NOTE

BEYOND *ANIMAL LEGAL DEFENSE FUND v. QUIGG*: THE CONTROVERSY OVER TRANSGENIC ANIMAL PATENTS CONTINUES

ELIZABETH JOY HECHT

INTRODUCTION

In April 1987, the United States Patent and Trademark Office (PTO) promulgated a rule stating that it "considers nonnaturally occurring, non-human multicellular organisms, including animals, to be patentable subject matter."[1] The PTO's issuance of the April

---

1. 1077 OFF. GAZ. PAT. OFFICE 24 (Apr. 21, 1987). The notice from the Patent and Trademark Office (PTO) stated:

> The Patent and Trademark Office now considers nonnaturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101 . . . . A claim directed to or including within its scope a human being will not be considered to be patentable subject matter within 35 U.S.C. § 101.

Id.; *see infra* notes 28-40 and accompanying text (providing explanation of requirements of 35 U.S.C. § 101 (patent statute)).

The PTO excluded humans from the definition of patentable subject matter because "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the [United States] Constitution." 1077 OFF. GAZ. PAT. OFFICE 24 (Apr. 21, 1987). Presumably, the PTO made this exclusion in its rule to avoid violation of the Thirteenth Amendment, which abolished slavery. The Thirteenth Amendment provides in relevant part: "Neither slavery nor involuntary servitude . . . shall exist within the United States . . . ." U.S. CONST. amend. XIII § 1. *See* Kevin D. De Bré, Note, *Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?*, 16 HASTINGS CON. L.Q. 221, 248 (1989) (suggesting that Thirteenth Amendment prohibition against slavery governs determination of patentability of humans). De Bré also urges that the PTO is neither empowered nor competent to make constitutional determinations. *Id.* Rather, Congress has the power to delineate the constitutional boundaries of patent law. *Id.* *See* U.S. CONST. art. I, § 8, cl. 8 (granting Congress legislative power over patents). Furthermore, De Bré argues that the granting of patents for humans would not necessarily violate the Constitution because a patent in a human genotype is not a "badge of slavery" in and of itself. *See* De Bré, *supra*, at 227-32.

Routinely, however, human genes are inserted into animals through transgenic experimentation, making the line between "human" and "nonhuman" increasingly less discernible. *See* Diana A. Mark, Comment, *All Animals Are Equal, But Some Are Better Than Others: Patenting Transgenic Animals*, 7 J. CONTEMP. HEALTH L. & POL'Y 245, 259-61 (1991) (examining complex ethi-

1987 rule has sparked widespread controversy and has raised concerns that the PTO overstepped its bounds in issuing such a rule. *Animal Legal Defense Fund (ALDF) v. Quigg*[2] commenced when a variety of animal rights activists, including the Animal Legal Defense Fund, and individual farmers challenged the PTO's authority in issuing the April 1987 rule. Because the Federal Circuit ruled that the plaintiffs lacked standing, the court never reached the issue of whether the 1987 rule constitutes valid law. *ALDF* brings into the judicial arena the controversy over animal patents, which has been brewing ever since the landmark case of *Diamond v. Chakrabarty*[3] recognized the first patent for a microorganism in 1980. Society stands to gain many benefits from transgenic animal research,[4] particularly in the agricultural and biomedical fields.[5] Detractors, however, voice concerns regarding the risks associated with the rapidly advancing technology. While *ALDF* illustrates both the moral and economic objections that animal patenting has raised, it fails to substantially analyze and resolve the controversy surrounding animal patents.

This Note primarily focuses on the issues that *ALDF* did not reach, namely, whether the PTO's 1987 rule constitutes valid law

---

cal issues involved in using human genes for creating transgenic animals and pointing out that there is no clearly articulated definition of human being). Mark asks the crucial question: how much human genetic material must an animal possess to be considered "human"? *Id.* at 259; *see 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 Committee on the Judiciary*, 101st Cong., 1st Sess. 243 (1989) [hereinafter *Hearings on H.R. 1556*] (testimony of Steven M. Wise, Esq., President, Animal Legal Defense Fund) (emphasizing that no fixed genetic definition of human being exists and expressing doubt that there ever will be such definition).

As biotechnological techniques continue to be perfected, the absence of a definition of human will become more and more problematic, making it necessary for such a definition to be created. *See* Mark, *supra*, at 260-61 (reasoning that, since possibility exists that humans may be created through recombinant DNA technology to be specifically adapted to particular environment, issue of what is human must be squarely considered in not too distant future); *see also* Janice A. Sharp, *Of Transgenic Mice and Men*, 16 W. ST. U. L. REV. 737, 748 (1989) (suggesting that Congress may eventually be required to address problem of defining what is human and explaining that problem will become especially pronounced if human genes are introduced into primates, which are already evolutionarily, and therefore, genetically related to human beings). Because the rapidly advancing transgenic techniques may make the genetic manipulation of human beings possible in the future, the question of defining what constitutes a human being (i.e., what percentage of human genes an organism must have) should be faced within the context of the patent system. *See infra* notes 277-78 and accompanying text (recommending that Congress address issue when drafting new patent statute to encompass transgenic animals).

2. 932 F.2d 920 (Fed. Cir. 1991).

3. 447 U.S. 303 (1980).

4. A transgenic animal is an animal into which researchers introduce foreign DNA while the animal is still in its embryonic stage. Rudolf Jaenisch, *Transgenic Animals*, 240 SCI. 1468, 1468 (1988). *See infra* notes 13-17 and accompanying text (detailing how transgenic animals are created through technique of microinjection).

5. *See infra* notes 86-95 and accompanying text (describing intended applications of genetically altered animals to agricultural and biomedical industries).

and whether transgenic animals should be patentable. The Note uses the case as a starting point to discuss the underlying issues implicated in animal patenting. Part I describes how transgenic animals are produced in the laboratory, provides background information on the patent statute, and traces the evolutionary progress of the U.S. patent statute through its extension to living organisms.

Part II provides an outline of the animal patent controversy. First, Part II discusses the beneficial impact transgenic animals are expected to have on society, explaining how the granting of transgenic animal patents will allow society to reap the benefits of biotechnology more easily and rapidly. Next, Part II details the arguments against animal patents as made by the respective groups of plaintiffs in *ALDF*. The animal rights groups object to animal patenting on moral grounds, believing that it will lead to the exploitation of animal life and increased animal suffering. Farmers, however, oppose animal patenting mainly on economic grounds, believing that they will be unable to afford to glean the benefits of the technology and that large corporations will essentially take over animal husbandry.

Part III outlines the Federal Circuit's decision in *Animal Legal Defense Fund v. Quigg*, discussing both the court's denial of standing to the plaintiffs and the court's determination that the 1987 rule was "interpretative," and, thus, expressly exempt from the notice and comment requirements of the Administrative Procedure Act (APA). Part IV focuses on the impact of the opinion with respect to the current controversy surrounding animal patents. Specifically, Part IV examines the validity of the plaintiffs' claims in *ALDF* for the purposes of standing and predicts which types of plaintiffs would be granted standing after *ALDF* to challenge the validity of animal patents. Next, Part IV addresses the issue of what forum has the authority to determine whether transgenic animals are patentable subject matter: the legislature, the judiciary, or the PTO. Part IV then describes proposed legislation regarding animal patents and existing administrative regulations that govern the treatment of transgenic animals used in experimentation. Part IV concludes with an examination of guidelines issued by the National Institutes of Health (NIH) to regulate recombinant DNA research.

