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Patenting Nonnaturally Occurring, Man-Made Life: A Practical Look at the Economic, Environmental, and Ethical Challenges Facing "Animal Patents"

by

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Patenting Nonnaturally Occurring, Man-Made Life: A Practical Look at the Economic, Environmental, and Ethical Challenges Facing "Animal Patents"

I. INTRODUCTION

On April 30, 1991, in *Animal Legal Defense Fund v. Quigg*[1] the United States Court of Appeals for the Federal Circuit held that various animal rights groups and animal husbanders lacked standing to seek both "a declaration that animals are not patentable subject matter and an injunction against the issuance of animal patents."[2] The action was brought challenging a Public Notice issued by the United States Patent and Trademark Office (PTO) on April 7, 1987, stating in part that the PTO "now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101."[3] The plaintiffs were concerned with the potential economic, environmental, and ethical problems resulting from this new rule. Unfortunately, because the case was dismissed for lack of standing, the court never reached the issue of whether the PTO's issuance of animal patents exceeded its authority under 35 U.S.C. § 101.

The *Animal Legal Defense Fund* decision was a defeat for those seeking to curb genetic engineering via the prohibition of animal patenting, but the challenges are far from dead. During the 102nd Congress, legislation was introduced into both Houses calling for a five-year moratorium on the patenting of genetically engineered animals, commonly referred to as transgenic animals.[4] The stated purpose of these bills was to provide time for Congress to fully assess, consider, and respond to the economic, environmental, and ethical issues raised by the patenting of such ani-

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1. 932 F.2d 920 (Fed. Cir. 1991).
2. *Id.*
3. 1077 OFFICIAL GAZETTE PAT. OFFICE 24 (Apr. 21, 1987).
4. S. REP. NO. 1291, 102nd Cong., 2d Sess. 1 (1992); H.R. REP. NO. 4989, 102nd Cong., 2d Sess. 1 (1992).

mals.[5] Neither bill passed, but the Senate version has been reintroduced in the 103rd Congress, modified to impose a two-year moratorium.[6]

This note addresses the legal development of animal patenting and challenges facing this controversial area of law. Part II includes an overview of genetic engineering. Part III outlines the legal development of animal patenting; in Part IV, the note addresses the *Animal Legal Defense Fund* decision. Part V examines specific challenges raised in opposing animal patents as well as supporting interests asserted in favor of them. Part VI of this note balances those opposing challenges and the supporting interests. This note concludes that Congress should promulgate legislation specifically providing for the issuance of transgenic animal patents and the regulation of the biotechnology industry.

II. BIOTECHNOLOGY AND TRANSGENIC ANIMALS

Traditionally, animal breeding practices have included selective breeding within species and cross-breeding between closely related species.[7] A breeder seeks to produce animals exhibiting desired characteristics, by selecting animals exhibiting specified or dominant characteristics.[8] The results of selective breeding are unpredictable as there is no guarantee that the desired characteristics will surface in the offspring. Additionally, the breeder "cannot select one trait without carrying" other, perhaps undesirable, traits with it.[9]

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5. *Id.*

6. S. REP. NO. 387, 103rd Cong., 1st Sess. 1 (1993). (This bill is being referred to as the "Life Patenting Moratorium Act of 1993.")

7. *Patents and the Constitution: Transgenic Animals, Hearings Before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the House Committee on the Judiciary*, 100th Cong., 1st Sess. 34 (1987) [hereinafter *Transgenic Animal Hearings*] (statement of Dr. Thomas Wagner, Edison Animal Biotechnology Center, Ohio Univ.); *id.* at 122 (testimony of Dr. A. Ann Sorensen, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation).

8. *Id.* at 37 (statement of Dr. Thomas Wagner).

9. *Id.*

The effectiveness of traditional animal breeding practices has been surpassed by biotechnology. Biotechnology is defined as any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop micro-organisms for specific uses.[10] New species of animals actually are created through various artificial techniques, whereas the results of traditional selective breeding techniques, at least theoretically, are limited to what could have been accomplished without man's intervention. Some of the techniques used today include microinjection, cell fusion, electroporation, and retroviral transformation.[11]

The application of these new technologies to animals is expected to produce many new results, including increased growth performance, higher disease resistance, and certain reproductive traits which will collectively lower costs to farmers and produce a more healthful product for the consumer.[12] Additionally, new breeds of sheep, goats, and cows that secrete valuable human pharmaceutical proteins into their milk are being developed.[13]

Another promising benefit of biotechnology is the development of laboratory animal models for the study of human diseases. On December 29, 1992, the PTO issued patents for three genetically engineered mice strains, the first such animal patents granted since the so-called "Harvard Mouse" patent was issued in April 1988.[14] One strain of mice, whose males develop enlarged prostrate

10. *Office of Technology Assessment, New Developments in Biotechnology: Patenting Life* 5, 183 (April 1989) [hereinafter *Patenting Life*].

11. *Patenting Life*, *supra* note 10, at 94.

12. *Transgenic Animal Hearings*, *supra* note 7, at 122 (testimony of Dr. A. Ann Sorensen).

13. Ann Moffat, *Transgenic Animals May Be Down on the Pharm*, 254 SCIENCE, Oct. 4, 1991, at 35-36. (Currently, the yields of human proteins from the milk of these animals are still too low for commercial production.) *See also* Ian Wilmut, Clark, & Simons, *A Revolution in Animal Breeding*, 119 NEW SCIENTIST, July 7, 1988, at 56-59 (explaining that one object of research has been to develop farm animals that produce proteins needed for the treatment of human disease).

14. 45 Pat. Trademark & Copyright J. (BNA) No. 1112 (Jan. 7, 1993). For a discussion on the utility of the "Harvard Mouse," *see infra* notes 97-98 and accompanying text (stating that the "Harvard Mouse" was developed as a model for breast cancer research).

glands, will be used to test potential drug treatments for prostrate enlargement as well as suspected carcinogens.[15] Another strain, mice that fail to develop a completely functional immune system, will be used in research of immune-system diseases such as AIDS.[16] The other mice, a virus-resistant strain, will be used to study the immune system's response to cancer.[17]

Although many potentially patentable animals are likely to be produced via recombinant DNA (deoxyribonucleic acid) techniques,[18] microinjection is the most commonly used method of transgenic research and the one most likely to lead to practical applications in mammals.[19] This technique involves injecting highly purified copies of certain genes of interest directly into a fertilized animal egg.[20] The egg is then surgically implanted in the reproductive tract of a receptive female which gestates the egg and brings it to term.[21] The injection process is tedious and laborious as it involves delicate and sensitive micromanipulations of the egg.[22] One drawback to this technique is that only a small fraction of injected eggs actually develop into transgenic animals. Approximately 85 percent of every 100 eggs collected are suitable for injection; of the 85 injected eggs, about 60 will survive the delicate microinjection procedure; six of the injected eggs placed in the host female

15. 45 Pat. Trademark & Copyright J. (BNA) No. 1112.

