission") set to work drafting a unified and compulsory convention on patent

1. Robin Whaite & Nigel Jones, *Biotechnological Patents in Europe—The Draft Directive*, 11 EUR. INTELL. PROP. REV. 145, 146 (1989) [hereinafter Whaite & Jones].

laws.[2] On October 20, 1988 the Commission issued its proposal to the Council of Ministers (the "Council") for a Directive on the Legal Protections of Biotechnologies (the "Draft Directive" or the "Directive").[3] The Draft Directive mandated that, upon its adoption, Member States of the EC should amend their respective national laws to reflect the unifying proclamations of the Commission.[4] Unanimous opinion embraces the notion that common patent protections will substantially increase the value of biotech patents in the EC, thus attracting more research capital to finance new generations of innovation.[5] Furthermore, a unified patent system is increasingly important to EC companies and their ability to compete successfully with rivals in Japan and the United States, who benefit from inclusive patent law protections. Despite these economic necessities, the Draft Directive has become the captive of public debate regarding the highly controversial issue of patenting living matter, which has raged in Europe for over five years. To date, only four EC Member States have substantially complied with the terms of the Draft Directive.[6] The remainder of the Member States, embroiled in public debate, recognize only the less inclusive patent protections proscribed by the European Patent Convention ("EPC").[7] The EPC laws, however, contain language that directly conflicts with the terms of the

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2. *See*, Biotechnological Inventions: Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, Oct. 20, 1988, O.J. C 10/3 (1989), *cited in*, Leslie William Melville, FORMS AND AGREEMENTS ON INTELLECTUAL PROPERTY AND INTERNATIONAL LICENSING 3-114 (Clark, Boardman Callaghan rev. ed. 1992) [hereinafter, DRAFT DIRECTIVE].

3. *Id.*

4. *Id.*

5. *Id.* The preamble of the proposed directive makes repeated reference to the importance of a unified patent system for protecting and promoting investment in biotechnologies, referring to biotech as an industry "considered of fundamental importance for the Community's industrial development." *Id.*

6. David Buchan, *The European Market: Biotech Groups Find Bright New World Slow to Dawn*, THE FIN. TIMES, Apr. 27, 1992, at 2. As of the time of this article Denmark, Germany, and the Netherlands have incorporated the terms of the draft directive into their national laws. *Id.* The United Kingdom presently provides more inclusive patent protections than the EC directive and is wrestling with the implementation of the directive. *Id.*

7. European Patent Convention, Oct. 5, 1979, *reprinted in* 15 I.L.M. 5 (1976) [hereinafter EPC]. The European Patent Convention was established in 1975 and now consists of 18 member countries. Contracting nations include all EC Member States in addition to Austria, Switzerland, Liechtenstein, Sweden, Monaco and Egypt. *Id.* Ireland was the latest addition completing ratification procedures in May of 1992.

Draft Directive, further complicating the status of biotech patents.

This article attempts to disentangle the mire of European patent authority and provide some picture of how the ultimate resolution of the proposed EC Directive will appear. Part I contains introductory and background materials on the biotech industry and the importance of patent protection to the future proliferation of technological innovation. Part I exposes current issues in the scientific and political realms of biotech patent law as well as the standard justifications for recognizing inventors rights, considerations that are presently shaping the debate in Europe.

Part II attempts to ground the reader in the fundamentals of biotechnology patent laws as developed in the United States in order to provide a basic conceptual foundation for comparing and evaluating the bodies of European law. This section begins by introducing the basic statutory terminology before turning to a discussion of the landmark United States Supreme Court opinion in *Diamond v. Chakrabarty*, where the Court held that genetically altered living matter may be patented.[8] The remainder of the section traces the legal developments spawned by the *Chakrabarty* decision.

Part III begins with an introduction of the various bodies purporting to govern patent rights in Europe and attempts to resolve the supremacy issues among them. Attention then shifts to the proposed Council Directive on biotech patents: the procedures for its adoption, the political forces shaping the debate of life patents in Europe, and the important proposals for amending the original draft. Finally, this article will speculate on the ultimate resolution of the Draft Directive as a united system of patent laws for the European Community Member States.

I. *ISSUES IN THE SCIENCE AND POLITICS OF BIOTECHNOLOGY PATENTS*

In 1953 J.D. Watson and Francis Crick discovered the double helical structure of the deoxyribonucleic acid ("DNA")

COOPERS & LYBRAND, EC COMMENTARIES: INTELLECTUAL PROPERTY 85, § 15.2 (Nov. 26, 1992).

8. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

molecule revealing the genetic code of life.[9] The DNA molecule contains nature's blueprints, determining the hereditary characteristics passed on from one generation of plant or animal to its offspring. Watson and Crick's work touched off an avalanche of genetic research seeking to unlock the secrets hidden within the double helix.[10] Their early work has since given rise to the modern multi-billion dollar industry known as biotechnology.

Modern biotechnologists continue to chart the frontiers of the DNA molecule with ever-increasing expedience and precision. At present, recombinant DNA research has led to the production of human growth hormones, human insulin, alpha interferon, and a hepatitis B vaccine.[11] These products represent only a minute fraction of the medical advances scientists expect to reap from genetic research in the near future. Experts believe that the cure to cancer, Alzheimer's, and other hereditary illnesses will ultimately be found by isolating the afflicted genes and substituting them with normal genetic material. Many also foresee the AIDS virus, the most significant medical threat of this century, being conquered through the application of genetic research.

The "biotech dream" is being realized far beyond the laboratories of medical technicians. Application of biotechnology in agriculture has resulted in faster and more accurate methods of enhancing crop production than those formerly attained through selective breeding techniques.[12] By studying a plant's genetic blueprints, researchers can isolate and alter the genetic material that determines its specific characteristics. Therefore, scientists can achieve in one generation with certainty what might have otherwise required years or decades of specialized breeding.

"Ag-biotech" crops promise higher yields of better tasting produce, which can be grown with less water and in inferior soil.[13] Progress is also being made toward the development of

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9. Edmund J. Sease, *From Microbes, To Corn Seeds, To Oysters, To Mice: Patentability of New Life Forms*, 38 DRAKE L. REV. 551, 552 (1989) (citing J.D. WATSON, THE DOUBLE HELIX 108 (1968)) [hereinafter Sease].

10. Sease, 38 DRAKE L. REV. at 552.

11. *Id.* at 569.

12. *Id.* at 552.

13. Sease, 38 DRAKE L. REV. at 568.

crops that are genetically resistant to disease and pests. Such advances promise to reduce agriculture's susceptibility to drought, and break its dependence on chemical pesticides and fertilizers that pollute the environment and have uncertain effects on the consumer.[14] In 1991 the "ag-biotech" industry was estimated to have generated $200 million in revenues.[15] Industry analysts predict continued rapid growth as new products are introduced and more capital pours into research.[16]

In addition to the environmental benefits of reduced chemical dependency in agriculture, recent biotech research has developed microorganisms for application in environmental clean-up. The process is called "bio-remediation" and involves the production of microorganisms which consume environmentally harmful matter and degrade it into safe natural byproducts.[17] Experts anticipate such technology to be helpful in the clean-up of oil spills, hazardous waste dump sites, and other environmentally toxic disasters.

Not all, however, are pleased with the prospects of harnessing the power of the gene or manipulating the genetic sequences. Opponents to the proliferation of biotechnologies "present a gruesome parade of horribles,"[18] drawing upon haunting images of cloning "Frankensteins" or the release of pathogenic microbes in an effort to raise public awareness. Though opponents of proliferation rely on somewhat unrefined methods, their concerns are real and demand the attention of the public and lawmakers. Opposition originates from three primary sources: (1) the agricultural community, (2) environmentalists, and (3) the "ordre public" or morally opposed.[19]

As the biotech industry in the United States began to blossom in the early 1980s, commentators predicted that its most

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14. Vice President's Council on Competitiveness, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 3 (Feb. 1991) [hereinafter "REPORT ON NATIONAL BIOTECHNOLOGY POLICY").

15. Joan C. Hamilton et al., *The Country Cousin is Blossoming, Too*, BUS. WK., Mar. 2, 1992, at 72.

16. Joan C. Hamilton, *Biotech: America's Dream Machine*, BUS. WK., Mar. 2, 1992, at 66.

17. REPORT ON NATIONAL BIOTECHNOLOGY POLICY, *supra* note 14, at 4.

18. Diamond v. Chakrabarty, 447 U.S. 303, 316 (1980).

19. *See generally* Al Gore, *Federal Biotechnology Policy: The Perils of Progress and the Risks of Uncertainty*, 20 U. MICH. J.L. REF. 965 (1987).

difficult task would be clearing the hurdle of public opinion. Then Senator from Tennessee Al Gore wrote, "the scientific community must realize that public perceptions will set the agenda for biotech regulation, research funding, and consumer support."[20] The American public, however, has been conspicuously absent from the research process. Pragmatic concerns regarding investment opportunities in biotech firms appear to be of greater importance to the American public than debating the moral implications of gene manipulation.

Unlike their American counterparts, the people of the Member States of the EC have assumed a prominent role in the establishment of regulatory policies in their respective nations. Europe has been engaged in a fierce five-year debate pitting farmers and environmentalists against the biotech industry, each competing for public support. The prize is the approval or rejection of the EC Directive pertaining to a unified system of legal protections for biotechnologies. As the people of the EC undertake this protracted policy debate, however, the future viability of European biotech companies as participants in the "biotech dream" is being threatened by competition from their foreign rivals.

A. *The Purpose of a Patent System*

The origins of definitive patent law can be traced to the lucrative silk trade of the Northern Italian City States during the 15th century. In 1474 the Council of Venice enacted what is generally regarded as the first patent statute, which granted an exclusive ten-year privilege to the inventor of any machine or process that expedited or improved silk making.[21] The statute assigned a special council to review applications and provided for express remedies against the infringement of any exclusive privilege grant.[22]

Inspiration for the Venetian law was purely commercial. It clearly demonstrates the Venetians' keen understanding of the economic power of a monopoly, and an underlying knowledge that humans are not purely altruistic beings. Adam Smith first

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20. *Id.* at 972.