Part V argues that transgenic animals should be patentable, recommends that Congress draft a new patent statute expressly encompassing transgenic animals within the scope of patentable subject matter, and proposes a model statute. In addition to amending the

patent statute, Part V recommends that Congress define what constitutes "human," in technical terms, so as to establish boundaries for scientists engaged in transgenic research. Part V also suggests ways that the existing administrative guidelines governing biotechnological research may be strengthened and critiques the proposed legislation concerning transgenic animal patents. This Note concludes that it is the role of the legislature, and not the courts or the U.S. Patent and Trademark Office (PTO), to determine whether animals are patentable subject matter. Therefore, although transgenic animals should be patentable, the PTO usurped Congress' role in issuing its 1987 rule.

I. BACKGROUND

A. The Science Behind Biotechnology: Transgenic Processes

DNA (deoxyribonucleic acid) is "the ultimate molecule of life."[6] It encodes the information that "direct[s] an [organism's] cells to grow, to differentiate into specialized structures, to divide, and to respond to environmental changes."[7] Genes are the basic subunit of DNA.[8] Biotechnology involves the science of gene splicing, otherwise known as recombinant DNA (rDNA) technique or "genetic engineering."[9]

Early genetic manipulation of animals was accomplished through classical breeding methods.[10] Through this technique, the breeder selects animals to mate based on which animals have the specific physical characteristics that the breeder wishes to pass along to the offspring, such as a certain color or weight.[11] The results from this

---

6. THOMAS D. GELEHRTER & FRANCIS S. COLLINS, PRINCIPLES OF MEDICAL GENETICS 9 (1990).

7. *Id.*

8. 1 BENJAMIN LEWIN, GENE EXPRESSION 3 (1974); *see* HOUSE COMM. ON JUDICIARY, TRANSGENIC ANIMAL PATENT REFORM ACT, H.R. REP. NO. 888, 100th Cong., 2d Sess. 28 (1988) [hereinafter PATENT REFORM ACT] (stating that gene is unit of DNA expressing single inherited characteristics).

9. PETER R. WHEALE & RUTH M. MCNALLY, GENETIC ENGINEERING: CATASTROPHE ON UTOPIA 20, 21 (1988) (listing hybridoma and recombinant DNA technologies as two fundamental innovations in genetic engineering since World War II, and stating that "recombinant DNA technology . . . empower humans with greatest ever power over inherited traits of life on the planet and . . . created the basis for the renaissance of genetic engineering."). *See generally* RECOMBINANT DNA AND CELL PROLIFERATION (Gary S. Stein & Janet L. Stein eds., 1984) (providing series of scientific articles discussing recombinant DNA technology); THE RECOMBINANT DNA DEBATE (David A. Jackson & Stephen P. Stich eds., 1979) (presenting different sides of debate over scientific, ethical, legal, moral, and sociological questions posed by recombinant DNA technology); *see also* PATENT REFORM ACT, *supra* note 8, at 28-29.

10. *See* Marsha L. Montgomery, Note, *Building a Better Mouse—and Patenting It: Altering the Patent Law to Accommodate Multicellular Organisms*, 41 CASE W. RES. L. REV. 231, 237 (1990) (discussing how classical breeding is accomplished).

11. *Id.* (listing color, weight, milk production, and speed as characteristics that cross-

process can be highly unpredictable, however, since breeders select the initial animals to be bred on the basis of manifest physical traits, rather than on specific genetic characteristics.[12]

Genetically altered animals may also be developed through transgenics. Transgenics involves the alteration of animals through the addition of DNA from an outside source, usually from another species of animal or from a human.[13] Microinjection is the most common modern method for creating transgenic animals and the method most likely to lead to practical applications in mammals.[14] Microinjection involves the injection of the targeted DNA directly into a removed fertilized egg.[15] After this injection, the fertilized egg is surgically implanted into the reproductive tract of the host female.[16] Only a small fraction of eggs survive the injection process, and even fewer express the inserted gene.[17]

Although microinjection is generally a laborious, complicated, and somewhat inefficient process, it is more effective than traditional methods for the production of genetically altered species.[18]

---

breeder might consider); *see* Iver P. Cooper, *Patent Protection for New Forms of Life*, 38 FED. B.J. 34, 43 n.60 (1979) (detailing phenotypic selection process).

12. Cooper, *supra* note 11, at 44; *see infra* notes 18-22 and accompanying text (enumerating ways in which transgenics is more efficient means of achieving same results as classical breeding).

13. OFFICE OF TECHNOLOGY ASSESSMENT, OTA REPORT BRIEF-PATENTING LIFE 1 (Apr. 1989), *reprinted in Hearings on H.R. 1556*, *supra* note 1, app. 3, at 517-18; *see* PATENT REFORM ACT, *supra* note 8, at 24-26 (tracing development of procedures used in production of transgenic animals from gene insertion into bacteria, ultimately leading to successful gene insertion in animals).

14. PATENT REFORM ACT, *supra* note 8, at 32; *see* Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 405 (1988) (maintaining that microinjection is transgenic technique now appearing to hold greatest commercial promise); *cf.* H.R. REP. No. 960, 101st Cong., 2d Sess., pt. 1, at 22 (1990) (indicating that while microinjection is presently most practical application of gene insertion, it may be replaced by other techniques as they are refined).

For an in-depth discussion of other transgenic techniques, see NATIONAL WILDLIFE FEDERATION, NAT'L BIOTECHNOLOGY POLICY CENTER, BIOTECHNOLOGY AND THE ENVIRONMENT 20-23, *reprinted in Hearings on H.R. 1556*, *supra* note 1, app. 3, at 536-40 (detailing modern transgenic techniques of chemical poration, electroporation, projectile transfer, cell transfer, and chimeras). Through the chimera technique, researchers have used two closely related species, goats and sheep, to produce a species called a "geep." PATENT REFORM ACT, *supra* note 8, at 34; *see id.* (explaining that process of producing chimera species aids researchers in understanding mammalian reproductive process).

15. Marcia Barinaga, *Making Transgenic Mice: Is It Really That Easy?*, 245 SCI. 590, 591 (1989).

16. *Id.*

17. *See id.* (finding 20% efficiency rate in using microinjection technique for transgenic generation); *see also* PATENT REFORM ACT, *supra* note 8, at 34 (indicating efficiency rate in transgenic mice production of less than 8% and only between .5 and 1% for agricultural animals). The Patent Reform Act states that only approximately 85 out of every 100 eggs collected are injectable. PATENT REFORM ACT, *supra* note 8, at 34. Of these, sixty survive the gene injection procedure, and six of the initial hundred result in live births. *Id.* Of the six offspring born alive, only one or two are transgenic. *Id.*

18. PATENT REFORM ACT, *supra* note 8, at 34.

For example, microinjection is a more accurate and precise mechanism for the introduction of a specific gene into the chosen host.[19] This method results in a quicker inter-positioning of the desired trait into a particular species of animal.[20] The process also allows the identified gene to be transferred by itself, free of any attendant but superfluous genetic material.[21] In addition, with the proper preparation, microinjection makes it possible to insert genes of almost any animal into the desired host.[22]

B. The Patent Statute

Much of the controversy surrounding animal patents centers around the specific statutory requirements of the patent system.[23] The issuance of animal patents creates unique problems within the patent system.[24] Thus, a basic understanding of the patent statute facilitates an informed analysis of animal patents within the context of the system.

The United States Constitution grants Congress expansive power to foster the progress of arts and sciences through granting authors, inventors, and artists exclusive rights to their achievements for a limited time to compensate them for their creative efforts.[25] The

---

19. *Id.* at 25-26.