16. *Id.*

17. *Id.*

18. *Patenting Life*, *supra* note 10, at 93. Recombinant DNA has been characterized as a kind of "biological sewing machine" that is used to stitch together the genetic fabric of unrelated organisms. JEREMY RIFKIN, ALGENY 7 (Viking Press 1983). A chemical scalpel known as a restriction enzyme first is used to split apart the DNA molecules from one source. A small segment of genetic material, such as a gene, is then separated out. The restriction enzyme is then used to slice out a portion of genetic material from a plasmid — a short strand of bacterial DNA. Both pieces of chemically separated DNA develop "sticky ends" as a result of the slicing process which are then attached, forming a genetic whole from the two original sources. Finally, the modified plasmid is used as a vehicle to insert the recombined DNA into a host cell. The receptor cell absorbs the plasmid and proceeds to duplicate it endlessly, producing identical copies of the new chimera. *Id.*

19. *Patenting Life*, *supra* note 10, at 94.

20. *Id.* at 95.

21. *Id.*

22. *Id.*

will result in live births; and of these six, only one or two will actually result in a transgenic animal.[23]

Many of these bioengineering techniques also can be used with comparable effectiveness in humans. Scientists already are considering the use of these techniques not only in eliminating harmful genetic traits in humans, but also as a way of genetically designing humans with a wide range of beneficial traits such as enhanced manual dexterity skills and improved memory retention.[24] Such "gene therapy" also has been hailed as the means for the total eradication of many diseases and disorders in humans, including sickle-cell anemia, Tay-Sachs disease, cystic fibrosis, hemophilia, and other genetic disorders.[25]

III. THE LEGAL DEVELOPMENT OF TRANSGENIC ANIMAL PATENTING

A. 35 U.S.C. § 101

The United States Constitution confers upon Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective writings and Discoveries. . . ."[26] Pursuant to this power, Congress established the United States Patent and Trademark Office (PTO) and promulgated legislation regulating the operations and activities of the PTO.[27] The statutory subject matter upon which a patent may be issued is defined in Section 101 of Title 35 of the United States Code:

> § 101. Inventions Patentable
> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may ob-

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23. *Id.* at 96.

24. RIFKIN, ALGENY, *supra* note 18, at 14.

25. Albert Gore, Jr. & Steve Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336, 352 (1985). *See also* Natalie Angier, *Of (Transgenic) Mice and Men*, 126 TIME 67, August 5, 1985 (predicting that people born with defective genes could have a "good" gene introduced into their bone marrow to provide missing proteins).

26. U.S. CONST. art. I, § 8, cl. 8.

27. Pub. L. No. 593, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1-376 (1988)).

tain a patent therefor, subject to the conditions and requirements of this title.[28]

In addition to meeting the requirement of statutory subject matter, a patent claim must meet other statutory requirements such as novelty,[29] utility,[30] and nonobviousness.[31] Determining that the subject matter requirement of § 101 has been met is pivotal in the overall decision of whether animals are patentable; even if the requirements of novelty, utility, and nonobviousness are met, no patent will issue for nonstatutory subject matter.

B. *Diamond v. Chakrabarty*

In 1980, the United States Supreme Court held in *Diamond v. Chakrabarty*[32] that nonnaturally occurring, man-made, living microorganisms plainly qualify as patentable subject matter within the definition of § 101.[33] At issue in *Chakrabarty* was whether a human-made, genetically engineered bacterium capable of breaking down crude oil constituted a "manufacture" or "composition of matter" within the meaning of the statute.[34] The Court relied on the legislative history and statutory construction of § 101 to conclude that Congress contemplated that the patent laws should be given wide scope.[35] The Court determined that

28. 35 U.S.C. § 101 (1988).
29. 35 U.S.C. §§ 101-102 (1988).
30. 35 U.S.C. § 101 (1988).
31. 35 U.S.C. § 103 (1988).
32. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
33. *Id.* at 309.
34. *Id.* at 307.
35. *Id.* at 308. The Court identified two periods of time in the legislative history where a broad construction was supported. First, the Court indicated that the Patent Act of 1793, authorized by Thomas Jefferson, embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." *Id.* (quoting 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington Ed. 1871)). Second, the Court pointed out that the 1952 recodification of the patent laws informed them that Congress intended statutory subject matter to "include anything under the sun that is made by man." *Id.* at 309 (quoting S. REP. NO. 1979, 82nd Cong., 2d Sess. at 5 (1952); H.R. REP. NO. 1923, 82nd Cong., 2d Sess. at 6 (1952)).

In relying on statutory construction to find a wide scoped intent of Congress, the Court concluded that "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Id.* at 308.

patentable subject matter was to "'include anything under the sun that is made by man.'"[36] The Court also stressed the nonnatural character of the new bacterium, stating that "the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own. . . ."[37]

The Court rejected the contention that the 1930 Plant Patent Act (PPA),[38] which afforded protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act (PVPA),[39] which afforded patent-like protection for sexually reproduced plants but excluded bacteria from such protection, evidenced congressional understanding that the terms "manufacture" and "composition of matter" did not include living things. The Court concluded that if these acts stood for such a premise, "neither Act would have been necessary."[40] The Court reasoned that these Acts were not passed because of an understanding that § 101 did not include living things, but rather, because of Congress' recent understanding of the plant breeder's role in producing patentable plants[41] and because plants were, in

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36. *Id.* at 309 (quoting S. REP. No. 1979, 82nd Cong., 2d Sess. at 5 (1952); H.R. REP. No. 1923, 82nd Cong., 2d Sess. at 6 (1952)).

37. *Chakrabarty*, 447 U.S. at 310.

38. Plant Patent Act of 1930, Pub. L. No. 71-245, 46 Stat. 376 (1930) (codified as amended at 35 U.S.C. § 161 (1988)). This Act provides in relevant part:

> Whoever 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 . . . .

39. Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified as amended at 7 U.S.C. § 2402 (1988)). This Act provides in relevant part:

> 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 . . . .

40. *Chakrabarty*, 447 U.S. at 311.