21. PETER D. ROSENBERG, 1 PATENT LAW FUNDAMENTALS, §§ 1.08, 1-24.15 (rev. ed. 1993).

22. *Id.*

articulated these concepts in 1776, penning the following thoughts regarding European trade expeditions: "It is the easiest and most natural way in which the state can recompense them for hazarding a dangerous and expensive experiment, of which the public is afterwards to reap the benefit."[23]

The motivations for modern patent laws have changed little over the centuries. Indeed, the preamble to the EC Council Directive on biotech patents accepts "the fact that 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."[24] Without such state-enforced protections, the inventing firm is denied the opportunity to recover its research & development ("R & D") costs by competitors receiving a free ride on the innovation. The free riders, who do not need to recoup R & D expenses, can undercut the inventing firm's price and deny it a fair return. Hence, in the absence of adequate patent protection, a firm has less incentive to invest in the development of new products and processes.[25]

Furthermore, without the recognition of exclusive rights to invention, innovators will conceal their advancements under veils of confidentiality in order to protect their investments. Patent laws require full disclosure of the protected subject matter, information that is freely available to the public. Without such protections, innovators will deliberately obstruct the dissemination of socially desirable information resulting in duplicative and unnecessary research.[26]

The biotech industry is particularly sensitive to patent concerns because of its inherent need for long-term cash commitments to finance protracted development cycles. For example, one U.S. biotech concern laid out $900,000 over several years to develop a more durable and productive maize hybrid, and $600,000 for a similar soybean variety.[27] If countries fail to protect such product development, biotech firms will have

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23. ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS 712 (1976); ROSENBERG, *supra* note 21 §§ 1.07, 1-24.12.

24. DRAFT DIRECTIVE, *supra* note 2, O.J. C 10/4 (1989).

25. Thomas M. Keane, *The Patentability of Biotechnological Inventions*, IR. LAW TIMES at 139 (June 1992).

26. *Id.*

27. Whaite & Jones, *supra* note 1 at 146.

little incentive to develop such beneficial products. When innovation does occur, it will be shrouded in secrecy.

The inherent value of the EC is the creation of a common market, which enables EC producers to exploit economies of scale by freely supplying goods and services to several nations, as opposed to just one.[28] As biotechnologies represent a valuable component of future world trade, a unitary system for patenting these technologies is crucial.[29] If the Member States of the EC desire to participate in the promise of biotechnology, they must ensure that their laws on the patentability of living matter comport with those protections offered by their principal competitors in this new industry, the U.S. and Japan.

II. *PATENTING LIVING MATTER IN THE UNITED STATES*

A. *Patentable Subject Matter Pre-*Chakrabarty

Pursuant to the expansive powers granted it by Article 1, § 8, clause 8 of the Constitution, Congress has authored a plethora of patent legislation.[30] The starting point of these statutes is Title 35, § 101 of the United States Code,[31] which states, "Whoever invents or discovers any *new* and *useful* process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[32] The term "new" is expanded upon in sections 102 and 103, which deny patents where the invention is "known or used by others" (novelty)[33] or obvious to a person learned in

28. Treaty Establishing the European Economic Community, Mar. 25, 1957, 1973 Gr. Brit. T.S. No. 1 (Cmd. 5/79-II), 298 U.N.T.S. 3 (1958) [hereinafter "EEC Treaty"]. Consistent with basic economic theory, the European Community articulated the benefits of a common commercial policy in Article 110 of the EEC Treaty, which states in pertinent part, "[t]he common commercial policy shall take into account the favorable effect which the abolition of customs duties between Member States may have on the increase in the competitive strength of undertakings in those States." *Id.* at art. 110, 298 U.N.T.S. at 58.

29. *See* Whaite & Jones *supra* note 1 at 154 (reprinting following portion of preamble of the Council Directive: "[w]hereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions can be considered of fundamental importance for the Community's industrial development").

30. U.S. CONST. art. 1, § 8, cl. 8.

31. 35 U.S.C. § 101 (1988).

32. *Id.* (emphasis added).

33. 35 U.S.C § 102 (1988). "A person shall be entitled to a patent unless- (a)

the art[34] Therefore, the three elements necessary to obtain a patent grant: (1) novelty, (2) utility, and (3) non-obviousness.

The language that follows the new and useful elements in section 101 defines the scope of patentable subject matter to include any "process, machine, manufacture, or composition of matter. . . ."[35] Subsequent judicial doctrine has further refined this scope by identifying several classes of non-patentable inventions including: scientific principles, laws of nature, physical phenomena, abstract ideas, and products of nature.[36] The exclusion of "products of nature" from patentable subject matter is pertinent to the current debate over the patentability of living matter.

1. The "Products of Nature" Doctrine

The "products of nature" doctrine is derived from the inherent truth that something cannot be "new" if it already exists in nature.[37] Discovery of a previously unknown plant variety is certainly new by dictionary definition, however the novelty element demands that an *inventive step* be taken by the applicant. The founder of the previously unknown plant cannot claim to have achieved any such step; therefore, the novelty requirement is lacking, which precludes patent protection.

The "products of nature" doctrine appears simple, yet courts have struggled with its application. Their primary difficulty has been determining what degree of intervention constitutes an inventive step, which transforms the subject matter from a product of nature into a patentable organism.[38] A classic illustration of the "products of nature" doctrine is found in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[39]

The *Funk Brothers* case originated as a patent infringement

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the invention was known or used by others . . . ." *Id.* The remainder of the statute contains definitions of knowledge and use. *Id.*

34. 35 U.S.C. § 103 (1988). "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been *obvious* at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *Id.*

35. 35 U.S.C. § 101 (1988).

36. Elizabeth J. Hecht, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023, 1030 (1992).

37. Sease, *supra* note 9, at 554.

38. *Id.*

39. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132 (1948).

action brought by the Kalo Inoculant Company against the Funk Brothers Seed Company, alleging that Funk Brothers had made unauthorized use of its patent of an inoculant for leguminous plants.[40] The patented inoculant consisted of a combination of six bacteria strains that were each independently known to act as inoculants in various leguminous plants.[41] Prior to Kalo's discovery, however, combinations of inoculant bacterium proved ineffective because they inhibited one another, a side effect that did not afflict Kalo's inoculant.[42]

The U.S. Supreme Court applied the "products of nature" doctrine to reject Kalo's patent stating that, "[t]he combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility."[43] In the Court's analysis, Kalo failed to demonstrate that the combination of non-inhibiting bacteria amounted to an inventive step.[44] Rather, the Court remarked of the mixed bacteria inoculant, "[i]t is no more than the discovery of some of the handiwork of nature and hence is not patentable."[45]

Concurring in the *Funk Brothers* decision, but rejecting the majority's application of the "products of nature" doctrine, Justice Felix Frankfurter identified glaring problems with the contemporary interpretation of the doctrine and suggested an alternative reading.[46] Justice Frankfurter was concerned that concepts like "the laws of nature" and "the work of nature" were "vague and malleable terms infected with too much ambiguity and equivocation."[47] Extrapolating from that point,

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40. *Id.* at 128-29. Leguminous plants are a unique species capable of removing nitrogen from the air and fixing it in the plant for conversion into organic nitrogenous compounds which provide nourishment. *Id.* Examples of the species include: clover, alfalfa, garden beans, garden peas and soy beans. *Id.* at 129. The bacteria contained in Kalo's inoculant facilitate the nitrogen fixing ability of leguminous plants, hence acting as a fertilizer. *Id.*

41. *Id.* at 129, n.3.

42. *Id.* at 130.

43. *Id.* at 131.

44. *Id.* at 131-32.

45. *Id.* at 131.

46. *Id.* at 132-35 (Frankfurter, J., concurring). Justice Felix Frankfurter concurred in the decision not to enjoin the Funk Brothers from using an inoculant similar in nature to that developed by Kalo. *Id.* He based his determination on the fact that the Funk Brothers' inoculant employed a different combination of bacterium than that contained in the Kalo inoculant, hence not infringing upon their patent, but rather utilizing the knowledge of the patent to develop a new product. *Id.* at 133.

47. *Id.* at 134.

"[e]verything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent."[48] Justice Frankfurter realized that the broad construction of these concepts would obstruct the effectiveness of the patent laws and deny the deserved protections for persons engaged in research and development of living subject matter, because they could not establish the "novelty" (inventive step) element. To avert this potential, Frankfurter posed an alternative reading of the "products of nature" doctrine that would recognize the "novelty" element where an invention was derived from the application of the laws of nature and achieved a new and useful end.[49]

Justice Frankfurter demonstrated remarkable foresight in identifying the inherent problems with the application of the "products of nature" doctrine. Indeed, as he had predicted, the U.S. Patent and Trademark Office ("PTO") used the "products of nature" doctrine as its principal weapon to challenge almost every patent application that sought inventors' rights in living matter. As a result of the Court's failure to heed this distant early warning, U.S. patent law relating to living subject matter was condemned to over thirty years of confusion and uncertainty.[50]

2. Plant Breeders' Rights

To escape the uncertainty within patent law, Congress enacted special legislation to recognize rights for plant breeders who would not otherwise qualify for protections under the patent laws due to the existence of the "products of nature" doctrine. These protections are provided within a confluence of the Plant Patent Act of 1930[51] and the Plant Variety Protection Act of 1970.[52] The first piece of legislation extended protections for breeders of new and distinct varieties of *asexually* reproducing plants.[53] The later Act extended the protections to

48. *Id.* at 135.
49. *Id.*
50. Sease, *supra* note 9, at 556-57.
51. 35 U.S.C. §§ 161-164 (1988).
52. 7 U.S.C. §§ 2321-2582 (1988).
53. 35 U.S.C. § 161 (1988). Section 161 entitled "Patents for plants" states:

new varieties of *sexually* reproduced plants, excepting fungi and bacteria.[54]

These plant breeders protections are considerably narrower than the standard utility patent, granted pursuant to 35 U.S.C. § 101.[55] The primary reason is that the subject matter qualifying for these protections is restricted to plant life that is not a microorganism.[56] Hence, left unprotected are any inventions related to animals, humans, or the microorganismic world in which biotechnology is most promising. A subordinate concern with the plant breeders rights is that they are undermined by several major exemptions, most notably those permitting researchers and farmers to utilize the protected plants free of licensing fees.[57] As these are the two major groups with a use for new plant varieties, these exemptions erode the substantial value of any exclusive rights in plants.