20. *Id.* Through microinjection, it is possible to produce a "species" carrying the desired trait in one generation, as opposed to the many generations selective breeding usually requires to establish a desired trait. *Id.* at 24.

21. *Id.* at 26. Selective breeding, however, often results in the accompaniment of large amounts of extraneous genetic material with the transferred gene of interest, thereby complicating the specific breeding objective. *Id.*

22. *Id.* By contrast, classical breeding methods traditionally require that the interposed genetic material be that of a closely related species, or of a different strain within a species. *Id.* It is important, however, to realize that current transgenic techniques only permit the interposition of "a handful of genes" into an animal with 50,000-100,000 or more genes. Lisa J. Raines, *The Mouse that Roared*, ISSUES IN SCI. & TECH., Summer 1988, at 67, *reprinted in Hearings on H.R. 1556*, *supra* note 1, at 611. Transgenics, therefore, does not fundamentally alter the physical character of the animal. *See id.* (claiming that genetic engineering would not "disrupt anything fundamental in an animal's architecture.").

23. *See* Mark W. Lauroesch, Note, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100, 109 (1989) (addressing concern that patent law provides insufficient protection for biotechnology and reasoning that level of complexity of living organisms inhibits effective disclosure to public).

24. *See* JoAnne E. Seibold, *Can* Chakrabarty *Survive the Harvard Mouse?*, 2 U. FLA. J.L. & PUB. POL'Y 81, 90-93 (1989) (outlining problems in patenting living organisms as: (1) timing of patent application; (2) accurately defining scope of patent; (3) satisfying deposit requirement; and (4) detecting patent infringement); Margaret J. Lane, *Patenting Life: Responses of Patent Offices in the U.S. and Abroad*, 32 JURIMETRICS J. 89, 92-93 (1991) (highlighting problems animal patents pose in satisfying section 112's enablement requirement).

25. U.S. CONST. art. I, § 8, cl. 8. This clause grants 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." *Id.* The patent owner is granted "the right to exclude others from making, using, or selling the invention throughout the United States," for a period of seventeen years. 35 U.S.C. § 154 (1988).

primary purpose of the patent system is to promote investment in research and development and to induce the early disclosure of the broadest range of useful technological information.[26] An invention must be useful,[27] nonobvious,[28] and novel[29] to be eligible for a patent.[30] In addition, the subject matter element of the statute requires that the invention be either a process,[31] machine,[32] manufacture,[33] or composition of matter.[34] While the scope of patentable subject

---

26. *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) ("[T]he ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure."); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974) (identifying purposes of patent laws as: fostering and rewarding invention; encouraging disclosure of inventions to stimulate further innovation; permitting public to practice invention following expiration of patents; and to assure that ideas in public domain remain there for free use of public); Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944) (stressing that patent laws are intended to stimulate research and development by giving inventors 17-year monopoly on their innovations).

27. 35 U.S.C. § 101 (1988). Section 101 provides:

> 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 therefor, subject to the conditions and requirements of this title.

Id. (emphasis added); *see* ERNEST B. LIPSCOMB III, LIPSCOMB'S WALKER ON PATENTS § 5:4, at 490-91 (3d ed. 1986) (stating that utility element of section 101 requires that invention have known purpose and that it operates to perform its intended purpose).

28. *See* 35 U.S.C. § 103 (1988) ("A patent may not be obtained . . . if . . . the subject matter as a whole would have been obvious . . . ."). To satisfy the requirement of nonobviousness, an invention cannot be "obvious" to a person having ordinary skill in the scientific field or "art." *Id.*

29. 35 U.S.C. § 102 (1988). An invention is deemed "novel" if it does not already exist in a prior invention, *id.* § 102(e)-(g), or if others in the United States do not possess knowledge of use, offer for sale, or publish the invention here or abroad. *Id.* § 102(a)-(b).

30. *Id.* §§ 101-103 (1988).

31. *Id.* § 101; *see* Cochrane v. Deener, 94 U.S. 780, 788 (1877) ("A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter, to be transformed and reduced to a different state or thing.").

32. 35 U.S.C. § 101 (1988); *see* Corning v. Burden, 56 U.S. 252, 267 (1853) (defining "machine" as "every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result.").

33. 35 U.S.C. § 101 (1988). A "manufacture" may be defined as "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery . . . ." American Fruit Growers, Inc. v. Brogdex Corp., 283 U.S. 1, 11 (1931).

34. 35 U.S.C. § 101 (1988). The term "composition of matter" refers to "all compositions of two or more substances and . . . all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids . . . ." Shell Dev. Co. v. Watson, 149 F. Supp. 279, 280 (D.D.C. 1957), *aff'd*, 102 U.S. App. D.C. 297 (1958) (citing 1 ANTHONY W. DELLER, WALKER ON PATENTS § 14, at 55 (1st ed. 1937).

Not only must the patent applicant's invention satisfy these statutory requirements, but the patent application itself must meet certain criteria. *See* 35 U.S.C. § 111 (1988) (requiring that specification and oath accompany application). Section 112's disclosure requirement requires that the patent application contain a thorough description of the invention, such that one skilled in the relevant art can make and use the invention without the exercise of independent inventive skills. *Id.* § 112. In addition, the patent application, in one or more claims, must set forth particularly and distinctly the subject matter of the invention. *Id.*

After the patent application is filed, a patent examiner examines the application to determine whether the invention satisfies the requirements of patentability (sections 101, 102, and 103). LIPSCOMB, *supra* note 27, § 12:7, at 25. If the examiner rejects the patent twice, the

matter appears broad, it is not unlimited.[35] It is well established that principles,[36] laws of nature,[37] physical phenomena,[38] abstract ideas,[39] and products of nature[40] are not patentable.

Animals possess one crucial quality that sets them apart from other patentable inventions (with the exception of plants): they are self-reproducing.[41] This distinguishing characteristic has raised many complex issues in extending the coverage of the patent statute to animals, especially within the agricultural industry.[42] As bi-

---

patent applicant may appeal to the Board of Patent Appeals and Interferences, which is the sole appellate tribunal within the PTO. *Id.* § 12:56, at 242. The Board has the power to affirm or reverse the examiner, or enter a new ground of rejection. *Id.* The Board does not have the authority to review favorable decisions by an examiner. *Id.* Any applicant who is dissatisfied with the Board's decision may appeal it to the United States Court of Appeals for the Federal Circuit. 35 U.S.C. § 145 (1988).

The Federal Circuit was created in 1982 as an amalgamation of the Court of Claims and the Court of Custom and Patent Appeals. LIPSCOMB, *supra* note 27, § 12:58, at 279. In conferring exclusive jurisdiction of all patent appeals on the Federal Circuit, Congress aimed to "provide nationwide uniformity in patent law." H.R. REP. No. 312, 97th Cong., 1st Sess. 20 (1981). A decision of the Federal Circuit is not appealable, but may be reviewed by the United States Supreme Court upon a grant of certiorari. LIPSCOMB, *supra* note 27, § 12:55, at 241.

35. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (maintaining that section 101 does not encompass every discovery).

36. *See* Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1853) (holding that principle in abstract is fundamental truth which cannot be patented).

37. *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 127-28 (1854) (holding that use of electro-magnetism for printing intelligible signs, characters, or letters at distance is not patentable).

38. *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (holding that one cannot obtain patent on phenomena itself, but only for process of applying phenomena to new and useful end).