41. *Id.* at 311, 313. The Court pointed out that in enacting the Plant Patent Act of 1930, Congress addressed a previous obstacle to patent protection for plants — that plants were believed to be "products of nature" for purposes of the patent law. *Id.* at 311. The Court noted that "[Congress] explained at length its belief that the work of the plant breeder 'in aid of nature' was patentable invention." *Id.* at 312 (citing S. REP. No. 315, 71st Cong., 2d Sess., at 6-8 (1930); H.R. REP. No. 1129, 71st Cong., 2d Sess. at 7-9 (1930)). Sexually reproduced plants were not included in this

fact, amenable to the "written description" requirement of the patent law.[42] In discounting a statement found in a letter from then Secretary of Agriculture Hyde to the chairmen of the House and Senate Committees considering the 1930 Act asserting that "the patent laws . . . at the present time are understood to cover only inventions or discoveries in the field of inanimate nature,"[43] the Court stated that "Secretary Hyde's opinion . . . is not entitled to controlling weight. His views were solicited on the administration of the new law and not on the scope of patentable subject matter—an area beyond his competence."[44] Additionally, the Court was persuaded by language found in the House and Senate Committee Reports suggesting that Congress "recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[45]

The Court also rejected the contention that since "genetic technology was unforeseen when Congress enacted § 101," the determination of whether microorganisms qualify as patentable subject matter should be deferred to Congress' judgment.[46] In support of his contention, the petitioner relied on a recent Supreme Court decision holding that the judiciary "must proceed cautiously when . . .

Act "because new varieties could not be reproduced true-to-type through seedlings." *Id.* at 313. The Plant Variety Protection Act of 1970 was passed because by that time "it was generally recognized that true-to-type reproduction was possible and that plant patent protection was therefore appropriate." *Id.* at 313.

42. *Id.* at 312. Plants were initially thought not to be amenable to the "written description" requirement of the patent law. The Court indicated that Congress had "relaxed the written description requirement in favor of 'a description . . . as complete as is reasonably possible.'" *Id.* (citing 35 U.S.C. § 162).

43. *Id.* at 312.

44. *Id.*

45. *Chakrabarty*, 447 U.S. at 313. The Committee Report language which the Court found persuasive stated:

> There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man . . . . On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man . . . .

Id. (citing S. REP. NO. 315, 71st Cong., 2d Sess. at 6; H.R. REP. NO. 1129, 71st Cong., 2d Sess. at 7 (1930)).

46. *Id.* at 314.

asked to *extend* patent rights into areas wholly unforeseen by Congress."[47] The Court conceded that "Congress, not the courts, must define the limits of patentability;" however, the Court added that "once Congress has spoken it is 'the province and duty of the judicial department to say what the law is'"[48] and that "our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose. Here, we perceive no ambiguity."[49] The Court construed the language of § 101 as fairly embracing microorganisms.[50]

In analogizing the decision with the principle expounded in *Parker v. Flook*,[51] which held a new algorithm for updating alarm limits during catalytic conversion unpatentable, the *Chakrabarty* Court indicated that the patent claim at issue had been "carefully scrutinized . . . to determine whether it was precluded from patent protection under 'the principles underlying the prohibition against patents for 'ideas' or phenomena of nature.'"[52] The Court stated that "*Flook* did not announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable per se."[53]

In dissent, Justice Brennan argued that the Court had misread § 101.[54] The dissenters would have left to Congress "the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available."[55] The dissent argued that by enacting the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 "Congress decided to make only a subset of animate 'human-made inventions' . . . patentable."[56]

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47. *Id.* at 314 (citing Parker v. Flook, 437 U.S. 584, 596 (1978)) (emphasis added).
48. *Id.* at 315 (quoting Marbury v. Madison, 1 Cranch 137, 177 (1803)).
49. *Id.*
50. *Chakrabarty*, 447 U.S. at 318.
51. 437 U.S. 584 (1978).
52. *Chakrabarty*, 447 U.S. at 315 (1980) (quoting *Flook*, 437 U.S. at 593).
53. *Id.*
54. *Id.* at 318 (Brennan, J., dissenting).
55. *Id.* at 319 (Brennan, J., dissenting).
56. *Id.* at 320, n.3 (Brennan, J., dissenting).

C. *Ex parte Hibberd*

In *Ex parte Hibberd*,[57] the Board of Patent Appeals and Interferences expanded the Supreme Court's holding in *Chakrabarty*. At issue in *Ex parte Hibberd* was the patentability of a maize seed, a maize plant, and a maize tissue culture.[58]

In *Hibberd*, the patent examiner contended that the passages of the PPA and the PVPA "implicitly excluded protection of these plants under Section 101."[59] In rejecting that contention the Board relied heavily on the Supreme Court's analysis of statutory construction and legislative history in *Chakrabarty*.[60] Finding that the legislative histories of the Acts provided no indication that their patent or patent-like protection be exclusive, the Board stated that "the Supreme Court's analysis of the legislative history of the plant-specific Acts makes it clear that the legislative intent of these acts was to extend patent [or patent-like] protection to plant breeders who were stymied by the two noted obstacles."[61] The two obstacles to obtaining patent protection on plants noted by the Supreme Court in *Chakrabarty* were: first, the belief that plants, "even those artificially bred, were products of nature not subject to patent protection;" and second, "plants were thought not amenable to the written description" requirement of the patent law.[62]

The Court reaffirmed the "cardinal rule" of statutory construction: "repeals by implication are not favored and . . . [w]hen there are two acts on the same subject, the rule is to give effect to both unless there is such a 'positive repugnancy' or 'irreconcilable conflict' that the statutes cannot co-exist . . . ."[63] The Court found that the statutes differed only in scope and concluded that "such differences

57. 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Int. 1985).
58. *Id.* at 443.
59. *Id.* at 445.
60. *Id.* at 444-46.
61. *Id.* at 445.
62. *Ex parte* Hibberd, 227 U.S.P.Q. at 445.
63. *Id.* at 445 (citing United States v. Borden Co., 308 U.S. 189, 198-99 (1939)).

fall far short" in supporting a finding of an "irreconcilable conflict" or a "positive repugnancy . . . ."[64]

D. *Ex parte Allen*

The Board of Patent Appeals and Interferences again was called upon to interpret and expand the *Chakrabarty* decision in *Ex parte Allen*.[65] The claimed patent was for a method of inducing polyploidy in oysters and for the resulting oyster produced by that process.[66] Polyploidy was induced by applying hydrostatic pressure to fertilized oyster eggs at a specified intensity for a specified duration thereby producing increased growth.[67] Although the patent claim was ultimately rejected on grounds of obviousness,[68] in addressing the patentability of the subject matter, the Board held that "the claimed polyploid oysters are non-naturally occurring manufactures or compositions of matter within the confines of patentable subject matter under 35 U.S.C. § 101."[69]

In rejecting the patent examiner's contention that the animal produced by polyploidy was controlled by the laws of nature and, therefore, not patentable,[70] the Board stated that "the Supreme Court made it clear in . . . *Chakrabarty* . . . that Section 101 includes man-made life forms."[71] The Board acknowledged that naturally occurring life forms do not qualify as patentable subject matter under § 101.[72] The issue then became whether the claimed subject matter was "made by man."[73] Because the examiner offered no evidence showing that the polyploid oysters could occur naturally without man's intervention, the examiner's rejection on this ground was reversed.[74] Four days after *Allen* was

64. *Id.* at 446.
65. 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Int. 1987).
66. *Id.* at 1425.
67. *Id.* at 1426-27.
68. *Id.* at 1425.
69. *Id.* at 1427.
70. *Ex parte* Allen, 2 U.S.P.Q.2d at 1426.
71. *Id.*
72. *Id.*
73. *Id.*
74. *Id.* at 1427.

decided the Commissioner of Patents and Trademarks issued the disputed Notice in *Animal Legal Defense Fund.*[75]

IV. *ANIMAL LEGAL DEFENSE FUND v. QUIGG*

In 1987, various animal rights groups, farmers, and animal husbanders filed suit in the District Court for the Northern District of California against then Commissioner of Patents and Trademarks, Donald J. Quigg, and then Secretary of Commerce, C. William Verity.[76] The suit was filed in response to a 1987 PTO rule which stated, *inter alia*, that the PTO considered non-naturally occurring, non-human multicellular organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101.[77] The

75. *See infra* note 77 and accompanying text (providing full text of the PTO's Notice).

76. Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728 (N.D. Cal. 1989).

77. *Id.* The full text of the PTO's rule appeared as follows:

Animals - Patentability

A decision by the Board of Patent Appeals and Interferences in *Ex parte Allen*, 2 USPQ2d 1425 (Bd. App. & Int. April 3, 1987), held that claimed polyploid oysters are nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980) as it had done in *Ex parte Hibberd*, 227 USPQ 443 (Bd. App. & Int., 1985), 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-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law. See e.g. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948); *American Fruit Growers v. Broadex*, 283 U.S. 1, 8 USPQ 131 (1931); *Ex parte Gravson*, 51 USPQ 413 (Bd. App. 1941).

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

rule expressly relied upon the decisions of *Ex parte Allen*, *Ex parte Hibberd*, and *Diamond v. Chakrabarty*.[78] The PTO, in issuing this rule, did not solicit public comment nor did they publish the rule in the Federal Register.[79]

The plaintiffs' complaint stated two causes of action: first, that the rule was promulgated in violation of the Administrative Procedure Act (APA), and second, that the rule was promulgated in excess of the defendants' statutory authority.[80] The defendants moved to dismiss both claims on the alternative grounds that the plaintiffs lacked standing and that the complaint failed to state a claim upon which relief may be granted.[81] In reaching the latter, the court assumed, without deciding, that the plaintiffs possessed the requisite standing to bring their claims.[82] The PTO argued that because the rule merely synthesized the decisional law that it cited the rule was "interpretive" and therefore exempt from the public notice and comment requirements of the APA.[83] The court agreed with the PTO's position and found that the decisions cited within the rule were the law at the time the rule was promulgated and that they continued to be the law.[84] Moreover, the court found that those decisions held precisely what the rule stated: "that non-naturally occurring, non-human multicellular living organisms, including animals, are patentable subject matter under 35 U.S.C. Section 101."[85] In granting the defendants' motion to dismiss the court concluded:

> Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "non-naturally occurring manufacture or composition of matter - a product of human ingenuity" (*Diamond v. Chakrabarty*), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter.
>
> April 7, 1987

1077 OFFICIAL GAZETTE PAT. OFFICE 24 (Apr. 21, 1987).

78. *Animal Legal Defense Fund*, 710 F. Supp. at 729.
79. *Id.*
80. *Id.*
81. *Id.*
82. *Id.*
83. *Animal Legal Defense Fund*, 710 F. Supp at 730-31.
84. *Id.* at 732.
85. *Id.*

> [the rule] is an interpretive rule as that term is used in 5 U.S.C. Section 553(b)(A) and is thereby exempt from the public notice and comment requirements of the APA. Furthermore, because the PTO is authorized to issue such rules or "notices," 5 U.S.C. Section 553, and because the Rule neither abridges nor enlarges the rights of anyone, the PTO could not, as a matter of law, have exceeded its statutory authority in promulgating it.[86]

On appeal to the United States Court of Appeals for the Federal Circuit, the district court's decision was affirmed on the alternative ground that the plaintiffs lacked standing.[87] The federal circuit ruled that the standing allegations made by the animal protection associations were "patently insufficient" under the controlling precedent.[88] The court conceded that for purposes of standing the alleged injury need not be economic in nature;[89] however, the requirement that the party seeking review must himself have suffered an injury could not be abandoned.[90] The court found that the APA did not authorize parties to utilize the judicial process as a means for which to vindicate their own value preferences.[91]

Since the district court granted the defendants' motion to dismiss, thereby forcing any reviewing court to accept as true all material allegations of the complaint,[92] the federal circuit did reach the issue of causation; i.e., whether the alleged injuries could be attributed to the Commissioner's actions. In finding that the alleged injury was not "fairly traceable" to the Commissioner's interpretation of 35 U.S.C. § 101, the court determined that third party action was necessary in order to realize the alleged injury—increased cruelty to animals.[93] The court reasoned that not only did the need for a successful animal patent issuance

86. *Id.*
87. Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991).
88. *Id.* at 936.
89. *Id.*
90. *Id.* (citing Sierra Club v. Morton, 405 U.S. 727, 738 (1972)).
91. *Id.*
92. *Animal Legal Defense Fund*, 932 F.2d at 925.
93. *Id.* at 936-37.

"sever any link" between the injury and the Commissioner's action,[94] but that additional third party action was required. Appellants would have to show either that the existing animal cruelty laws are insufficient or that the issuance of animal patents would somehow cause or encourage others to disobey these laws.[95] The court refused to equate the issuance of animal patents with the disobeyance of animal cruelty laws.[96]

V. ECONOMIC, ENVIRONMENTAL, AND ETHICAL CHALLENGES FACING ANIMAL PATENTS

Recent advances in biotechnology and transgenic animal research, together with the PTO's Notice following *Allen*, have spurred increased fear and controversy over the effects of such research. As a result, groups opposed to transgenic animal research have sought to impede its progress by attacking the patentability of transgenic animals through efforts to eliminate a perceived incentive—economic gain. The challenges brought by these groups are consolidated into three major areas of concern: economic, environmental, and ethical.

A. Economic Concerns

There is ample evidence to support the proposition that transgenic research will subside as a result of lost economic incentives if animal patent barriers are erected. In 1988, two researchers at Harvard University were awarded a patent for the "Harvard Mouse,"[97] genetically engineered to provide more effective breast cancer research and heralded as providing an incentive for research into the field of transgenetics.[98] The PTO has noted a significant increase in the number of animal patent applications since the

94. *Id.*

95. *Id.* at 937.

96. *Id.*

97. 36 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 888, at 271-72 (1988); U.S. Patent No. 4,736,866.

98. Malcolm Gladwell, *Mouse Patent May Bolster Research Efforts; New Genetic Techniques Could Reduce Drug Costs*, WASH. POST, Apr. 13, 1988, at F1.