Legal protections available through the plant breeders rights and the patent laws, complicated by the "products of nature" doctrine, were illusory at best. Consequently, early biotechnologists found little in the way of support for their innovative research. Due to the absence of adequate assurances to protect individual inventions, the business community perceived biotechnology as an unattractive investment opportunity.

> [w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.

Id.

54. 7 U.S.C. § 2402 (1988). Specifically, § 2402 entitled "Right to plant variety protection; plant varieties protectable" states in pertinent part that:

> (a) The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor, subject to the conditions and requirements of this subchapter unless one of the following bars exists.

Id.

55. *See supra* notes 31-35, and accompanying text (for a discussion of 35 U.S.C. §§ 101-103).

56. *See* 7 U.S.C. § 2402 (1988) (limiting protection to plants "other than fungi, bacteria, or first generation hybrids").

57. *See* 7 U.S.C. §§ 2543-2544 (1988) (stating that farmers exemption is created in § 2543 and researchers exemption in § 2544).

B. *Patentability of Living Matter:* Diamond v. Chakrabarty[58]

Prior to 1980 the PTO and the federal court system engaged in a seemingly determined effort to abjure the patentability of living matter. Despite the anomalous patent, such as that issued to Louis Pasteur in 1873 for his purified culture of yeast,[59] the courts invariably rejected patents that involved living subject matter. Their most effective weapon was the "products of nature" doctrine, the success of which is illustrated in *Funk Brothers*.[60] Where that doctrine failed, the PTO and private plaintiffs reasoned that the two plant protection acts of 1930 and 1970 demonstrated a Congressional intent that the only living organisms to be afforded patent protections were those qualifying under one of the acts.[61] It would inevitably require the Supreme Court of the United States to embrace this issue and champion the biotech industry.

In 1980 the U.S. Supreme Court issued an opinion in what

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58. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

59. Robert B. Kambic, *Hindering the Progress of Science: The Use of the Patent System to Regulate Research on Genetically Altered Animals*, 16 FORDHAM URB. L. J. 441, 448 (1988).

60. Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948). A glaring example of the misapplication of the products of nature doctrine is presented in American Fruit Growers, Inc. v. Brogdex, 283 U.S. 1 (1931), popularly known as the "orange rind" case. Sease, *supra* note 9, at 556. The orange rind case originated as a patent infringement suit brought by the Brogdex Company against American Fruit Growers, Inc. (AFG). *American Fruit Growers*, 283 U.S. at 5. Brogdex alleged that AFG had made unauthorized use of its patented process for impregnating the rind of oranges with borax, which rendered them resistant to blue mold decay. *Id.* at 6. AFG responded by challenging the validity of the patent arguing that the orange was a product of nature and retained that character despite the impregnation of borax. *Id.* at 10. The patentee maintained that the combination of natural fruit and borax resulted in a distinct new orange not found in nature and therefore patentable. *Id.* at 8.

The Supreme Court disagreed with Brogdex and held the patent invalid, proclaiming that a product must "possess new and distinctive form, quality or property" as evidenced by a "change in the name, appearance or general character of the fruit." *Id.* at 11-12. This opinion has been widely criticized by commentators who contend that (1) the borax did not naturally occur in orange rinds, thus adding a new quality to the fruit, and (2) injecting the borax into the rind significantly changed the character of the fruit by making it resistant to the ruinous blue mold decay. *See*, Sease, *supra* note 9 at 555.

61. *In re* Bergy, 596 F.2d 952, 965 (C.C.P.A. 1979). In re *Bergy* was the companion case to *Chakrabarty* which held that a biologically pure culture of microorganisms was patentable subject matter. *Id.* at 973. The PTO argument, urging that the Plant Protection Act and Plant Variety Protection Act evidenced a Congressional intent to remove plant life from coverage under the patent laws, was rejected by the Court of Customs and Patent Appeals. *Id.* at 979-80.

is unequivocally heralded as the landmark case in biotechnologically related patent law, *Diamond v. Chakrabarty*.[62] The case was brought forth by a microbiologist challenging a ruling by the PTO denying his application to patent a genetically engineered strain of bacteria capable of breaking down multiple components of crude oil. Chakrabarty's invention was a process for introducing specific plasmids[63] capable of breaking down four different oil components into a host Pseudomonas bacteria. The unaltered, naturally occurring Pseudomonas had no capacity for degrading the oil.[64] However, the modified Pseudomonas was to have significant value for the treatment of oil spills.

PTO examiners denied Chakrabarty's application based on the dual analysis that: (1) micro-organisms are non-patentable "products of nature," and (2) as living things, they are per se non-patentable subject matter.[65] The "products of nature" argument was subsequently rejected by the Patent Office Board of Appeals upon recognition that Pseudomonas possessing the special characteristics of Chakrabarty's bacterium are not naturally occurring.[66] The Board, however, affirmed the PTO ruling on the second argument, explaining that Congress's special provisions under the Plant Patent Act of 1930 constituted conclusive evidence that section 101 was not intended to cover living things.[67] The Supreme Court granted review on the issue of "whether respondent's [Chakrabarty's] micro-organism constitutes a 'manufacture' or 'composition of matter' within the meaning of [35 U.S.C. § 101]."[68]

Step one of the Court's analysis required defining the concepts "manufacture" and "compositions of matter."[69] The

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

63. STEDMAN'S MEDICAL DICTIONARY 1096 (24th ed. 1982). A plasmid is an extra-chromosomal ring of DNA (hereditary material) that replicates autonomously in bacteria. *Id.*

64. Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).

65. *Id.* at 306.

66. *Id.* at 306 n.3. Footnote four refers to In Re *Bergy*, 596 F.2d at 971, which rejected the PTO's argument respecting the "products of nature" doctrine. The Court stated that it agreed with the appellant that the claimed bacteria might not be considered " 'products of nature,' because Pseudomonas bacteria containing two or more different energy-generating plasmids are not naturally occurring." *Id.*

67. *Id.* at 306.

68. *Id.* at 307.

69. *Id.* at 308.

term "manufacture" was defined according to its dictionary definition, to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combination, whether by hand-labor or by machinery."[70] A composition of matter was cited in prior case law as including "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gasses, fluids, powders or solids."[71]

Step two involved the reading of these terms in their statutory context.[72] The Court proclaimed that the combination of such expansive terms as "manufacture" and "composition of matter" modified by the all inclusive "any" was indicative of Congress's intention that the patent laws be read broadly. The Court also referred to Committee Reports from the 1952 recodification of the patent laws,[73] which stated Congress's intent that the statutory subject matter include "*anything under the sun that is made by man*."[74] In conclusion, the Court held that the language of section 101 fairly embraced Chakrabarty's invention of the Pseudomonas organism, thus dispelling the notion that living matter is not patentable.[75]

With this decision the Supreme Court opened a new world of opportunity to U.S. industry. Many companies hesitated to see if Congress would accept the Supreme Court's invitation to enact regulations to cover the freshly exposed area of patents on living matter. As the resulting legislative paralysis became apparent, an excited rush into genetic research ensued. *Chakrabarty*'s broad interpretation of patentable subject matter provided U.S. companies with the promise of patents to pro-

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70. *Id.* Oddly enough, this definition was quoted from American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931). Certainly, the impregnation of the orange rind with borax, seems to have been given the fruit a "new quality or property" due to Brogdex's inventive labor. *Id.*

71. *See Chakrabarty*, 447 U.S. at 308 (citing to Shell Development Co. v. Watson, 149 F. Supp. 279, 280 (D.D.C. 1957)).

72. *See* 35 U.S.C. § 101 (1988).

73. *See*, S. REP. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess., 6 (1952). In 1952 Congress recodified the patents laws, the original language of which was written by Jefferson. *See* 35 U.S.C. §§ 101-376 (1988) which forms the present U.S. patent law.

74. Diamond v. Chakrabarty, 447 U.S. at 309; S. REP. No. 1979, 82d Cong., 2d Sess., at 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess., at 6 (1952).

75. *Chakrabarty*, 447 U.S. at 308-09.

tect their investments. As the result, U.S. industry greatly expanded its commitment to genetic engineering, establishing an early position of world dominance, which it has yet to yield.

C. *Post-Chakrabarty Developments in the United States*

The *Chakrabarty* opinion employed expansive language that broadened the narrow reach of the patent laws to encompass living organisms as patentable subject matter allowable under 35 U.S.C. § 101.[76] Yet, despite the sweeping construction of this precedent-setting opinion, the future patentability of living matter remained uncertain. It has required a dozen years of judicial and legislative activity following *Chakrabarty* to re-affirm that the comprehensive language, "anything under the sun that is made by man," means in essence what it says. To date the only express limit on the patentability of life is to preclude any patent "claim directed to or including within its scope a human being,"[77] a narrow exclusion attributed to the thirteenth amendment's prohibition of slavery.[78] The following section discusses the major judicial, legislative, and PTO activity that has occurred since the *Chakrabarty* decision.

1. *Ex parte Allen* Decided April 3, 1987

Ex parte Allen[79] was brought before the PTO's Board of Patent Appeals and Interferences challenging the PTO examiner's denial of a patent for a method of inducing polyploiding in Pacific oysters.[80] The process involved the maintenance of specific temperature controls during fertilization and incubation in addition to applying predetermined levels of hydrostatic pressure on the fertilized eggs.[81] This caused the formation of an additional set of chromosomes, which rendered the oyster sterile and capable of growing much larger with a higher meat content, due to the absence of reproductive activity.[82]

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76. *Id.*

77. 1077 OFF. GAZ. PAT. OFFICE 24, Apr. 21, 1987 [hereinafter PTO NOTICE].

78. *See* Kevin D. De Bré, Note, *Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?*, 16 HASTINGS CONST. L. Q. 221 (1989). Commentators suggest that the 13th Amendment's prohibition on slavery precludes the grant of an exclusive property right (patent) in any matter directed to the human being. *Id.*

79. Ex Parte Allen, 2 U.S.P.Q.2d 1425 (1987).

80. *Id.*

81. *Id.* at 1426.