39. *See* Gottschalk v. Benson, 409 U.S. 63, 67-68 (1972) (finding that mathematical algorithm is akin to mental process and therefore not patentable). The prohibition on patents for abstract ideas also extends to business methods. *See* Hotel Security Checking Co. v. Lorraine Co., 160 F. 467, 469 (2d Cir. 1908) (holding that system of bookkeeping designed to prevent fraud in hotels and restaurants is not patentable).

40. *See* General Electric Co. v. De Forest Radio Co., 28 F.2d 641, 642-47 (3d Cir. 1928), *cert. denied*, 278 U.S. 656 (1929) (denying patent for substantially pure tungsten on grounds that it was product of nature).

41. *See* Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1068 (1988) (emphasizing that patented animal is unlike other patented inventions, in that no active human intervention is necessary for animal to be copied); *see also Hearings on H.R. 1556*, *supra* note 1, at 30-31 (statement of Howard Lyman, on behalf of National Farmers Union, American Agriculture Movement, and Save the Family Farm Coalition) (claiming that patents that involve self-reproducing life forms need to be handled differently than those for other inventions). The patent system has already addressed the self-reproducing quality of plants. *See infra* note 256 and accompanying text (discussing enactment of Plant Variety Protection Act (PVPA) as means of alleviating problems involved with plant self-reproduction in terms of patenting plants and farmers' use of patented plants in growing crops). Although Congress has considered such legislation for the patenting of animals, Congress has not yet enacted it due to similar problems that will arise in the context of the breeding of patented animals. *See* John M. Czarnetzky, Note, *Altering Nature's Blueprints for Profit: Patenting Multicellular Animals*, 74 VA. L. REV. 1327, 1330, 1355-56 (1988) (proposing draft of Animal Patent Act that applies concepts embodied in Plant Protection Act (PPA) and PVPA to patenting of multicellular animals).

42. *See Hearings on Patents and the Constitution: Transgenic Animals Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 100th

otechnological research rapidly advances, so must our patent laws continue their evolutionary process and advance with it.[43]

C. Patent Law and its Applicability to Living Organisms

1. Patenting microorganisms: Diamond v. Chakrabarty

In 1972, Ananda Chakrabarty, a microbiologist, filed a patent application for a strain of genetically altered *Pseudonomas* bacterium capable of digesting multiple components of crude oil, a characteristic which makes them useful in controlling oil spills.[44] The patent examiner granted the claims for the process that produced the bacterium, but not for the organism itself on the grounds that: (1) the microorganism is an unpatentable product of nature, and (2) living organisms are not patentable subject matter under section 101 of the patent statute.[45] Chakrabarty appealed the rejection of his claims to the Patent Office Board of Appeals, and the Board affirmed the examiner, but only as to the second ground.[46] In rendering its decision, the Board relied on the legislative history of the 1930 Plant Patent Act in which Congress extended patent protection to certain asexually reproducing plants and concluded that section 101 did not cover living things, such as Chakrabarty's

---

Cong., 1st Sess. 179 (1987) [hereinafter *Patent Hearings*] (statement of Robert P. Merges, Professor, Columbia School of Law) (predicting that problems of animal patenting in farming industry will center on detecting infringement and enforcing rights of animal patent owner); *see also infra* notes 110-16 and accompanying text (providing more detailed explanation of farmers' specific objections to animal patenting); *infra* notes 253-61 and accompanying text (describing proposed legislation for farmer's exemption from payment of royalties for offspring of patented animals as attempt to alleviate complex problems that patented animals pose to agricultural industry). *See generally* Jade L. Hlavinka, *Can Patent Law Accommodate the Novel Challenges of the Biotech Industry?*, 31 S. TEX. L. REV. 301, 315 (1990) (highlighting problems that self-reproduction poses in licensing of patented living organisms).

43. *See* 135 CONG. REC. E3008 (daily ed. Sept. 12, 1989) (statement of Rep. Cardin) ("Although biotechnology is a new and constantly changing field, the basis on which one receives a patent is not . . . . [W]e have reached the point at which we must examine whether our patent system is keeping up with technology . . . ."); *see also infra* notes 273-75 and accompanying text (recommending that Congress amend patent statute to better accommodate biotechnological innovations and presenting model of amended statute).

44. Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980). The researcher developed the bacteria through the cross-breeding of four different strains of oil-eating bacteria into one microorganism. *Id.* at 305 n.1. No naturally occurring bacteria was capable of breaking down the components of crude oil. *Id.* at 305.

45. *Id.* at 306; *see supra* note 40 and accompanying text (reiterating that products of nature do not constitute patentable subject matter); *supra* note 27 (quoting 35 U.S.C. § 101). Prior to *Chakrabarty*, a life process of an organism was patentable, but not the organism itself. *See* Guaranty Trust Co. v. Union Solvents Corp., 54 F.2d 400, 410 (D. Del.) (holding that life process of bacterial organism is patentable subject matter), *aff'd*, 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933).

46. *Chakrabarty*, 447 U.S. at 306. The Board dismissed the first ground of the examiner's rejection, that the microorganism was an unpatentable product of nature, because Chakrabarty's strain of *Pseudomonas* bacteria was not naturally occurring. *Id.* at 306 n.3.

genetically altered bacterium.[47] The Court of Customs and Patent Appeals (CCPA) reversed on the second ground,[48] and the Supreme Court granted certiorari to determine whether living organisms were patentable subject matter under section 101.[49]

In the landmark case of *Diamond v. Chakrabarty*,[50] the Supreme Court held that genetically altered microorganisms were patentable subject matter within the meaning of section 101 as a "manufacture" or "composition of matter."[51] The Court, in concluding that microorganisms should be considered patentable subject matter, relied on evidence that Congress intended section 101 to be construed broadly, encompassing "anything under the sun that is made by man."[52]

In reaching its decision, the Court rejected the government's argument that Congress, in enacting two separate statutes governing the patenting of plants,[53] intended to exclude all other types of living organisms from patent protection.[54] After examining the relevant congressional reports, the Court determined that Congress recognized that the relevant distinction for purposes of product patentability was between products of nature, whether living or not, and human-made inventions, rather than between living and nonliving things.[55] Therefore, the Court found nothing in the exclusion of bacteria from plant patent protection to support the government's position.[56]

---

47. *Id.* at 306.

48. *In re* Chakrabarty, 571 F.2d 40, 43 (C.C.P.A. 1978). In reversing the Board's decision, the CCPA relied on the authority of its prior decision in *In re Bergy*, which held that the question of whether microorganisms are alive is without legal significance for purposes of the patent laws. *Id.* (citing *In re* Bergy, 563 F.2d 1031, 1038 (C.C.P.A. 1971)).

49. Parker v. Bergy, 444 U.S. 924 (1979). The CCPA, after the grant of certiorari, consolidated *Chakrabarty* and *Bergy*. *Chakrabarty*, 447 U.S. at 306. Before the Supreme Court decided *Chakrabarty*, however, *Bergy* was dismissed as moot. Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

50. 447 U.S. 303 (1980).

51. Diamond v. Chakrabarty, 447 U.S. 303, 307, 310 (1980). The patent statute provides that: "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 therefor . . . ." 35 U.S.C. § 101 (1988) (emphasis added).

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

53. The two relevant plant statutes are the 1930 Plant Patent Act, 35 U.S.C. § 161, which extends patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act (PVPA), 7 U.S.C. § 2402 (a), which affords protection for certain sexually reproduced plants, but excludes bacteria from its protection. *Chakrabarty*, 447 U.S. at 310-11.

54. *Chakrabarty*, 447 U.S. at 310-14. The Commissioner of the PTO argued that Congress, in passing the plant acts, excluded living organisms from falling within the terms "manufacture" or "composition of matter." The Commissioner contended that any other finding would be inconsistent with the statutory promulgation. *Id.* at 311.