"Harvard Mouse" patent.[99] Additionally, patents for the isolation of human DNA fragments have created a race to obtain these patents, thereby enabling the patent holder to exercise dominion over their use in transgenic research efforts.[100]

The most dramatic evidence of the economic incentive resulting from animal patenting has been the significant increase in the stock values of corporations engaged in biotechnology research. During the first four months of 1991, United States biotechnology companies raised one billion dollars through public stock offerings.[101] Just four months after the United States Supreme Court decision in *Chakrabarty*, Genentech raised $36 billion in one day by its public stock offering.[102] A 1984 National Academy of Sciences study estimated that a potential yearly business of between $40 billion and $100 billion lies in the biotechnology industry.[103] Based on these observations, it fairly can be concluded that, without the promise of patent protection for useful and novel transgenic animals, much of the research in this field would no longer exist.[104]

One of the major challenges voiced by animal patenting opponents is the negative effects that patenting will have on the economy. They allege adverse impact primar-

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99. 43 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 1058 (Nov. 22, 1991).

100. *See* Dick Thompson & Frederick Ungeheuer, *The Race to Map Our Genes*, TIME, Feb. 8, 1993, at 57 (describing how French researchers have pulled ahead of their United States counterparts in the current race to produce a complete genetic map of human chromosomes, and highlighting the fact that unlike the U.S. researchers, the French intend to donate their map to the United Nations as a gift to the world).

101. Mark Crawford, *Wall Street Takes Stock of Biotechnology*, 132 NEW SCIENTIST Nov. 23, 1991, at 36.

102. RIFKIN, ALGENY, *supra* note 18, at 11.

103. *Coordinated Framework for Regulation of Biotechnology: Hearing Before the Subcommittee on Investigations and Oversight and the Subcommittee on Natural Resources, Agriculture Research and Environment and the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology*, 99th Cong., 2nd Sess. 6 (1986) [hereinafter *Regulating Biotechnology*] (statement by Rep. Schneider, R.I.).

104. *See Transgenic Animal Hearings*, *supra* note 7, at 21 (statement of Rene D. Tegtmeyer, Assistant Comm'r for Patents) (stating that the grant of animal patent rights has in fact encouraged research). *But see Chakrabarty*, 477 U.S. at 317 (stating that the grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks).

ily in two areas of economic interest: agriculture and academic research.

Farmers, particularly low production family operations, are concerned that their costs of operation significantly will increase if they are forced to pay licensing fees and royalties to obtain and reproduce patented animals.[105] It is argued that animal patents will result in increased costs to consumers if producers are forced to pay these royalties on the initial acquisition of the animals and reproduction of succeeding generations.[106] This would allow patent holders to reap unfair benefits from royalties which would further frustrate the imbalance of wealth between corporate and small farmers.[107] Small farmers fear that large farming corporations eventually will dominate the market with patented animals, thus driving small farming operations out of business.[108] This fear may have materialized already in the seed industry where some economists have attributed higher seed prices to the protection provided by the PVPA.[109]

Although large-scale commercial production of transgenic agricultural animals is possible, it is considered unlikely in the near future.[110] Transgenic animals used in biomedical research are anticipated to be developed first because current research is focused in this area.[111] Researchers predict that it may be ten years or more before commercial herds or flocks of transgenic animals are produced.[112]

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105. *Animal Legal Defense Fund*, 932 F.2d at 932; *Transgenic Animal Hearings*, *supra* note 7, at 90 (testimony of Jack Doyle, Director, Agricultural Resources Project, Environmental Policy Institute); *Patenting Life*, *supra* note 10, at 136.

106. *Patenting Life*, *supra* note 10, at 136; *Transgenic Animal Hearings*, *supra* note 7, at 108 (statement of the Hon. Charlie Rose, Seventh District Rep, N.C.).

107. *Patenting Life*, *supra* note 10, at 136.

108. *Id. See also Transgenic Animal Hearings*, *supra* note 7, at 108 (statement of the Hon. Charlie Rose).

109. *Patenting Life*, *supra* note 10, at 80. *See also Transgenic Animal Hearings*, *supra* note 7, at 115 (statement of Cy Carpenter, President, National Farmers Union) (stating that five major corporations now control 120 seed companies that were formerly independent prior to seed protection).

110. *Patenting Life*, *supra* note 10, at 16.

111. *Id.*

112. *Id.* at 98.

Patenting proponents argue that in the absence of animal patents, the small farmer surely will be hurt. Their argument is, without patent rights, large farming corporations exclusively will license the use of their animals with vertical integrators, thereby resulting in a concentration of commercialized farming with a significant advantage over small farmers who lack the more commercially desirable animals.[113] To support this assertion proponents emphasize that merely four or five companies produce 90 percent of the chickens in this country.[114] Not all small farmers share the anti-patenting concerns voiced by their constituents. The American Farm Bureau Federation, which represents 3.5 million farm families, generally supports the patenting of genetically altered animals.[115]

Patenting proponents also advance supportive arguments based on international economics. Although the United States is still the leader in the commercial exploitation of biotechnology,[116] proponents fear this lead could be lost without a system to support the patenting of genetically engineered animals.[117] European countries see the U.S. patent system as an unprecedented model which they want to emulate.[118] In fact, the Office of Technology Assessment has predicted that in the near future (five to ten years) the European Community, with its traditional strengths in pharmaceuticals and agriculture, poses the greatest threat to U.S. competitiveness in biotechnology.[119] Because Japan has made biotechnology a national priority, proponents ar-

113. *Transgenic Animal Hearings*, *supra* note 7, at 39 (statement of Dr. Thomas Wagner).

114. *Id.*

115. *See Transgenic Animal Hearings*, *supra* note 7, at 112 (statement of Dr. A. Ann Sorensen) (stating that her organization supports the granting of animal patents if they act as an incentive for the commercialization of genetically improved animal breeds).

116. Diane Gershon, *U.S. Biotech in Good Health*, 353 NATURE 785 (1991).

117. *See Transgenic Animal Hearings*, *supra* note 7, at 136-38 (statement of William H. Duffey, General Patent Counsel, Monsanto Corp.) (arguing that the Europeans and Japanese may overtake our lead in this industry if a moratorium issues). *See also* Philip H. Abelson, *Biotechnology in a Global Economy*, 255 SCIENCE 381 (1992) (stating that our dominant role in biotechnology is being "frittered away" as a result of such impediments as delays in the issuance of patents).

118. *Transgenic Animal Hearings*, *supra* note 7, at 136.