82. Sease, *supra* note 9, at 563.

The examiner supported its denial on the dual grounds of unpatentable naturally occurring subject matter and obviousness.[83] The Patent Appeals Court eventually upheld the PTO examiner's refusal to grant a patent on the grounds that "prior art" (previous discoveries) disclosed the methods of polyploiding other species of oysters, hence Allen's hydrostatic process was *obvious*.[84] Despite this basis for rejecting the patent application, the court went out of its way to discuss *Chakrabarty*, specifically noting that the polyploid oyster plainly qualified as patentable subject matter.[85]

Although Allen was denied a patent because of the obviousness of his invention, this case is significant because for the first time a court expressly provided that complex living organisms, beyond the microscopic world of bacteria, are not per se excluded from patent protection. Hence, the *Allen* court's broad construction of 35 U.S.C. § 101 venerated the comprehensive scope of patentable subject matter articulated in *Chakrabarty* as including "anything under the sun that is made by man."[86]

2. PTO Notice Announced April 7, 1987

Days after the *Ex parte Allen* opinion was announced, the PTO issued a notice articulating a major policy shift at the examiner's office.[87] The notice expressed the PTO's intent to bring itself into full compliance with the Supreme Court's *Chakrabarty* decision a laggardly seven years after it was handed down.[88] Evidently, *Allen* admonished the PTO that the Supreme Court, not the examiner's office, was responsible for interpreting the laws of the United States.[89]

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83. Ex Parte Allen, 2 U.S.P.Q.2d 1425, 1426 (1987).

84. *Id.* at 1427.

85. *Id.* at 1426. ("The examiner has presented no evidence that the claimed polyploid oysters occur naturally without the intervention of man . . . [and as] non-naturally occurring manufactures or compositions of matter are within the confines of patentable subject matter under 35 U.S.C. § 101.").

86. *Id.*; *Chakrabarty*, 447 U.S. at 309.

87. PTO NOTICE, *supra* note 77.

88. *Id.*

89. *Id.* The notice states in pertinent part:

> The Board relied upon the opinion of the Supreme Court in *Diamond v. Chakrabarty* . . . as controlling authority that Congress intended statutory subject matter to 'include anything under the sun that is made by man.' The Patent and Trademark Office now considers non-naturally occurring non-

Issue of this notice sent an unequivocal message to U.S. industry that the PTO would relax its contentious stance toward biotechnological patents encompassing living matter. This alleviated a great deal of the risk borne by biotech research firms and promised to expedite the patent process by reducing the likelihood of legal challenge. One can only speculate as to the importance of this PTO notice to the biotech boom of the late 1980s, although fundamental financial and economic principles hold that lower risk attracts capital resources which lowers economic barriers to entry.

3. The Harvard Mouse Patent Issued April 12, 1988

Little more than one year after the heralded PTO notice articulating the Office's new liberal policy toward the patentability of living matter, the United States Patent Office issued its first patent on a multi-cellular living organism.[90] The patented subject matter was a mouse developed by researchers at Harvard (the "Harvard Mouse" or "Mouse") which had been genetically engineered to be highly susceptible to cancer. The Mouse's ability to rapidly develop cancer made the animal a more effective model for studying the contributions of genetics to the development of cancer.[91]

Though *Chakrabarty* and *Ex parte Allen* had cleared the way for the patentability of complex organisms, the Harvard Mouse was significant as the first actual granting of a patent on a living mammal. Prior to this time the biotech industry had only words as assurances that their scientific advancements would be protected. The granting of a patent for the Harvard Mouse demonstrated that the PTO would follow through with the intentions it had articulated in its Notice of April 7, 1987. Equipped with an empirical example of a genetically engi-

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> human multi-cellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101 . . . .
> Accordingly, the Patent and Trademark Office is now examining claims directed to multi-cellular living organisms, including animals. To the extent that the claimed subject matter is directed to non-human 'non-naturally occurring manufacture or composition of matter — as product of human ingenuity,' such claims will not be rejected under 35 U.S.C. § 101 as being directed to nonstatutory subject matter.

Id.

90. U.S. Pat. No. 4,736,866, Apr. 12, 1988.

91. Sease, *supra* note 9, at 565.

neered product on which the Patent Office had conferred patent recognition, the biotech industry attracted greater infusions of optimism and capital.[92] Hence, this relatively simple organism represented a historical step in the evolution of biotechnology.

4. Transgenic Animal Patent Reform Acts of 1988 and 1989

The PTO notice and subsequent patent grant in the Harvard Mouse enraged many animal rights activists and raised economic concerns among farmers. Activist groups abhorred the idea of genetically engineering a living organism so that it would be inherently susceptible to an agonizing disease like cancer. Organizations of small farmers realized their inability to pay for the future of genetically superior animals and crop strains that only the larger agri-business concerns could. They feared extinction at the hands of corporate agriculture, which could combine scale economies with biotechnology to bury the smaller competition.

Such concerns prompted a number of attempts to enact protective legislation at the expense of the biotech industry. The first major effort was the Transgenic Patent Reform Act of 1988 (H.R. 4970).[93] Protections afforded by this proposed legislation focused exclusively on the agricultural industry providing a patent law exemption for farmers who would use the technology only on the farm, thus not allowing any transfer or sale of embryos, germ cells, or semen of a patented animal.[94] This bill failed to pass in 1988 as did a nearly identical bill before the 101st Congress in 1989.[95] No legislative efforts have reached this stage since the failure of these two bills, nor does the impetus appear in the House of Representatives to support a third effort in the immediate future.

5. *Animal Legal Defense Fund v. Quigg*[96] Decided April 30, 1991

The biotech industry was proceeding full steam ahead in 1991, unrestricted by the controls of public sentiment antici-

92. *Id.* at 566.
93. H.R. 4970, 100th Cong., 2d. Sess. (1988).
94. *Id.*
95. H.R. 1556, 101st Cong., 1st Sess. (1989).
96. Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991).

pated by then Senator Al Gore. Indeed, the meager public opposition was falling on deaf ears. Rebuffed by their attempts at arousing the public's concern regarding biotech research and their legislative efforts to curtail life patents, the coalition of environmental and animal rights activists sought relief in the U.S. court system. The coalition realized its first opportunity in *Animal Legal Defense Fund v. Quigg*.[97]

The plaintiff, Animal Legal Defense Fund ("ALDF"), was a national nonprofit corporation headquartered in San Rafael, California, which works as an advocate for the interests and welfare of animals. In pursuit of this objective ALDF filed suit in 1988 challenging the PTO's authority in issuing the notice of April 7, 1987 regarding the Patent Office's position that animals qualified as patentable subject matter.[98] The ALDF petition sought an injunction compelling the PTO to cease issuing patents for animals on the dual grounds that the PTO had (1) violated procedural requirements for issuing such a notice by skirting public notice and comment requirements,[99] and (2) that patenting animals threatened the breach of a variety of animal protection laws constituting a substantive violation.[100]

The case was summarily dismissed by the District Court, which found the PTO notice to fall within a narrow exception to the public notice and comment requirements.[101] Although the Circuit Court upheld the lower court's dismissal, it subsumed the grounds relied on by the District Court finding that ALDF had suffered no legally cognizable injury and therefore lacked standing to sue.[102] Though finding a lack of standing obviated the need for the court to discuss 35 U.S.C § 101, referring to patentable subject matter, the court reaffirmed the liberal definition precipitating this case: "[t]he issue, in our view, in determining whether the claimed subject matter is patentable under section 101 is simply whether that subject matter is made by man."[103] A patent grant on living matter will be

97. *Id.*

98. *See* PTO NOTICE *supra* note 77 (reprinting relevant text challenged in Animal Legal Defense Fund v. Quigg, *supra* note 98).

99. 5 U.S.C § 553 (b), (c) (1988).

100. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 923-24 (Fed. Cir. 1991).

101. *Id.*

102. *Id.* at 922.

103. *Id.* at 928.

granted provided there is human intervention in the development process such that the subject is not found in nature. Thus, the courts denied ALDF a forum in which to discuss the moral and ethical considerations of patenting living matter.

6. Dominance from Progressivism

The court in *Animal Legal Defense Fund* averted the controversy looming over animal patents, namely whether our society has adequately considered the risks associated with manipulating the genetic make-up of complex animal life. Disregarding the merits of the ALDF case, the issues of morality encompassing biotech patents may best be resolved by a legislature elected by the people rather than a court of judges who are largely insulated from the popular electorate.[104] Nevertheless, opponents to animal patents have now lost in both the courts and the legislative arena, clearing the way for the life patents and proliferation of the biotech industry.

Beginning with *Chakrabarty*, the U.S. Judiciary has crafted a pro-business policy, continually reaffirming its position that the patent laws include anything under the sun that is made by man. Concurrently, Congress has remained content for 13 years to accept *sub silentio* the courts' expansive definition of the scope of patentable subject matter. The liberal policies toward patenting living matter in the United States are the most progressive in the world and provide the most expansive protections available. Hence, it comes with little surprise that the United States is presently the world's land of opportunity for realization of the biotechnology dream, leading the world in biotechnological innovations.

III. *PATENTABILITY OF BIOTECHNOLOGIES IN EUROPE*

A. *Sources of European Patent Law*

Europe presently has two sources of law that purport to govern patent grants and a third being drafted, including (1)

104. Diamond v. Chakrabarty, 447 U.S. 303, 322 (1980) (Brennan, J., dissenting). In fact this argument was made by Justice Brennan in his dissent to the Chakrabarty opinion, although Brennan urged the court to narrowly interpret the patent laws to exclude the patentability of living matter absent the express intention of the Congress. *Id.* "It is the role of the Congress, not this Court, to broaden or narrow the reach of the patent laws." *Id.*

the agreements of the European Patent Convention ("EPC"), (2) the national laws of the individual European states, and (3) the Draft Directive of the European Community.[105] The confluence of these three sources of patent laws are vitiating the property rights of biotech interests. In no area do the laws threaten to so diverge and complicate matters as in the area of life patents. This section discusses the various sources of patent law and further attempts to resolve potential supremacy issues among the governing entities.