55. *Id.* at 313.

56. *Id.*

The decision, however, was sharply divided (5-4) with Justices Brennan, White, Marshall, and Powell vigorously dissenting.[57] The dissent argued that the majority misinterpreted the applicable legislation and that Congress, through the enactment of the plant patent statutes, expressly intended to exclude bacteria from the scope of the patent statute.[58] Furthermore, the dissenters claimed it is the role of Congress, not the Court, to expand or contract the patent laws, especially where, as here, serious matters of public concern are involved.[59]

The Court's broad interpretation of patentable subject matter in *Chakrabarty* led to an explosion in the number of companies engaging in genetic engineering.[60] Patents are now routinely issued for microorganisms which yield a wide variety of benefits to society, including perfecting methods of food production, developing new useful drugs, decomposing components of toxic waste, shielding crops from adverse climatic conditions, and facilitating more productive means to manufacture chemicals.[61]

2. *Patenting plants:* Ex parte Hibberd

In 1985, in *Ex parte Hibberd*,[62] the Board of Patent Appeals and Interferences further extended the scope of the patent laws by concluding that nonnaturally occurring, manmade, multicellular plants are patentable subject matter under section 101.[63] In *Hibberd*, the Board ruled that a corn plant containing an abnormally high level of amino acid was within the scope of patentable subject matter.[64] In

---

57. *Id.* at 318 (Brennan, J., dissenting).
58. *Id.* at 319-21 (Brennan, J., dissenting).
59. *Id.* at 321-22 (Brennan, J., dissenting).
60. *See* Albert Gore Jr. & Steve Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336, 339 (1985) (emphasizing extent to which investment in biotechnology research has grown in wake of *Chakrabarty*). *See generally Patent Hearings*, *supra* note 42, at 148 (statement of William H. Duffey, on behalf of Intellectual Property Owners, Inc. & Industrial Biotechnology Association) (restating estimation made by Office of Technology Assessment (OTA) that biotechnology will be $100 billion industry by end of century).
61. Robert B. Kambic, Note, *Hindering the Progress of Science: The Use of the Patent System To Regulate Research on Genetically Altered Animals*, 16 FORD. URB. L.J. 441, 442-43, 452 n.113 (1988) (tracing development of post-*Chakrabarty* patented microorganisms, discussing various applications of such organisms, and stating that as of 1988, PTO has granted almost 200 patents for genetically altered bacteria); *see* Jane M. Marciniszyn, *What Has Happened Since* Chakrabarty?, 2 J.L. & HEALTH 141, 150-56 (1988) (focusing on development of bioengineered pharmaceuticals since *Chakrabarty* and indicating that, as of 1988, FDA has approved five drugs derived from biotech research: human insulin (1982), human growth hormone (1985), alpha interferon (1986), monoclonal antibody (1986), and hepatitis B vaccine (1986)).
62. 227 U.S.P.Q. 443 (Bd. Pat. App. & Int. 1985).
63. *Ex parte* Hibberd, 227 U.S.P.Q. 443, 447 (Bd. Pat. App. & Int. 1985).
64. *Id.* at 446. Specifically, the patent relates to maize plant technologies, including seeds, plants, and tissue cultures which have increased free tryptophan levels or that are capable of producing plants or seeds having increased tryptophan content. *Id.* at 443.

the initial review, the patent examiner rejected the application on the basis that utility patent protection of plants was not available under section 101 by reason of the Plant Patent Act and the Plant Variety Protection Act.[65] The Board of Patent Appeals rejected this argument and relied on the Supreme Court analysis in *Chakrabarty*, deciding that Congress did not intend the plant patent acts to be the exclusive form of protection for plant life.[66] Following this decision, the PTO announced that it would examine patent applications for plant tissues, cells, seeds, and whole plants that fulfilled the requisite criteria of the patent statute.[67]

3. Patenting higher life forms: Ex parte Allen

In *Ex parte Allen*,[68] the Patent Appeals Board took the next step up the evolutionary scale and built upon the *Chakrabarty* and *Hibberd* decisions.[69] *Ex parte Allen* involved a patent application for a man-made, nonnaturally occurring strain of Pacific polyploid oysters.[70] These oysters, made sterile by induced polyploidy, grew much larger than normal oysters.[71] The examiner rejected the application on the grounds that: (1) the polyploid oysters are living organisms, thus falling outside the scope of the patent statute; and (2) the oysters do not satisfy the nonobviousness test for patentability, because the organism is not sufficiently different from those produced by other known means.[72]

The Board of Patent Appeals reversed the examiner's determination on the first ground, holding that *Chakrabarty* makes it clear that the patent statute encompasses man-made life forms.[73] Therefore, pursuant to the Supreme Court's decision in *Chakrabarty*, the Board held that the polyploid oysters were nonnaturally occurring "manufactures" or "compositions of matter" within the scope of section

---

65. *Id.* at 446; *see supra* note 53 (explaining extent of coverage of PPA and PVPA).

66. *Hibberd*, 227 U.S.P.Q. at 447 (citing *Chakrabarty*, 447 U.S. at 310-12).

67. 1060 OFF. GAZ. PAT. OFFICE 4 (Oct. 8, 1985); *see supra* notes 27-40 and accompanying text (outlining specific requirements of patent statute).

68. 2 U.S.P.Q.2d 1425 (Bd. Pat. App. & Int. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988).

69. *Ex parte* Allen, 2 U.S.P.Q.2d 1425, 1425-27 (Bd. Pat. App. & Int. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988).

70. *Allen*, 2 U.S.P.Q.2d at 1425. A polyploid organism is an organism with more than two sets of chromosomes. PETER J. RUSSELL, ESSENTIAL GENETICS 309 (2d ed. 1987). Humans have two sets of chromosomes and are diploid organisms. *Id.* The oysters at issue in *Allen* were not created by transgenics, but by a mechanical process involving the application of hydrostatic pressure to the organisms. *Allen*, 2 U.S.P.Q.2d at 1425.

71. *Allen*, 2 U.S.P.Q.2d at 1426-27. Polyploid oysters offer an important advantage over naturally occurring oysters as they do not devote significant portions of their body weight to reproduction and are thus edible year-round. *Id.* at 1425, 1427.

72. *Id.* at 1426.

73. *Id.*

101.[74] The Board, however, upheld the examiner's finding that the polyploid oyster failed to meet the nonobviousness test for patentability and, thus, denied the patent.[75] The Federal Circuit affirmed the Board's decision.[76]

4. The PTO announcement concerning animal patentability

The Patent Board's decision in *Allen* spearheaded a new PTO policy.[77] On April 7, 1987, within days of the Board's decision, the PTO issued a rule announcing that nonnaturally occurring, nonhuman, multicellular organisms, including animals, are patentable subject matter within the scope of section 101.[78] After the decision in *Allen*, however, the PTO, at the request of Representative Kastenmeier of Wisconsin, agreed to place a voluntary eight-month moratorium on further animal patents to allow Congress time to debate the various issues involved in patenting animals.[79] On the same day the moratorium expired, April 12, 1988, the PTO issued its first, and to date only, animal patent.[80]

5. The Harvard mouse

The PTO granted the animal patent to two Harvard University researchers for the invention of the "Harvard mouse," a mouse genetically altered to be highly susceptible to cancer.[81] The Harvard researchers developed the animal to serve as a more effective model for studying how genes contribute to various forms of cancer, particularly breast cancer.[82] Since granting the patent for the Harvard Mouse, the PTO has been deluged with patent applications for

---

74. *Id.*

75. *Id.* at 1427-29.