119. Gershon, *supra* note 116.

gue that it will overtake our lead just as it did in microelectronics if the U.S. does not continue its aggressive pursuit.[120]

Congress considered the royalty issue when the House of Representatives passed H.R. 4970, the Transgenic Animal Patent Reform Act.[121] As a solution to this issue the Act stated in part:

> It shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation, or sell such animal or the offspring of such animal.[122]

According to the bill, it would be an act of infringement "for a person to sell the germ cells, semen, or embryos of a patented transgenic farm animal."[123] Other solutions proposed during congressional consideration of the royalty issue included:

[1] creating broad-based exemptions for various users (e.g., farmers);

[2] creating limited exemptions in meeting certain conditions (e.g., farms operating as single family enterprises, limited gross receipts, total acreage, number of animals);

[3] limiting royalty collection to a specified number of generations of a patented animal;

[4] creating a tribunal, based on the Copyright Royalty Tribunal, to set rates and distribute funds for certain classes of patented animals;

[5] prohibiting animal patents, removing any royalty issue from the patenting context; and

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120. *Transgenic Animal Hearings*, *supra* note 7, at 137 (statement of William H. Duffey, General Patent Counsel, Monsanto Corp.). *See also* Peter Gwynne, *Biotech Grows in Hong Kong*, 352 NATURE 273 (1991) (stating that "several Asian governments regard biotechnology as an obvious successor to consumer electronics as they struggle to succeed in the world's high-technology markets").

121. H.R. Rep. No. 4970, 100th Cong., 2d Sess. (1988) (unenacted).

122. *Id.* at 2.

123. *Id.*

[6] relying on existing patent infringement provisions for patented animals (e.g., no action by Congress).[124]

Additional to the economic concerns surrounding animal patents opponents fear that academic research will become more commercialized[125] thereby increasing the level of secrecy among academic researchers. This secrecy will result in shifting academic agendas away from education-oriented objectives toward more commercially lucrative projects.[126] Collaboration between industry and academia is approximately four to five times greater in biotechnology than in other fields.[127] Further frustrating these concerns is the tremendous amount of financial support given to academia by the federal government. The concern here is that private industry will benefit disproportionately from taxpayer-supported funding.[128]

Patenting proponents disagree with the secrecy argument for three reasons. First, many "research grants and contracts carry provisions which require public reporting of research within a given time period, usually sixty to ninety days."[129] Second, the PVPA has shown that "this law has not stifled the flow of research information among plant scientists despite fears" of some opponents at the time of the enactment.[130] Third, "most researchers believe the patenting process is much more conducive to information shar-

124. *Patenting Life*, *supra* note 10, at 122.

125. David Blumenthal et al., *University-Industry Research Relationships in Biotechnology: Implications for the University*, 232 SCIENCE 1361 (1986).

126. OFFICE OF TECHNOLOGY ASSESSMENT, *New Developments in Biotechnology: U.S. Investment in Biotechnology* 4, 6 (1988).

127. *Id.*

128. OFFICE OF TECHNOLOGY ASSESSMENT, *Technology, Public Policy, and the Changing Structure of American Agriculture* 3, 71 (1985); *Transgenic Animal Hearings*, *supra* note 7, at 307 (statement of Stewart Huber, President, Wisconsin Farmers' Union Milk Marketing Coop.). *See also id.* at 68 (testimony by Mr. Doyle, Director of the Agricultural Resources Project of the Environmental Policy Institute) (stating that the trend towards research collaboration between government, industry, and universities "is worrisome because it blurs the traditional roles of government as a regulator, and the university as society's neutral arbiter and adviser").

129. *Transgenic Animal Hearings*, *supra* note 7, at 212 (statement by Leo M. Walsh, Dean, College of Agriculture and Life Sciences, Univ. of Wisconsin-Madison).

130. *Id.*

ing among scientists than is the 'trade secret' route."[131] Without the patent system, scientists will either engage in no disclosure or merely partial disclosure.[132]

B. Environmental Concerns

Another major concern expressed by patenting opponents is the potential environmental risks resulting from the deliberate release of genetically engineered organisms into the environment.[133] Deliberate release may be necessitated by field testing requirements because the organism's utility cannot be realized absent environmental release.[134] For instance, the oil-eating bacteria, whose patentability was at issue in *Chakrabarty*, involved environmental release as a prerequisite to achieving its intended use.[135] Opponents also fear that an "Andromeda Factor" mistakenly could be created or inadvertently escape from a laboratory isolation unit and threaten life on Earth.[136]

Fundamentally, the environmental concerns voiced by opponents involve the potential disastrous effects that such releases may pose to the delicate ecological balance of the natural environment.[137] Additionally, a major concern is that transgenic animal releases will result in depletions of the gene pools of various species.[138]

Patenting supporters argue that by equating "natural" with "safe," opponents are ignoring the risks posed by in-

131. *Id.*

132. *Id.* at 260.

133. OFFICE OF TECHNOLOGY ASSESSMENT, *New Developments in Biotechnology - Background Paper: Public Perceptions of Biotechnology* 2 (1987); Clara Frontali, *Unspoken Fears*, 353 NATURE 496 (1991); *Transgenic Animal Hearings*, *supra* note 7, at 426 (testimony of Margaret Mellon, Director of the Biotechnology Project, National Wildlife Federation).

134. *See* Gore & Owens, *supra* note 25, at 341 (arguing that "it does little good to have a 'bug' that can eat hazardous waste if it is never released into a contaminated area").

135. *See supra* text accompanying note 34.

136. *Transgenic Animal Hearings*, *supra* note 7, at 346 (statement of Dr. John Barnes, D.V.M., Alliance For Animals).

137. Gore & Owens, *supra* note 25, at 340.

138. *See Transgenic Animal Hearings*, *supra* note 7, at 114 (statement of Cy Carpenter, President, National Farmers Union) (arguing that animal patenting will result in a shrinking of the gene pool and will increase reliance on only a few animal forms which have been patented and are controlled in corporate or other hands).

cautious environmental introductions of "natural" organisms.[139] Indeed, history is replete with problems resulting from artificial introductions of non-native species into certain ecosystems. A few examples include the gypsy moth, introduced into this country for silk production which now destroys thousands of acres of forests each year; starlings, first introduced as pets which now travel in massive numbers creating ecological and health hazards; and kudzu, introduced into southern states to control soil erosion which now has multiplied to the point of eliminating other native forms of vegetation.[140] It is argued that because of the inherent precision of genetic engineering, it is more controllable than traditional selective breeding practices and actually should decrease the number of problems.[141] Other patenting supporters counter the depletion of the gene pool argument by claiming it is in the best interest of biotechnology companies to maintain as complete a gene pool as possible for future use.[142]

C. Ethical Concerns

Ethical concerns raised by patenting opponents rest primarily on a broad base of moral, religious, philosophical, and metaphysical grounds.[143] Perhaps this is the argument most passionately presented against animal patenting. It is

139. Frontali, *supra* note 133, at 496 (arguing that the most dramatic predictions made for recombinant organisms apply equally to conventional ones and proposing tentative classifications of possible environmental risk groups ranked according to level of concern as follows: (1) organisms which were never recognized to pose a risk to the environment; (2) organisms which may cause transient ecological imbalances or transient biogeochemical effects; (3) organisms which might be pathogens or pests for plants or animals but have limited diffusion or persistence; (4) organisms which might transfer unwanted genetic traits to other species; (5) organisms which may cause persistent undesirable ecological imbalances or persistent biogeochemical changes; and (6) dangerous and highly diffusive pathogens or pests, either for animals or for plants). *See also* Henry I. Miller et al., *Risk-Based Oversight of Experiments in the Environment*, 250 SCIENCE 490 (1990) (arguing that regulation schemes should be risk-based).