1. European Patent Convention

The European Patent Convention ("EPC") is presently comprised of eighteen nations, including all the Member States of the European Community plus Austria, Liechtenstein, Monaco, Sweden, Switzerland and Egypt.[106] It was conceived in 1973 when the original eleven member nations jointly adopted the basic principles of the Strasbourg[107] and International Union for the Protection of New Varieties of Plants ("UPOV")[108] Conventions agreeing to establish a unified system for patent registration. The EPC's principal purpose was to enable a patent applicant seeking patent rights in more than one country to achieve this result with a single application to a central authority.[109] By empowering a central body to issue and register patents pursuant to standardized conventions, the EPC abates the costly and burdensome process of obtaining patents on an individual basis in each of the

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105. *See supra* notes 2-6 and accompanying text (discussing Draft Directive).

106. COOPERS & LYBRAND, *supra* note 7.

107. Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, Nov. 27, 1963, Eur. T.S. No. 47 [hereinafter THE STRASBOURG CONVENTION]. The Strasbourg Convention of 1963 laid down the commonly accepted principals upon which the EPC would be created. *Id.*

108. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89, T.I.A.S. No. 10199 [hereinafter UPOV]. UPOV is an international convention conceived for the protection of new plant varieties and ensuring plant breeders a fair return on their investments. *Id.* at 2708. UPOV presently has 21 signatory nations committed to unifying their respective laws concerning plant patents. *Id.* In 1991, UPOV underwent substantial revision to address the developments in biotechnological sciences and their impact on the generation of new plant varieties, although, the deadline for incorporating these changes is not until 1995. *See* "Patenting Life; Intellectual Property Rights in Plants", BIOTECH. BUS. NEWS, May 8, 1992.

109. COOPERS & LYBRAND, *supra* note 7.

signatory nations. This cost-effective and time-efficient patent system facilitates both investment and innovation.

The EPC issues a "European patent" vesting the holder with a bundle of national patents representing the exclusive rights to that invention in each of the contracting countries. The rights and protections of a European patent are commensurate with those afforded a national patent granted by the individual country. Therefore, issuance of a European patent instantaneously creates a collection of national patents governed by the independent laws of the various contracting states. This is consistent with the governing principal of the EPC that it may not replace or supersede the national patent system already in effect in the contracting states.[110]

The EPC is a registration system, not a legislative body. Once the European patent is granted its enforceability is determined by the courts and parliaments of 18 independent member countries.[111] A single European patent may be interpreted and modified within the various contracting countries to represent 18 varying degrees of patent protections.[112] Therefore, the impact of the EPC is limited to facilitating registration of patents but accomplishes nothing toward the unification of property rights, which is the most valuable element of a patent convention.

a. Patentable Subject Matter Under the Articles of the EPC

The scope of patentable subject matter is set forth in EPC Articles 52 and 53.[113] Paragraph one of Article 52 provides that a European patent shall be granted for "any invention which is susceptible of *industrial application*, which are *new* and which involve an *inventive step*."[114] The elements listed above are parallel to the "utility, novelty and non-obviousness" factors necessary for a patent in the United States.[115] Hence, patent fundamentals in the EPC are essentially the same as those applicable in the United States.

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110. ROSENBERG, *supra* note 21, at 19-61.

111. *Id.*

112. *Id.*

113. *See* ROSENBERG, *supra* note 21 at 19-63 (reproducing Articles 52 & 53 of Community Patent Convention in full).

114. *Id.*

115. *Id.*

EPC Article 53, entitled "Exceptions to Patentability," asserts that a patent shall not be granted where the subject matter of the patent is (1) "contrary to 'ordre public' or morality" or (2) "plant or animal varieties or essentially biological processes for the production of plants or animals."[116] The patent laws of the United States likewise deny property rights in plant and animal varieties and basic biological processes,[117] however the concept of "ordre public" is unique to the EPC.

"Ordre public" provides an opportunity for concerned citizens to challenge a pending EPC patent either before it is issued or any time after its issue. Were such an exception to exist in U.S. patent laws it could empower such groups as the Animal Legal Defense Fund[118] with automatic standing to challenge patent grants that people might find morally offensive. Therefore, citizens of the EPC possess the power to shape the regulatory agenda respecting biotechnologies through the judicial process, unlike their American counterparts confined to the agonizingly slow bureaucracy of its legislature. This additional power of the people has the unfortunate impact of increased risks and costs to the biotech researcher due to potentially lengthy time delays.

b. The Harvard Mouse's Trek through the EPC

The same Harvard Mouse that became the first patent granted for a new variety of animal in the United States has also made an appearance in Europe, seeking patent approval from the EPC. This scenario is a valuable illustration of the effectiveness of the "ordre public" as a weapon for the con-

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116. *Id.*

117. *See, e.g.*, Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948). Inherent in the element of "novelty" is a ban on patenting plant or animal varieties, for something cannot be "new" if it already exists naturally. *Id.* at 130. The Supreme Court denied a patent for the combination of several bacteria strains capable of inoculating the seeds of leguminous plants. *Id.* at 132. The Court reasoned that because the combination of bacteria strains did not change the characteristics of the individual bacteria the patentee had done little more than discover the handiwork of nature. *Id.* at 131.

118. *See* Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) (denying ALDF standing to challenge PTO Notice of April 7, 1987 pertaining to PTO's intent to recognize patentability of animals). Standing was denied in this case because ALDF did not comport with the technical requirements of showing an "injury in fact." *Id.*

cerned citizen and the correspondingly negative impact on biotech producers.

In 1990, European biotech concerns won a significant victory when the EPC Technical Board of Appeals held in *In re Harvard* that the EPC does not exclude the patenting of animals as a per se category.[119] The Board interpreted the Article 53 exception, which purports to exclude plant or animal varieties from patentability, to exclude only existing varieties, not *new* and *distinct* plants or animals engineered by biotechnology.[120] With this decision, the EPC Board expanded the scope of patentable subject matter, moving in the direction of the United States, which in *Chakrabarty* first recognized the right to patent animal life.

The EPC Technical Board of Appeals, however, stopped short of granting a patent by remanding the case for further inquiry on the issue of whether the exploitation of the invention would be contrary to "ordre public."[121] On remand the EPO ruled that the usefulness of the invention to humanity outweighed the suffering caused to the animal. Despite its definitive statement, the EPO provided for a period of public comment, allowing those opposed to the Harvard Mouse patent to bring their objections before the EPO prior to February 12, 1993.[122] This has touched off a fierce effort by animal welfare activists, the Greens,[123] who fear that the Harvard Mouse patent will provide massive financial incentive to find new ways of exploiting animals and promote unnatural and inhuman treatment of them. Though the fate of the Harvard Mouse patent appears a relative certainty at this point, the Greens have vowed to continue their campaign with renewed vigor. They have planned new offensives on a variety of fronts, including

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119. *In re* Harvard, 5 Eur. Pat. Off. Rep. 501 (Tech Bd. App. 1990).

120. *Id.* at 510.

121. *Id.*

122. *Biotechnology: Debate on Ethical Issues Flares Up Anew*, EUR. ENV'T, Jan. 19, 1993, *available in* LEXIS, Nexis Library, OMNI File.

123. "Rio Ambush for EC Patents," BIOTECH. BUS. NEWS, June 19, 1992, *available in* LEXIS, Nexis Library, OMNI file. The term "Greens" is used to define the coalition of peoples who possess a heightened consciousness towards the human condition, environmental pollution and animal welfare. It is derived from the name of the political organization, the Green Party, through which the voices of these various interests converge. *Id.*

(1) new appeals to the EPC Board of Appeals,[124] (2) challenging the Harvard Mouse patent in the independent courts of each of the EPC nations, and (3) using the current controversy as a bully pulpit to shape the pending European Community patent directive in such a manner that it will compel an overhaul of the EPC or otherwise emasculate its power. Regardless of the success or failure of the Greens' cause, it will dramatically increase the costs of patenting the Harvard Mouse and undoubtedly discourage future biotech innovations that threaten to provoke the same vehement opposition.

2. Patent Laws of the Various EC Nations

As discussed above, the EPC is exclusively a patent registration system, therefore the degree of protection afforded the inventor depends entirely upon the patent laws of the independent nations. Though a discussion of the patent laws of each of the Member States of the EC is beyond the scope of this discussion, it is sufficient to understand that the patent laws of the various countries cover a spectrum in degrees of protection afforded to biotechnological innovations. This lack of uniformity is precisely the weakness that groups such as the Greens will exploit. The expense of litigating the validity of a patent in 18 different countries, each with distinct patent laws, is almost preclusive, rendering the Harvard Mouse patent seemingly valueless.

Such an outcome is a virtual certainty in Europe, where only three nations presently have patent laws that expressly permit the patentability of living matter. Far and away the most progressive countries are Germany and the United Kingdom with patent laws respecting biotechnologies that parallel those of the United States and Japan. This comes as little surprise because Germany and the U.K. have been the most committed to the industrial development of biotechnologies.

The United Kingdom was early to adopt a liberal policy toward the patentability of living subject matter. In 1976, the

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124. *Biotechnology: Debate on Ethical Issues Flares Up Anew*, EUR. ENV'T, Jan. 19, 1993, *available in* LEXIS, Nexis Library, OMNI File. Presently, opponents to the Harvard mouse patent plan to dispute the issue of industrial application of the genetically engineered mouse. *Id.* Their claims cling to the concerns of some scientists that the mouse developed by Harvard researches is not a useful model for identifying cancer causing substances or developing anti-cancer drugs for use to humans. *Id.*

U.K. Court of Appeals upheld a patent for the production of tetracycline, finding that the cultivation of mutant strains was a manner of new manufacture.[125] By finding a manner of new manufacture, the U.K.'s courts obviated discussion of the "products of nature" doctrine that so perplexed the American judiciary.[126] Germany likewise exhibited an early liberal stance toward the patentability of living matter. In the famous case of *Baker's Yeast*,[127] decided in 1975 (five years before *Chakrabarty*), Germany's Federal Supreme Court held that micro-biological processes are not per se unpatentable solely because they made use of living organisms.[128] However, despite the liberal policies of the few, the conservative positions on the patentability of living matter taken by the many prevent a unified European treatment, which is critical to Europe's ability to compete in the biotech industry of the twenty-first century.