76. *In re* Allen, 846 F.2d 77 (Fed. Cir. 1988) (affirming without published opinion).

77. *See* Dresser, *supra* note 14, at 403 (characterizing *Allen* as providing impetus for PTO's issuance of 1987 rule).

78. 1077 OFF. GAZ. PAT. OFFICE 24 (Apr. 7, 1987); *see supra* note 1 (setting forth 1987 rule).

79. 36 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 888, at 271-72 (1988); *see infra* notes 238-40 and accompanying text (discussing other proposed legislation for placing moratoria on animal patents).

80. 36 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 888, at 271-72 (1988).

81. U.S. Patent No. 4,736,866. The PTO issued this patent within a month after the Federal Circuit affirmed the Board's *Allen* decision. *In re* Allen, 846 F.2d 77 (Fed. Cir. 1988). The co-inventors of the Harvard mouse are Dr. Philip Leder and Dr. Timothy Stewart. H.R. REP. No. 960, 101st Cong., 2d Sess., pt. 1 (1990). *See generally Mouse Patent, a First, Issued to Harvard*, N.Y. TIMES, Apr. 13, 1988, at A1 (detailing how mouse was created and explaining its intended applications in biomedical field). The two researchers isolated the gene that causes cancer in many mammals, including humans. *Id.* Once isolated, the researchers injected the gene into a fertilized mouse egg that developed into the Harvard mouse. *Id.*

82. *See* Alun Anderson, *Oncomouse Released*, 336 NATURE 300, 300 (1988) (explaining that mice carry cancer-producing gene, ras oncogene, that has been shown to be common component in variety of human cancers, plus mouse mammary tumor virus promoter that ensures

transgenic animals.[83]

II. THE CONTROVERSY OVER ANIMAL PATENTS

A. The Beneficial Effects of Transgenic Animals

Researchers, scientists, and scholars predict that patented animals will provide tremendous benefits for society, expect them to have commercial application in the agricultural, biomedical, pharmaceutical, and chemical industries.[84] In fact, transgenic animals antici-

---

that oncogene is activated in breast tissue, so that mice develop human breast cancer within few months of birth).

Use of the Harvard mouse was to result in more efficient laboratory testing of suspected carcinogens than was previously possible with ordinary mice. *See* 35 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 876, at 508 (1988) (stating that Harvard mice are useful because modified genes make them susceptible to carcinogens at levels comparable to those which might cause cancer in humans, thereby eliminating need for extreme overdoses required to cause comparable results in unmodified animals). Apart from its direct biomedical applications to the study of cancer, the development of the Harvard mouse stands to make significant contributions to the entire field of transgenic research. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1084-85 (1989) (predicting that mouse will serve as valuable model to researchers trying to design other transgenic mammals).

83. *See* 43 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 1058, at 65 (Nov. 22, 1991) (quoting Michael Gough, manager of Office of Technology Assessment's Biological Applications Program, as stating that there are approximately 157 animal patent applications currently pending at PTO). The PTO estimates that about 80% of the current applications are directed to animals that have utility in biomedical applications, with the majority of the remainder directed to agricultural uses. 137 CONG. REC. S7819 (daily ed. June 13, 1991) (letter from Harry Manbeck, Assistant Secretary and Commissioner of Patents and Trademarks to Sen. Hatfield (Apr. 5, 1991).

84. *See* Edmund J. Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 DRAKE L. REV. 551, 566 (1989) (dividing application of transgenic animals to agriculture into two main areas: livestock and crops); Mark, *supra* note 1, at 251-52 (describing how transgenic research may be able to provide for direct gene therapy to combat various types of genetic disorders, as well as hormone and enzyme deficiencies); *see infra* notes 91-95 and accompanying text (discussing anticipated contribution of genetically altered animals to biomedical field).

For a thorough discussion of the expected impact of transgenic animals on the pharmaceutical industry, see David Manspeizer, Note, *The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland*, 43 RUTGERS L. REV. 417, 425 (1991) (suggesting that transgenic animals may be used as "miniature drug factories"); *see also Patent Hearings*, *supra* note 42, at 372 (statement of Dr. Leroy Walters, Kennedy Institute of Ethics, Georgetown University) (commenting on attempts by researchers to produce Factor IX blood clotting drug for hemophiliacs through blood or milk of mice or sheep); Dresser, *supra* note 14, at 409 (setting forth potential contributions "molecular farming" could make to pharmaceutical industry and indicating that researchers have reported success with "molecular farming" in both mice and silkworms); *Hearings on H.R. 1556*, *supra* note 1, at 469 (statement of Alan Smith, Integrated Genetics) (setting forth that process of "molecular farming" involves insertion of foreign genes for certain valuable proteins into fertilized eggs of host species, with aim of obtaining protein from the resultant transgenic animal's milk). Most recently, researchers have induced the "molecular farming" process in goats. *See* Malcolm Gladwell, *Animals Altered To Produce Medicine in Milk*, WASH. POST, Aug. 27, 1991, at A1 (describing how "molecular farming" in goats has resulted in producing one of most expensive heart attack drugs on market, tissue plasminogen activator (TPA), in goat's milk).

For a discussion of the anticipated effect of genetically altered animals on the chemical industry, see Sease, *supra*, at 569-70 (predicting that chemical companies will be developing biological controls for pathogens to protect already established markets for herbicides and

pated for use in the biomedical and agricultural fields account for the bulk of the animal patent applications now pending at the PTO.[85]

1. Agriculture

Within the agricultural industry, transgenics promises to achieve the benefits of classical breeding more quickly and precisely.[86] Conceivably, scientists could genetically alter livestock to require less nutrients and to produce higher yields of meat with decreased fat and cholesterol levels.[87] Likewise, researchers may genetically alter poultry to maximize meat and egg production.[88] In addition, transgenics may lead to the creation of farm animals that are more resistant to disease.[89] Although no transgenic farm animal patents exist to date, such animals have already been developed through trans-

---

insecticides); *see also id.* (suggesting that raw chemical companies will invest in efforts to patent biological production of some chemicals currently in production, as well as new chemicals to compete with chemicals presently on market).

85. 137 CONG. REC. S7818 (daily ed. June 13, 1991) (statement of Sen. Hatfield); *see Hearings on H.R. 1556*, *supra* note 1, at 265 (statement of Richard D. Godown, President, Industrial Biotechnology Association) (delineating two types of transgenic animal research currently being pursued as: (1) farm animals designed for improved food or dairy production; and (2) laboratory animals that may serve as models for human diseases).

86. *See Patent Hearings*, *supra* note 42, at 219 (statement of Winston J. Brill, Ph.D., Agracetus Corp.) (stating that, although goals of genetic engineering and classical breeding are generally identical, former is more controllable and should decrease number of problems associated with breeding). *See generally supra* notes 18-22 and accompanying text (highlighting benefits of transgenics as compared to classical breeding methods).

87. *See* Sease, *supra* note 84, at 566 (claiming that it may be possible to create livestock of improved nutritional value). Sease also predicts that researchers may be successful in altering genetic makeup of hide-producing animals, such as cows and sheep, to maximize the production of hides. *Id.*; *Patent Hearings*, *supra* note 42, at 264 (statement of Richard Godown, President, Industrial Biotechnology Association) (noting that prospects in transgenic farm animals include cows that produce more milk than normal, pigs that bear twice the usual number of piglets, and fish that grow larger than normal varieties); *see* Dresser, *supra* note 14, at 407-08 (describing positive effect of growth hormone on transgenic pigs as requiring much less food per unit of weight gain than normal swine); Peter Gorner & Ronald Kotulak, *Cattle-Cloning Labs Transform the Barnyard*, CHI. TRIB., Apr. 10, 1990, § 1, at 1 (stating that scientists expect to create cows that produce skim milk and chickens that lay low-cholesterol eggs). *See generally* Raines, *supra* note 22, at 69 (emphasizing that lowering fat content in typical American diet will reduce number of deaths from cardiovascular disease, now nation's leading killer).