140. Gore & Owens, *supra* note 25, at 342; *Transgenic Animal Hearings*, *supra* note 7, at 246.

141. *Transgenic Animal Hearings*, *supra* note 7, at 219 (statement of Winston J. Brill, Ph.D., Vice President, Research and Development, Agracetus Corp.).

142. *Id.* at 119 (statement of Dr. A. Ann Sorensen).

143. *Patenting Life*, *supra* note 10, at 17.

unlikely that legislative or judicial line-drawing on this issue will substantially affect a particular person's beliefs.[144] The religious and philosophical beliefs regarding the moral obligations owed by humans to animals was debated long before the legal concept of species ownership came into existence.[145] Patenting proponents argue that the property rights granted through the issuance of animal patents differ little from previously accepted notions of human control and ownership of animals.[146] They insist that given the current social consensus of breeding, buying, selling, confining, eating, and performing research on animals, the practice of patenting animals seems relatively benign.[147]

Opponents disagree, arguing that profound new issues are raised.[148] Animal rights groups fear that patenting will result in increased animal suffering as the biotechnology industry races to obtain animal patents.[149] These groups point to specific abnormalities that some transgenic animals already have suffered, including lethargy, crossed eyes, sterility, and premature death.[150] It is also argued that the animal may experience tremendous discomfort if the pat-

144. *See Patenting Life*, *supra* note 10, at 137 (predicting that arguments based on philosophical, metaphysical, and theological considerations are not likely to be reconciled between persons holding opposing and strongly held beliefs). The ethical concerns raised against the issuance of animal patents are somewhat akin to the current debate over abortion rights. *See* Planned Parenthood of Southeastern Pennsylvania v. Casey, __ U.S. __, __, 112 S. Ct. 2791, 2806 (1992) (acknowledging that men and women of good conscious will likely always "disagree about the moral and spiritual implications of terminating a pregnancy").

145. *Patenting Life*, *supra* note 10, at 127.

146. *See Transgenic Animal Hearings*, *supra* note 7, at 120 (statement of Dr. A. Ann Sorensen) (arguing that man has been manipulating and refashioning the animals around us for centuries through classical selective breeding and not just to meet food demands but also to provide us with a variety of pet breeds).

147. *Id.* at 389 (statement of LeRoy Walters, Ph.D., Director, Kennedy Institute of Ethics, Georgetown Univ.).

148. *Id.*

149. *Transgenic Animal Patent Reform Act of 1989: Hearings on H.R. 1556 Before the Subcomm. on Courts, Intellectual Property, and the Administration of Justice of the House Comm. on the Judiciary*, 101st Cong., 1st Sess. 242 (1989) (statement of Steven M. Wise, President of the Animal Legal Defense Fund).

150. *Id.* at 124; *Patenting Life*, *supra* note 10, at 16.

enting process requires the animal to be confined in a certain way.[151]

Patent supporters counter these arguments by claiming that animal suffering actually will be reduced by engineering disease-resistant traits into farm animals.[152] Such "gene therapy" also has been hailed as the means for the total eradication of many diseases and disorders in humans, including sickle-cell anemia, Tay-Sachs disease, cystic fibrosis, hemophilia, and other genetic disorders.[153] Additionally, the National Institute of Health (NIH) has promulgated guidelines for the use and care of laboratory animals that are binding upon institutions which receive NIH research grants.[154]

Various religious groups claim that man is "playing God" by developing genetically engineered animals.[155] They argue that reverence for all life created by God is eroded by economic pressures to view animal life as if it were an industrial product invented and manufactured by humans.[156]

Patenting proponents are quick to point out that the patent system is the wrong place to regulate matters of ethical, social, or moral concern, since a patent does not confer the right to do something which otherwise could not be done.[157] A patent merely grants the right to exclude others from making, using, or selling a patented invention for a

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151. *Transgenic Animal Hearings*, *supra* note 7, at 131 (statement by Rep. Cardin).

152. *Patenting Life*, *supra* note 10, at 134; *Transgenic Animal Hearings*, *supra* note 7, at 259 (statement of Richard D. Godowin, President, Industrial Biotechnology Assoc.).

153. Gore & Owens, *supra* note 25, at 352.

154. GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES, 51 Fed. Reg. 16958 (NIH 1986).

155. *See generally* PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SPLICING LIFE: THE SOCIAL AND ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS 53 (1982) [hereinafter *Splicing Life*]; *Transgenic Animal Hearings*, *supra* note 7, at 110 (statement of the Hon. Charlie Rose).

156. *Transgenic Animal Hearings*, *supra* note 7, at 399 (testimony by Rev. Wesley Granberg-Michaelson, National Council of the Churches of Christ in the U.S.A.).

157. *Id.* at 147 (statement of William H. Duffey, Intellectual Property Owners, Inc. and Industrial Biotechnology Assoc.).

limited time.[158] A patent owner remains entirely subservient to all other state and federal laws and regulatory agencies.[159] In the words of one Congressional witness, "it would be a most clumsy, imprecise and Sisyphean task to attempt to replace all of society's many other rules by tinkering with the throttle . . . of the research and development engine which the patent system is here to stimulate."[160]

There is one thing that both sides of the animal patent controversy generally agree on: human beings are not considered patentable. Indeed, the PTO specifically excluded human beings from patentable subject matter in its controversial 1987 Notice, wherein it recognized "multicellular living organisms, including animals" to be patentable subject matter.[161] The most likely objective reason for the PTO's position is that the 13th Amendment to the Constitution prohibits property rights in a human being.[162]

VI. BALANCING THE COMPETING INTERESTS - RECOMMENDATIONS

Many of the arguments and concerns that militate against animal patenting are based on premonitions of what could happen. Patenting opponents elicit a worst-case scenario of the perceived risks of biotechnological advances that have not been realized to date. Because of the experience that researchers have gained, which dispels many of the original concerns of biotechnology, opponents now bear the procedural burden of proving danger for most types of experiments, rather than requiring the proponents of such

158. *Id.* at 153; IRVING KAYTON, 1 PATENT PRACTICE 1-5 (Patent Resources Institute 1992).

159. *Transgenic Animal Hearings*, *supra* note 7, at 153 (statement by William H. Duffey, Intellectual Property Owners, Inc. and Industrial Biotechnology Assoc.).

160. *Id. See also id.* at 303 (statement of Michael S. Ostrach, Sr., Vice President and General Counsel, Cetus Corp.) (arguing that the patent system should not be "jury-rigged" to reflect social concerns).