3. European Community—The Draft Directive

The EPC made substantial strides toward a unified system of European patent laws, yet it was conceived with several tragic flaws that prevent it from significantly benefiting Europe's blossoming biotech industry. The EPC's most prominent defect is its lack of power to enforce unified treatment of patents. Subscribers to the EPC vested the EPC with the authority to grant patents inclusive of all states, however they reserved the independent power to reject such patents if found contrary to the laws of the individual State.[129] The product is a unifying agreement inherently susceptible to disunity. This defect is most clearly pronounced in the controversial realm of biotech patents.

Recognizing the failures of the EPC, the World Intellectual Property Organization ("WIPO"),[130] and other interna-

125. American Cyanamid v. Berk Pharmaceuticals, 1976 R.P.C. 231 (1976).

126. *See supra* notes 39-49 and accompanying text (discussing *Funk Bros.*).

127. Baker's Yeast Decision, 1975 GRUR 430 (BGH 1975), *reprinted in* 6 INT'L REV. INDUS. PROP. & COPYRIGHT L. 207-19 (1975).

128. *Id.*

129. ROSENBERG, *supra* note 23, at 19-61.

130. Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3 [hereinafter WIPO]. WIPO is a specialized agency of the United Nations, having been formally established under a convention dated July 14, 1967. *Id.* Its primary function is to administer the Patent Cooperation Treaty which is committed to harmonization of world patent laws.

tional organizations to consummate a harmonious treatment of biotech patent laws, the EC commissioned its own organization, the Community Patent Convention ("CPC"). The CPC soon proved as ineffective as its predecessors, and largely for the similar reason that it lacked authority to compel compliance. Frustrated by the impotence of unifying treaties and realizing that time was increasingly of the essence, the European Community took the initiative.

The European Council, an independent body composed of the heads of state of the Member States, which had begun work on biotechnology issues as early as 1985, originated the Draft Directive.[131] Their product, "Biotechnological Inventions: Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions," was submitted to the European Council on October 20, 1988.[132]

a. Patentability of Living Matter Under the Draft Directive

Chapter 1 of the proposed Directive, entitled "Patentability of Living Matter," is composed of nine brief articles that address the proposed subject matter that could qualify for patent protection. Because this is the critical component of the Draft Directive, the most relevant portions, comprising Articles 2, 3,4, and 5, are reproduced here, followed by a brief commentary.

> ARTICLE 2 — A subject matter of an invention shall not be considered unpatentable for the reason that it is composed of living matter.

This simple proposition establishes that the subject of living matter is not to be preclusive of patentability. Article 2 recognizes an immense scope of patentable subject matter, which the succeeding articles clarify and refine.[133]

> ARTICLE 3 — 1. Micro-organisms, biological classifications other than plant or animal varieties as well as parts

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However, similar to the EPC, WIPO possesses no enforcement powers to compel conformity. Every Member State of the EC is independently a member of WIPO. COOPERS & LYBRAND, *supra* note 7.

131. DRAFT DIRECTIVE, *supra* note 2, O.J. C 10/3 (1989); The Single European Act, O.J. L 169/1 (1987) art. 2, (amending the EEC Treaty, *supra* note 28, and defining European Council, which is separate body from the Council of Ministers).

132. DRAFT DIRECTIVE, *supra* note 2, O.J. C 10/3 (1989).

133. DRAFT DIRECTIVE, *supra* note 2, art. 2, O.J. C 10/4 (1989).

> of plant and animal varieties other than propagating material thereof of the kind protectable under plant variety protection law shall be considered patentable subject matter.
>
> 2. Notwithstanding the provisions of paragraph 1, plants and plant material shall be considered patentable subject matter unless such material is produced by the non-patentable use of a previously known biotechnological process.

Article 3 recognizes that micro-organisms, such as the oil connoisseur patented in *Chakrabarty* and certain biological classifications, may be patented.[134] It simultaneously carves out two sizable exceptions from the broad proposition articulated in the previous article: (1) plant and animal varieties, and (2) material produced by previously known processes.

Subparagraph 1 eliminates plant and animal varieties and propagating material of those plants and animal varieties as a per se non-patentable class.[135] This exception parallels the treatment accorded in the United States, which prohibits such patents under the "products of nature" doctrine. Therefore, EC courts will also be confronted with the definitional difficulties regarding the products of nature that Justice Frankfurter discussed in *Funk Brothers*.[136] Recall Justice Frankfurter's prophesy that the malleable terms "the work of nature" and "the laws of nature. . .could fairly be employed to challenge almost every patent."[137]

It is common opinion that subparagraph 1 would permit a utility patent to be granted for a plant or animal that exhibits qualities distinct from the original variety.[138] This would extend the protections of the utility patent to plant and animal varieties that might have otherwise qualified for the guardianship of UPOV[139] plant patent laws, though the directive is in no way intended to interfere with the system of breeders'

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134. DRAFT DIRECTIVE, *supra* note 2, art. 3, O.J. C 10/4 (1989).

135. DRAFT DIRECTIVE, *supra* note 2, art. 3(1), O.J. C 10/4 (1989).

136. Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

137. *Id.* at 135.

138. *See* UPOV, *supra* note 108, 33 U.S.T. 2703, 815 U.N.T.S. 89.

139. *Id.* UPOV protections were amended in 1991 to reflect developments in biotechnology and will not be practically enforceable until 1995. *Id.*

rights.[140] Such protections are concurrent to those offered by the United States which, in the case of *Ex parte Hibbard*, granted a utility patent for a strand of corn plant developed to contain abnormally high amino acid levels.[141] The benefit of the utility patent is that in both cases, under U.S. laws and the Draft Directive, patent protections are significantly broader than those available under the respective plant protection laws, the U.S. Plant Patent Act or UPOV.[142]

Article 3, subparagraph two expressly excludes from patentability material that is produced by previously known processes. This exception is redundant with the requirement that the subject matter of a patent possess an "inventive step" or otherwise be "non-obvious."[143] The previously discussed U.S. case *In re Allen* provides an ideal illustration of this point. In *Allen* a researcher sought to patent a process for creating an infertile Pacific oyster which involved the application of hydrostatic pressure in a carefully controlled environment. A patent was denied because the court found it to be common knowledge that variations of Allen's processes had produced infertility in other varieties of oysters.[144] Hence, Allen's discoveries were an "obvious" extension of prior work which involved no "inventive step."

The recognition of patents on new processes used to arrive at an invention comports with U.S. law which provides in 35 U.S.C § 101, "[w]hoever invents or discovers any new and useful *process*, machine, manufacture, or composition of matter . . . ."[145] Of significance is that Article 4 creates the opportunity to obtain a patent on the process of arriving at a plant or animal variety, which standing alone are precluded from pat-

140. Whaite & Jones, *supra* note 1, at 148-49.

141. Ex Parte Hibbard, 227 U.S. PAT. Q. 2d 443, 446 (1985).

142. Sease, *supra* note 9, at 149.

143. *See* 35 U.S.C § 103 (1988) entitled "Conditions for patentability; non-obvious subject matter." 35 U.S.C. § 103 states in pertinent part that "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *Id.*

144. Ex parte Allen, 2 U.S. Pat. Q. 2d 1425, 1428 (1987).

145. 35 U.S.C. § 101 (1988), entitled "Inventions patentable" states in full text, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." *Id.*

entability under Article 3(1).[146] As an example, "The insertion of a particular segment of DNA into the genome of a seed will still be patentable subject matter, even if the resulting new plant constitutes a variety and is not itself patentable."[147]

Chapter 1 of the EC Draft Directive announces a scope of biotech patent protections on level with those recognized in the U.S. and Japan.[148] The significance is expressed by its drafters in the Directive's preamble, "Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions can be considered of fundamental importance for the community's industrial development."[149] If accepted, the Directive will enable biotech concerns doing business in the European Community to better compete in the global market. New EC protections should recapture lost R & D investment that formerly sought out the more advantageous patent laws in the U.S. and Japan.[150] In sum, ratification of the Draft Directive should achieve the critical goals stated in the Directive's preamble.

b. Resolving Conflicts Between the EPC and the Draft Directive

The intent of authoring the Draft Directive was to create a unified system for recognizing patents on living matter, which the EPC failed to accomplish. The scope of patentable material and the protections afforded by the EC patent far exceed the benefits offered by the EPC patent. Therefore, the clear intent of the EC in proposing a directive was to supersede all existing conventions purporting to govern biotech patent rights. Hence, if ratified, the Draft Directive will reign

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146. DRAFT DIRECTIVE, *supra* note 2, arts 4-5, O.J. C 10/5 (1989) states:

ARTICLE 4 — Uses of plant or animal varieties and processes for the production thereof shall be considered patentable subject matter.

ARTICLE 5 — Microbiological processes shall be considered patentable subject matter, [i.e.]. . .a process (or processes) carried out with the use of or performed upon or resulting in a micro-organism.

Id.

147. Whaite & Jones, *supra* note 1, at 149.

148. COOPERS & LYBRAND, *supra* note 7, § 11.2; *see also* DRAFT DIRECTIVE, *supra* note 2, O.J. C 10/4-5 (1989).

149. Whaite & Jones, *supra* note 1, at 152.

150. *Id.* at 145.

supreme with respect to Member States of the EC, though the EPC will retain a subordinated role for the four non-EC members party to that convention: Austria, Liechtenstein, Switzerland and Sweden.[151]

The Draft Directive asserts supremacy vis-à-vis the national patent laws of the individual contracting states.[152] Unlike the EPC, the Draft Directive is backed by the enforcement powers of the European Community and can coerce legislative action in any Member State by threat of sanctions. Indeed, Article 1 of the pending Directive proclaims that "Member States shall ensure that their national patent laws comply with the provisions of this directive."[153] The enforcement power of the EC will forge success where the other conventions, lacking such authority, failed.

c. Ratification of the Draft Directive

The original text of the Draft Directive was submitted by the European Commission[154] to the Council[155] on October 20, 1988. From this point the proposed Directive must be af-

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151. ROSENBERG, *supra* note 21, at 19-61.

152. *See supra* notes 106-118 and accompanying text (discussing EPC). That convention did not replace or supersede the national patent systems in effect in the contracting states, consequentially, the contracting nations may limit the effectiveness of the EPC as applicable in their jurisdictions. EPC, *supra* note 7, 15 I.L.M. 5 (1976).