88. *See* Sease, *supra* note 84, at 566 (predicting impact of transgenic research on poultry production).

89. *See Patent Hearings*, *supra* note 42, at 259 (statement of Richard D. Godown, President, Industrial Biotechnology Association) (claiming that one of most promising areas of transgenic research in agriculture is engineering of disease-resistant traits into farm animals with goals of reducing animals' suffering and increasing farmers' profitability); *id.* at 223 (statement of Winston J. Brill, Agracetus Corp.) (explaining that, if efforts to create disease-resistant farm animals succeed, farmers could decrease amount of antibiotics and hormones currently given to livestock, thereby diminishing negative health effects that such substances have on human consumers); Raines, *supra* note 22, at 68 (stating that scientists may be able to create cattle that are resistant to "shipping fever" disease, reducing animals' chances of suffering during transportation to feedlots or to market and diminishing major source of economic loss for ranchers).

genic experimentation.[90]

2. Biomedical research

Currently, the bulk of transgenic animal research is being directed toward applications in the biomedical field.[91] Researchers are developing genetically altered mice, such as the Harvard mouse, to serve as models for human diseases, including Acquired Immune Deficiency Syndrome (AIDS), cystic fibrosis, Alzheimer's disease, and many forms of cancer.[92] Since many of these types of diseases do not normally occur in most laboratory species, those seeking cures must genetically alter laboratory animals to develop the maladies.[93] Manipulating complex animal systems is necessary to provide an understanding of the diseases and to test approaches that might bring about safe and effective treatment.[94] In addition, the

---

90. *See* Vernon G. Pursel et. al, *Genetic Engineering of Livestock*, 244 SCI. 1281, 1281-88 (1989) (commenting on laboratory development of transgenic pigs in laboratory which had significant weight gain coupled with reduced fat content); *Hearings on H.R. 1556*, *supra* note 1, at 232 (statement of Dr. Margaret Mellon, Director, National Wildlife Federation) (claiming that researchers at University of Wisconsin can genetically engineer cows that are capable of producing milk with higher concentration of casein, an important ingredient in cheese).

91. *See* 137 CONG. REC. S7819 (daily ed. June 13, 1991) (letter from Harry Manbeck, Assistant Secretary and Commissioner of Patents and Trademarks, to Sen. Hatfield (Apr. 5, 1991)) (stating that majority (80%) of animal patents pending at PTO are intended for biomedical research).

92. *See Hearings on H.R. 1556*, *supra* note 1, at 74 (statement of Steven Holtzman, Vice President for Corporate Development, DNX, Inc.) (listing various types of genetic and infectious human diseases that researchers are attempting to introduce into animals through transgenic techniques); *id.* at 74-75 (explaining that creation of transgenic animals avoids exposing humans to experimental drugs before drugs have been tested on specially designed lab animals).

93. *See Patent Hearings*, *supra* note 42, at 372 (statements of panel including Dr. Leroy Walters, Kennedy Institute of Ethics, Georgetown University) (explaining that although human enzyme deficiency disorder, Lesch-Nyhan syndrome, has no model in animals, researchers have been able to introduce malfunctioning gene causing syndrome into mouse); Manspeizer, *supra* note 84, at 428 (noting that Massachusetts General Hospital has patent pending for mouse carrying human insulin gene so that animal could be used in discovering further treatment for diabetes).

In addition, the development of transgenic animals may make it possible to substitute the testing of lower-order animals, such as mice, for higher-order animals, such as primates, that have traditionally been used. *See id.* at 426 (explaining that, since humans and chimpanzees are only animals known to be susceptible to AIDS, scientists are presently engineering mice capable of contracting disease, so that mice, rather than primates, may be used in AIDS testing).

94. *See, e.g.*, *Hearings on H.R. 1556*, *supra* note 1, at 198 (statement of Philip Leder, M.D., Prof., Dep't of Genetics, Harvard Medical School & co-inventor of Harvard mouse) (urging that availability of reliable, genetically uniform animal model, through transgenics, allows researchers to screen drugs more rapidly to combat various human diseases); *id.* at 154 (testimony of Philip Chen, Ph.D., National Institutes of Health) (claiming that transgenic animal research will provide insights into mechanisms of disease causation and bases for new therapeutic approaches); *The Use of Animals in Medical Research and Testing: Hearings Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. 64 (1981) (testimony of Dr. William Raub, National Institutes of Health) (maintaining that laboratory animals play crucial role in improving means to treat, prevent, and cure human diseases). Dr. Raub stated that laboratory animal experimentation has accounted for

development of transgenic animals is anticipated to perfect the process of toxicology testing, enabling scientists to screen for environmental hazards more precisely.[95]

B. The Advantages of Granting Animal Patents

Animal patent advocates claim that the grant or denial of animal patents is not likely to halt transgenic research.[96] The availability of patent protection for transgenic animals, however, will be instrumental in enabling society to reap the numerous benefits that transgenic animals promise by providing incentives to inventors to engage in such research.[97] Moreover, advocates argue that the issuance of animal patents will promote industry-wide disclosure of important transgenic research developments.[98] Biotechnological research projects tend to be extremely costly and time-consuming, usually lasting many years.[99] Animal patent supporters contend that patents are an important means by which these researchers can pro-

---

much of the advancement that has been made in the biomedical field: "Virtually every major advance . . . stems in whole or in part from research performed with animals." *Id.* Furthermore, he claimed that without the use of animals, research on serious diseases, such as heart disease, cancer, and diabetes . . . would come to a virtual standstill." *Id.*

95. *See* Raines, *supra* note 22, at 65 (maintaining that use of transgenic animals in carcinogenicity testing will produce more accurate results because animals' bioengineered sensitivity to suspect materials will permit testing in smaller amounts, thereby minimizing major source of criticism of current testing methods: that amounts used in testing greatly exceed amounts to which humans are likely to be exposed); *see also* Manspeizer, *supra* note 84, at 426-27 (predicting that development of transgenic animals will decrease amount of guesswork currently involved in toxicology testing, in that transgenic mouse could clearly reveal causal connection between given chemicals and genetic damage).

96. *Patent Hearings*, *supra* note 42, at 364 (testimony of Nicholas J. Seay, Esq.) ("Technological development will ratchet forward, never backward . . . . Eventually, the technology will be developed in any event. . . ."); *see* Lauroesch, *supra* note 23, at 116 (asserting that transgenic research will continue, despite prohibition on animal patents, as long as market for biotechnological products exists).

97. *See Hearings on H.R. 1556*, *supra* note 1, at 82 (testimony of Steven Holtzman, Vice President for Corporate Development, DNX, Inc.) (commenting that Congress and Supreme Court have repeatedly emphasized that purpose of patent system is to promote progress in research and development of technologies); *see also Patent Hearings*, *supra* note 42, at 21 (testimony of Ruth D. Tegtmeyer, Assistant Commissioner of Patents) (indicating that issuance of patents has stimulated research and encouraged development of useful new products); *cf.* H.R. REP. No. 960, 101st Cong., 2d Sess., pt. 1, at 27 (1990) (asserting that absence of patent protection would not prevent research on transgenic animals, but would most likely discourage private sector investment in biotechnology research).