161. *See supra* note 77 (stating that "[a] claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 U.S.C. § 101").

162. U.S. CONST. amend. XIII. *See also Transgenic Animal Hearings*, *supra* note 7, at 25 (testimony of Rene D. Tegtmeyer, Assistant Commissioner for Patents) (surmising that the 13th Amendment to the Constitution would prohibit property rights in a human being that limit freedom and liberties).

testing to prove safety.[163] This is not to suggest that all hazards of biotechnology adequately have been controlled. To the contrary, it is not clear that all hazards have been perceived. Caution and attention to these concerns are required to ensure continued safety.

Most arguments on both sides of the animal patenting controversy concern issues that would be materially unchanged whether or not patents are permitted. This is true because most arguments center on issues that existed prior to the current patenting debate; e.g., debates on animal rights, over the effect of high technology on American agriculture, on the distribution of wealth, international competitiveness, and on the release of novel organisms into the environment.[164] Based on this observation, one may fairly ask why biotechnology opponents have attacked the patent system with such vigor. The answer is two-fold: the patent system is a highly visible vehicle by which biotechnology opponents may voice their concerns, and a cause and effect relationship does exist in that the promise of patent protection provides much incentive for biotechnological advancement.

The concerns voiced by these opponents deserve due consideration, but they should not operate to prohibit or delay the pace of biotechnological innovation through prevention of or moratoriums on the patenting process for three major reasons: (1) the United States can ill afford to lose its lead in yet another emerging technology that has tremendous economic potential;[165] (2) biotechnology is expected to provide tremendous benefits to society; and (3) many of the concerns raised by patenting opponents are either overstated or can be dealt with adequately through proper legislation and regulation. A decision must now be made prescribing "how" biotechnology and animal patenting will be reconciled with the concerns of all interested groups.

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163. *Splicing Life*, *supra* note 155, at 12-13.

164. *Patenting Life*, *supra* note 10, at 137.

165. *See generally Transgenic Animal Hearings*, *supra* note 7, at 116 (testimony of Dr. A. Ann Sorensen) (voicing concern over losing our competitive edge in biotechnology to other nations).

Consideration of the nature of the concerns expressed over the animal patenting controversy is essential to fashioning an appropriate legal resolution. The competing economic, environmental, and ethical considerations involved in biotechnology, and the related arguments over the utilization of the patent system as a means of furthering or restricting such use are deeply rooted in matters of public policy. Once it is conceded, as it must be, that the PTO is not the proper entity to effectuate social policy,[166] it becomes apparent that if a balance is to be reached between all of the competing social concerns proffered, then that balance must be somehow struck by legislative action. The PTO's position with respect to the allowance of animal patents is supported by legal precedents such as *Chakrabarty* and *Ex Parte Allen*. Aside from the universal statutory requirements of novelty, utility, nonobviousness, etc., these precedents are all the PTO need concern itself with. Administration of the patent system as a means of implementing public policy must be handled by Congress either directly or through the powers it delegates to regulatory agencies.

Congress' task at this point is two-fold. First, it specifically should adopt the PTO's position regarding the patenting of "nonnaturally occurring, nonhuman, multi-cellular living organisms" by promulgating such legislation. Such action is necessary to foreclose any argument that animals cannot be regarded as patentable subject matter.[167] This may be accomplished by incorporating the PTO's 1987 Notice into 35 U.S.C. § 101.[168] Alternatively, Congress could pass a non-human Animal Patent Act similar to the Plant Patent Act of 1930.[169] Second, Congress should pass legis-

166. *See supra* notes 157-160 and accompanying text (providing proponents' views on why the patent system is the wrong place to regulate matters of ethical, social, or moral concern).

167. *See supra* text accompanying notes 54-56 (explaining that the dissent in *Chakrabarty* determined Congressional intent was not to include animals as patentable subject matter).

168. *See* Elizabeth Joy Hecht, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues* 41 AM. U. L. REV. 1023, 1071 (1992) (suggesting specific wording to be adopted by Congress in amending § 101).

169. *See supra* note 38 and accompanying text.

lation providing the appropriate regulatory oversight to an administrative body, or bodies, such as the NIH or the USDA. This action is necessary because the current regulatory scheme for oversight of recombinant DNA research is inadequate.[170] The NIH guidelines, for example, currently are inadequate, because they apply only to federally funded research.[171] Congress' legislative scheme should also provide for a farmer's exemption similar to the one included in the Transgenic Animal Patent Reform Act.[172]

These solutions obviously will require some time to develop and implement, but a two-year moratorium on the issuance of animal patents is unwarranted. Such action seriously would jeopardize this country's role as a leader in biotechnology advances, and also would frustrate fulfillment of the promising benefits that biotechnology offers society, such as the development and manufacture of pharmaceuticals used in the treatment of serious diseases.[173] The PTO's current posture regarding animal patenting should be allowed to continue unabated during congressional deliberations, eschewing a potentially disastrous derogation of our international lead in this evolving industry.

VII. CONCLUSION

Animal Legal Defense Fund did little to resolve the continuing controversy over animal patenting. Despite this

170. *See generally Regulating Biotechnology*, *supra* note 103 (discussing an appropriate regulatory system for the biotechnology industry through coordination with the Biotechnology Science Coordination Committee (BSCC)). A description of the regulatory scheme for biotechnological research is beyond the scope of this note. For an in depth study of such, *see* Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491, 547 (1987) (describing the present regulatory system as having many gaps and ambiguities which need to be tightened and clarified for it to work effectively).

171. *Splicing Life*, *supra* note 155, at 103. *See also supra* note 154 and accompanying text (describing the NIH guidelines as binding on only those institutions which receive NIH grants).

172. *See supra* text accompanying notes 122-124 (citing specific provisions in the Transgenic Animal Patent Reform Act precluding infringement by farmers who reproduce a patented animal or sell its offspring).

173. *See supra* note 13 and accompanying text (explaining that valuable pharmaceutical proteins are being developed and recovered from the milk of farm animals).

shortcoming, it was effective in drawing attention to the need for a thoughtful legal resolution of this controversy. It is a controversy born of conflicting social policies which utilize the patent system as its vehicle of expression. Patenting opponents have attacked the patent system as a means of voicing their concerns over biotechnology. For those who see biotechnology as a method of furnishing many benefits to society, the patent system provides a much needed incentive for vigorous pursuit of those ends.

Legislative action is required to balance these competing interests. Congress' task is to promulgate legislation that maximizes the potential development and use of biotechnology by means of the patent incentive, while minimizing the potential risks by means of regulatory oversight. A moratorium on the issuance of animal patents while Congress labors on this task is unwarranted. Such a delay would unduly jeopardize this country's lead in the biotechnology industry, and unnecessarily restrict the availability of biotechnology products. Nonoccurrence of the possible scenarios enunciated by anti-patenting critics serves to support a moratorium's disutility.

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