153. *See* DRAFT DIRECTIVE, *supra* note 2, art. 1, O.J. C 10/4 (1989).

154. *See* EEC Treaty, *supra* note 28, arts. 155-63, 298 U.N.T.S. at 71-73. The European Commission is a special 17 member board established in Title VI, section 3, articles 155-163. *See* EEC Treaty, *supra* note 28, arts. 155-63, 298 U.N.T.S. at 71-73. The Commission is empowered to "formulate recommendations" for delivery to the European Parliament where "the Commission considers it necessary." EEC Treaty, *supra* note 28, art. 155, 298 U.N.T.S. at 71. In this instance the Commission recognized the problem of insufficient legal protections for biotech innovations and responded with the draft directive on biotechnology patents. *See* DRAFT DIRECTIVE, *supra* note 2, art. 1, O.J. C 10/4 (1989). The Draft Directive then proceeds to the European Parliament which decides whether to adopt the directive. EEC Treaty, *supra* note 28, art. 149, 298 U.N.T.S. at 70. Therefore, the Commission is prone to be nepotistic toward the directive on biotech patents to which it gave rise. "Debate on Biotechnology Ethical Issues Flares Up Anew," EUROPEAN INSIGHT, Jan. 15, 1993, *available in* LEXIS, NEXIS library, CURRENT File.

155. The Council of Ministers is a body of delegates from the Member States, each state represented by a Single Minister. EEC Treaty, *supra* note 28, art. 146, 298 U.N.T.S. at 70. The Council is the final word on EC legislation, though it must enact such legislation pursuant to strict rules allowing for substantial input from the European Parliament. EEC Treaty, *supra* note 28, art. 149, 298 U.N.T.S. at 70.

firmed by the Council and adopted as its "common position."[156] Next, the Council is compelled to consult the European Parliament,[157] which may pursue one of four paths: (1) take no action, (2) approve by simple majority, (3) reject the common position, or (4) propose amendments and return to the Commission.[158]

In the case of the Draft Directive on biotech patents the European Parliament elected to propose numerous amendments, returning it to the Commission for reconsideration. At this stage the Commission may adopt or reject the proposed amendments. If it chooses to reject the Parliament's suggestions, the Directive proceeds to the Council and may be adopted only by unanimous vote—a virtual impossibility.[159] Alternatively, if the Commission elects to adopt the proposed amendments, then ratification may be concluded upon a qualified majority vote of the Council.[160] In this instance the Commission, reluctant to submit to all the requested amendments proposed by the Parliament, has elected to seek a compromise with the Parliament. The ensuing negotiation has evolved into a protracted and highly public debate and resulted in the repeated postponement of the deadline contained in the original text of the Draft Directive.

Opposition members within the European Parliament believed that greater protections were needed to protect farmers and animal rights, and ensure a strict code of "bio-ethics."[161] Opponents have employed scare tactics to rally popular opinion against the Draft Directive, confronting the public with the gruesome parade of horribles in an effort to raise public aware-

156. *Id.* The Council votes are weighted in proportion to national economic prowess according to a predetermined formula; adoption of a common position requires a qualified majority, which is 54 of the possible 76 votes. EEC Treaty, *supra* note 28, art. 148, 298 U.N.T.S. at 70. Note that the United Kingdom and Germany control 20 of these weighted votes. *Id.*

157. *See* EEC Treaty, *supra* note 28, art. 149, 298 U.N.T.S. at 70 (describing voting procedure). The European Parliament is composed of representatives elected directly by the Member States. *See* EEC Treaty, *supra* note 28, arts. 137-44, 298 U.N.T.S. at 67-69.

158. T.C. HARTLEY, THE FOUNDATIONS OF EUROPEAN COMMUNITY LAW 30-1 (2d ed. 1991).

159. *Id.* at 34-5.

160. *Id.*

161. "Debate on Biotechnology Ethical Issues Flares Up Anew," EUROPEAN INSIGHT, Jan. 15, 1993, *available in* LEXIS, NEXIS Library, CURRENT File.

ness.[162] Through their success in stimulating a dialogue on the patentability of living matter, opponents have earned the clout to impose numerous amendments on the Draft Directive and have successfully prolonged its ratification for over four years.

The most recent success occurred this past Spring when opposition groups again delayed the ratification process with the introduction of several proposed amendments during an April Parliamentary session.[163] The changes demanded include: (1) an absolute prohibition on patents of human materials, (2) greater animal rights protections, and (3) a limited farmer's exemption from the patent laws. Discussion of these proposed changes, which experts agree could radically alter the Draft Directive, will follow.

B. *The Struggle to Pass the Draft Directive*

1. Forces Shaping the Debate

There are three primary forces competing for public support in the debate over the Draft Directive on biotechnology patents. These groups are: (1) the "Greens," which is used generically to refer to all persons harboring moral or ethical objections to the patenting of living matter, a large majority of whom are self-proclaimed environmentalists, (2) family farmers, and (3) the various biotech trade associations.

The Greens evoke images of Nazi-like experimentation, animal suffering, irreversible changes in the human gene pool and devastating effects of inadvertently introducing a pathogen into the environment in effort to win public support through fear of the unknown.[164] Most Greens are not per se opposed to biotech research, but desire strict planning controls imposed upon researchers to avert potential disaster. Their concerns are shared by many people, including Vice President of the United States Al Gore, who drew this analogy in a 1987 law review article, "[i]f we had taken more time to comprehend the implications of nuclear technology when it

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162. "EC Under Pressure to Address Concern on Biotechnology," FOOD AND DRINK DAILY, May 14, 1992, *available in* LEXIS, NEXIS Library, CURRENT File.

163. *EC Patent Directive Moves Ahead?*, BIOTECH. BUS. NEWS, May 8, 1992, *available in* LEXIS, Nexis Library, OMNI File.

164. "EC Under Pressure to Address Concern on Biotechnology," FOOD AND DRINK DAILY, May 14, 1992, *available in* LEXIS, NEXIS Library, CURRENT File.

was created, we might have developed a keener appreciation for those choices before us."[165] Through the volatile combination of powerful imagery and a genuine concern, the Greens-led opposition has become a formidable power in EC politics, especially within the European Parliament.

The second major opposition power resides with the family farmers' lobby which, similar to its American cousins, is a sacrosanct lot evoking a strong sense of paternalism among the non-farming citizenry. The genetic revolution promises agriculture dramatic increases in the yield of crops and livestock. For example, several biotech companies are presently working on "bovine somatotrophin," a genetic enhancement which enables a dairy cow to produce 25% more milk than an unaltered animal. Such innovations occur despite the United States having spent $1.8 billion on dairy buy-back subsidies in 1986 to cut dairy supplies by only 8.7%.[166]

Ag-biotech burns the family farmer's candle at both ends. First, the high start-up costs, stemming from the purchase of expensive technologies, preclude the family farmer who is incapable of reaping the scale economies necessary to afford bio-ag. Second, as illustrated above, enhanced production due to biotech will saturate the markets, driving prices down and profit margins even thinner than they already are. Extinction of the venerable family farmers of Europe and the United States at the hands of agri-business conglomerates presents an appealing victim behind which the public can rally.

Trade associations of biotech producers have only recently mobilized their resources to counter the swelling tide of opposition. The most influential body appears to be the European Secretariat of the National BioIndustry Associations ("ESNBA") formed in 1992, composed of the national biotechnology associations from seven of Europe's most active research nations.[167] The purported purpose of the ESNBA is as a collator and disseminator of information on biotech-related issues and as a contributor to the development of EC regula-

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165. Gore, *supra* note 19, at 967.

166. Whaite & Jones, *supra* note 1, at 152.

167. "Europeans Form New Biotechnology Organization," 12 GENETIC TECH. NEWS, No. 2 at 3, *available in* LEXIS, Nexis Library, OMNI File. The membership represents the following countries: Belgium, Denmark, France, Italy, The Netherlands, Spain and the United Kingdom. *Id.*

tory policy.[168] Its ultimate goal would be the passage of a directive as close to that originally proposed by the Commission as is politically expedient, though none believe such an expansive doctrine will be the result. One should expect this coordination of resources, however, to prove extremely powerful in the ensuing debates regarding the draft directive.

2. Significant Amendments Sought

Having introduced the parties seeking to influence the ultimate outcome of the Draft Directive, attention will now focus on the most significant changes presently being sought. The most controversial amendments concern the European Parliament's desire to curtail the liberal treatment of living subject matter contemplated by the Draft Directive. Principal advocates for the proposed amendments are the Green Party Members and Social Democrats in the European Parliament, while the ESNBA and other biotech interests are pressuring the European Commission to hold tough against change and salvage the Directive with minimal alterations.

The fate of the Draft Directive is within the dominion of the polarized European Parliament and European Commission, which must forge a compromise. The major changes sought include: (1) an absolute prohibition on patents of human materials, (2) greater animal rights protections, and (3) a limited farmers' exemption from the patent laws.[169] These will be discussed in the order introduced above.

a. Human Body Unpatentable

The European Parliament has, since the Draft Directive's introduction, relentlessly pursued the European Commission on the issue of patentability of the human body. Their demands were simple: an outright ban on patents that encompassed the human body. Indeed, the amended text of the draft directive submitted by the European Commission on October 20 of 1992 incorporated these demands, rendering unpatentable: "the human body or parts of the human body per se . . . processes for modifying the genetic identity of the human

168. *Id.*

169. *European Parliament Demands Key Changes in Biotech Patent Legislation*, PHARMACEUTICAL BUS. NEWS, Apr. 22, 1992, *available in* LEXIS, Nexis Library, OMNI File.

body for a non-therapeutic purpose which is contrary to the dignity of man."[170] The first phrase states that the human body is not patentable under any circumstances, which raises several interesting issues regarding the patent applications for genetic sequences currently pending before the U.S. Patent and Trademark Office. The subsequent language recognizes that *processes* for modifying genetic identity are patentable in certain instances, while implying by omission that the modified genetic material is itself unpatentable. Further issues that will require future interpretation include a "non-therapeutic purpose" and the concept of "contrary to the dignity of man."

The recent amendments to the Draft Directive raise many issues encompassing the attempt of the United State's National Institute of Health ("NIH") to patent more than 2,000 fragments of human genetic sequences.[171] The NIH's Human Genome Project, which receives over $3 billion in funding from the U.S. Government,[172] is intent on identifying all 50,000 to 100,000 human genes and deciphering their contribution to the composition of the human being.[173] The information contained within these genes is considered a treasure trove of knowledge that will reveal the biotech supermedicines of the future. Through patenting this material the U.S. hopes to develop a new infrastructure in biotechnology, reserving the exclusive rights to benefit from its findings.

The patenting efforts of the NIH have drawn a storm of criticism from those opposed to patenting the human body, the international science community and the NIH's own project directors.[174] To date, no patents have been issued, nor have the issues encompassing the "utility"[175] of such a patent,

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170. *Biotechnology: Debate on Ethical Issues Flares Up Anew*, EUR. ENV'T, Jan. 19, 1993, *available in* LEXIS, Nexis Library, OMNI File.

171. John Carey, *This Genetic Map Will Lead to a Pot of Gold*, BUS. WK., Mar. 2, 1992 at 74.

172. *Id.*

173. *Id.*

174. *Id.*

175. *See* "EC Under Pressure to Address Concern on Biotechnology," FOOD AND DRINK DAILY, May 14, 1992, *available in* LEXIS, NEXIS Library, CURRENT File. Though NIH scientists have identified various sequences, they have made no representations as to the "utility" of any of the gene sequences. Similar to the European Patent Convention requirement for an industrial application of the patent technology, the "utility" element requires the patent applicant to demonstrate the usefulness of the patent. *Id.*

its "obviousness"[176] or the thirteenth amendment implications[177] of patenting human beings been addressed. The U.S. Congress has, for the moment, preempted this field with hearings scheduled for the 103rd Congress.[178] In addition, several international efforts, such as the Rio Summit, which occurred during the summer of 1992,[179] have been launched in an attempt to reach a global resolution of these and other issues encompassing biotechnology and life patents.

In the interim, several European biotech concerns have retaliated by filing patent applications with the EPC to insure protections for those gene sequences that they have discovered.[180] The common belief among commentators on this issue is that the EPC will not grant patents on gene sequences because of lack of an industrial application and/or because of an affront to the "ordre public."[181] In light of the language contained in the recent amendments to the Draft Directive it is even less likely that the EPC will move swiftly on these applications.

b. Assurances for Protection of Animal Rights

Environmentalists and animal rights groups are the backbone of the effort to include in the Draft Directive language that denies legal protections for biotech inventions that pertain to animals. These "Greens," as they have been dubbed by the media, reject the notion of "life patents," contending that higher life forms should not be subject to exclusive ownership.

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176. A logical extension of the "products of nature" doctrine, which denies patentability of things already existing in nature, could be made to deny patents concerning the human body or its components which are naturally occurring. In *Funk Brothers*, the U.S. Supreme Court rejected a patent where the scientists were perceived as doing little more than discovering the handiwork of nature. Funk Brothers Seed Co. v. Kalo Innoculant Co., 333 U.S. 127 (1948). However, the precedential value of *Funk Bros.* is in limited in light of Diamond v. Chakrabarty, 447 U.S. 303 (1980).

177. Hecht, *supra* note 36 at 1023, n.1.

178. *Pressure for Consensus at US Congress Hearing*, BIOTECH. BUS. NEWS, May 22, 1992, *available in* LEXIS, Nexis Library, OMNI File.

179. *Rio Ambush for EC Patents*, BIOTECH. BUS. NEWS, June 19, 1992, *available in* LEXIS, Nexis Library, OMNI File.

180. "Gene Patenting Debate Continues," BIOTECH. BUS. NEWS, May 8, 1992, *available in* LEXIS, NEXIS Library, CURRENT File.

181. *Gene Patenting Debate Continues*, BIOTECH. BUS. NEWS, May 8, 1992, *available in* LEXIS, Nexis Library, OMNI File.

Their objections hint of the exploitation of which would be contrary to the "ordre public" and morality limitations found in Article 53 of the EPC. Indeed, the Green coalition within the European Parliament has made significant progress toward its demands for a ban on certain animal patents reflective of EPC Article 53.[182]

The specific amendment achieved by European Parliament members makes ineligible for patent "processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man."[183] EC experts believe that this amendment is intended to create a balancing test similar to that used by the European Patent Office in granting the patent to the Harvard Mouse[184]—a test interpreted as a simple balancing of the detriment of animal suffering against the benefit of the innovative technology to humanity.[185] Although this amendment represents a good faith effort by the European Commission to arrive at a compromise, it is doubtful that the Green coalition in the European Parliament will be satisfied with the balancing approach which they have already reacted against in the EPC's Harvard Mouse patent.

Regardless of the form or content of animal rights protections incorporated into the Draft Directive, one thing is certain: it will be the incessant weapon utilized by groups opposing "life patents," as it would seem to grant automatic standing. The Green faction is a stalwart for the cause of inhibiting the rapid developments in life patenting, and the group's performance in the EPC hearings on the Harvard Mouse patent has demonstrated their resolve.[186] Biotech companies can expect the Greens to remain a contentious source of resistance to "life patents," challenging the industry's progress at every step.

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182. *EC Patent Directive Moves Ahead?*, BIOTECH. BUS. NEWS, May 8, 1992, *available in* LEXIS, Nexis Library, OMNI File.

183. *Biotechnology: Debate on Ethical Issues Flares Up Anew*, EUR. ENV'T, Jan. 19, 1993, *available in* LEXIS, Nexis Library, OMNI File.

184. *Id.*

185. *Id.*

186. *Rio Ambush for EC Patents*, BIOTECH. BUS. NEWS, June 19, 1992, *available in* LEXIS, Nexis Library, OMNI File.

c. The Farmers' Exception

Industry reports estimate that agricultural-biotech products generated $200 million in worldwide revenues for 1991,[187] despite the industry's relative infancy. The agricultural world is not far away from being compelled to compensate biotech firms handsomely when they succeed at genetically engineering the sturdier and better tasting tomatoes, higher yielding dairy cows, and insect resistant wheat crops, unless international patent laws evolve to reflect the position taken by many members in the European Parliament.

European Parliament members have succeeded at carving out another exception in the proposed biotech patent directive that creates a "farmers' privilege." This privilege exempts farmers from having to pay royalties for the use of seeds from genetically modified plants or for the breeding of farm animals in order to renew their stock.[188] Farmers are prohibited from selling protected property such as the seed or breeding of an animal for income, though the developer of the technology is still largely deprived of their property interests. This move represents a radical departure from the EPC's, which does not recognize an exception for farmers from patent enforcement.

Though the European Commission has again come forward with an olive branch in an effort to ratify the biotech directive, it has been cautious to preserve the competitiveness of Europe's biotech industry. The amendment permits farmers to resow their crops with patented technology in perpetuity without having to make additional payments to the patent holder. Farmers, however, must acquire the original rights to patented crops at some point. Therefore, the holder of such patented technology can simply adjust its pricing policy to extract the full value of using the technology in perpetuity.

Furthermore, one may expect that as biotechnology investment and research increase, product life cycles will decline. Thus, rights in a given crop or livestock will likely diminish fleetingly as new and improved genetically engineered products are introduced. This high rate of technology turnover substantially undermines the right to use an agricultural patent in perpetuity. Therefore, though the European Commission

187. Hamilton, *supra* note 16, at 72.

188. *EC Patent Directive Moves Ahead?*, *supra* note 182.

has made a concession to the European Parliament, the terms of the amendment are not significantly threatening to the bio-ag industry.

IV. *CONCLUSION: A CALL TO ACTION*

Our conclusion should begin by again commending the European peoples for dutifully accepting their role in shaping the Draft Directive on biotech patents through vigorous public debate. Europeans have taken the initiative to think through the implications of granting life patents, an obligation all but abandoned by citizens in the U.S. and other countries that hastily enacted liberal biotech patent protections. However, five years of contentious deliberations have rendered the EC in a now desperate situation to enact some form of legislation to adequately protect its biotech industry.

While the United States pursues its policy of patenting "anything under the sun that is made by man" European biotech concerns are able to patent nothing under their own Community laws, and are limited to the narrow and uncertain opportunities provided by the European Patent Convention (EPC). With every passing day, Europe concedes ground to the U.S. and Japan, who are rushing ahead into this "industry of the future" to stake their claim to the $50 billion prize. The time has now come for the governing bodies of the European Community to expedite the ratification process for the Draft Directive on biotechnologies as a top priority.

The European Commission has come forth with a series of significant amendments tailored to meet the demands of the European Parliament, and although they likely fall short of all that the European Parliament desired, the amendments represent a good faith compromise. Now the European Parliament must determine whether the Commission has gone far enough or, in the alternative, whether they are flexible enough to meet the Commission somewhere in the middle. Should the European Parliament hold steadfast and refuse to compromise, the Commission will face a difficult decision: whether to pursue an emasculated directive that overrides the EPC, or to scrap the Directive in hopes that the EPC can further develop and adequately protect biotech patents.

The European Parliament must likewise be aware of this

potential. While the Draft Directive hung in limbo over the past five years, Ireland, Denmark, and Portugal joined the EPC, such that every Community Member State is now also a signatory to the EPC. For the European Parliament the implications are clear: if it maintains support for the directive any longer, the Commission may drop the Directive in preference to the potentially greater protection afforded by the EPC. Indeed, the EPC has recently granted a patent for the Harvard Mouse, which it determined using the same straight balancing test incorporated into the Commission's proposed amendments, and in addition the EPC lacks a farmers' privilege. Perhaps the best tactic for the European Parliament and its Green backers would be to accept this compromise EC Draft Directive over which they may influence the enactment of amendments at some future date, rather than risk the empowerment of the EPC.

Clearly, both the Greens, whose interests are represented by the European Parliament, and the biotech industry, championed by the European Commission, must recognize what each other stands to lose if this debate is protracted any longer. The present environment of uncertainty coupled with the risks represented by failure should prove conducive to consensus building among the various governing bodies of the European Community. An expedient compromise is in the best interest of both the Greens and the biotech industry and one should suspect that the European Parliament will treat favorably the October 20, 1992 amendments submitted by the Commission.