98. *See Patent Hearings*, *supra* note 42, at 209 (statement of Leo Walsh, Dean, College of Agriculture, University of Wisconsin) (expressing view that patenting process encourages greater sharing of information among scientists than does trade secrecy protection, an alternative avenue of protection available if biotech industry is denied patent protection); *supra* note 26 and accompanying text (charging that primary purpose of patent system is to induce early disclosure of technological information).

99. *See Patent Hearings*, *supra* note 42, at 129 (statement of Dr. A. Ann Sorensen, American Farm Bureau Federation) (stressing that transgenic research demands substantial financial resources); *id.* at 358 (statement of Nicholas J. Seay, Esq.) (commenting that, generally, it may take years or even decades to start project, develop product, and put product to ultimate commercial use).

tect their significant investments.[100] Other arguments in support of animal patents have focused on the need for animal patent protection in the United States, so that this country may maintain its position as the world leader in transgenic research.[101]

C. *The Arguments Against Animal Patents*

Although transgenic animals are anticipated to contribute substantially to society, animal rights groups, farmers, environmentalists, and religious leaders have strenuously opposed the development of this new technology.[102] These groups may have different specific objections to biotechnology, but in essence, they all

---

100. *See* Reagen A. Kulseth, Note, *Biotechnology and Animal Patents: When Someone Builds a Better Mouse*, 32 ARIZ. L. REV. 691, 692 (1990) (recognizing biotech companies' need for transgenic animals to protect their considerable investments in transgenic research projects).

101. *See* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 3 (1984) (indicating that United States is world leader in biotechnology and that federal policy goal is to preserve international competitiveness of American firms); *cf. infra* notes 243-44 and accompanying text (presenting argument that prohibition of animal patents will seriously undermine United States' worldwide competitive edge in biotech industry).

Other animal patent advocates have pointed out that another benefit of affording patent protection for genetically altered animals is that patent royalties and grants would result in increased funding for biological research. *See* Sharp, *supra* note 1, at 751 (determining that such funding would result from royalties on patented animals and grants from companies and industries for right of first refusal on potentially patentable experimental results).

102. For a thorough discussion of the environmental concerns that have been raised in response to animal patenting, see Merges, *supra* note 41, at 1056-57 (discussing environmental concerns about animal patenting and categorizing objections as fear of: (1) deliberate release of genetically engineered animals and resultant immediate ecological disasters; (2) indirect ecological dangers over long period of time; and (3) deletions of total gene pool of world); *see also* Manspeizer, *supra* note 84, at 432 (describing environmental opposition to genetically altered animals in terms of: (1) chance of survival in wild; (2) likelihood of propagation; (3) chance of dispersal; (4) chance that such animals will prove harmful, or, due to competitive advantages, begin to replace naturally occurring species; and (5) possibility of transfer of genetic material from transgenic animals to normal animals); Note, *Designer Genes That Don't Fit: A Tort Regime for Commercial Releases of Genetic Engineering Products*, 100 HARV. L. REV. 1086, 1092 (1987) [hereinafter Note, *Designer Genes*] (warning of possibility of dispersal of altered organisms throughout ecosystem by insects and wind). *But see Patent Hearings*, *supra* note 42, at 428 (statement of Dr. Margaret Mellon, Director, Biotechnology Project of the National Wildlife Federation) (claiming that creating transgenic species able to survive exposure to acid rain and to resist pollution will actually preserve environment); *id.* at 526 (statement of Iver P. Cooper, Patent Counsel, The Association of Biotechnology Companies) (charging that biotechnology industry has vested interest in preserving genetic diversity of animals because genetic material is unique resource for biotechnologists).

For a discussion of the religious objections to animal patenting, see Dresser, *supra* note 14, at 411 (outlining religious objections to transgenic animal patents as: (1) objectification and exploitation of animal life; and (2) destruction of species integrity); Merges, *supra* note 41, at 1060-61 (discussing religious and ethical concerns that animal patenting will destroy animals' distinct form of autonomy); Manspeizer, *supra* note 84, at 437-40 (describing religious concerns about transgenic animal patents as centering on claim that "man is playing God" and concern that animal patenting will lead to patenting of genetically altered human beings). *But see* Raines, *supra* note 22, at 67 (claiming that concept of species integrity is inconsistent with what is currently known about biology and that species are not bounded in any strict sense); Manspeizer, *supra* note 84, at 437 (reasoning that religious and ethical objections to animal patents are hard to rebut because they rely on pure emotion, as well as unproven assertions).

argue that the dangers associated with animal patenting outweigh its potential benefits.[103] The two major types of opposition to animal patents are moral arguments made by animal rights groups and economic objections raised by individual farmers.[104]

1. Animal rights groups

Perhaps the strongest moral opposition to animal patenting comes from animal rights activists who fear that the rush toward animal patents will serve to increase animal suffering.[105] These groups believe that scientists, in the race to patent animals, are likely to neglect animal welfare.[106] In addition, animal rights activists claim that transgenic research will necessarily produce animals with painful and distressing abnormalities.[107] Animal rights leaders contend that the current regulatory framework for laboratory research does not adequately address the problems of animal suffering.[108] Therefore, animal rights organizations view animal

---

103. *See* Kulseth, *supra* note 100, at 702-09 (providing reasons for strong opposition by various groups to transgenic animal patents).

104. *See generally Hearings on H.R. 1556*, *supra* note 1, at 71 (testimony of Steven Holtzman, Vice President of Corporate Development, DNX, Inc.) (labeling objections from these two groups as major opposition to animal patents).

105. *See id.* at 110-11, 115-18 (statement of John A. Hoyt, President, Humane Society of the United States) (voicing concern that granting of animal patents will present society with new animal health and welfare problems). *But see* Manspeizer, *supra* note 84, at 441 (presenting argument that animal patenting will actually serve to diminish animal suffering by decreasing number of animals needed to achieve statistically significant results and by creating disease-resistant animals).

106. *See Hearings on H.R. 1556*, *supra* note 1, at 116 (statement of John A. Hoyt, President, Humane Society of the United States) (claiming that patenting will create financial incentive for increased experimentation, raising accompanying possibility of greater animal suffering). Throughout various congressional debates, Senator Hatfield expressed similar concerns that the quest for animal patents will lead to severe exploitation of laboratory animals. 137 CONG. REC. S7818 (daily ed. June 13, 1991) (statement of Sen. Hatfield) ("Animals, after all, are more than just instruments of commerce. . . ."); *see* 133 CONG. REC. 13914-15 (1987) (statement of Sen. Hatfield) (pointing out risk of allowing profit and convenience to control motivation for creation of transgenic animals). Consequently, Senator Hatfield has introduced several bills proposing that a moratorium be placed on animal patents. *See infra* notes 238-51 and accompanying text (discussing proposed moratoria on animal patents).

107. *See Hearings on H.R. 1556*, *supra* note 1, at 124-33 (statement of Dr. Michael W. Fox, Vice President/Bioethics and Farm Animals Division, Humane Society of the United States) (describing specific abnormalities that transgenic animals have displayed, including premature death, impaired immune systems, susceptibility to arthritis, gastric ulcers, and infertility).

108. *Id.* at 117 (statement of John A. Hoyt, President, Humane Society of the United States). During the hearings, Mr. Hoyt stressed the inadequacy of the Animal Welfare Act (AWA), the major law protecting animals. *Id.* Specifically, under current USDA enforcement, the AWA does not cover rats or mice, which comprise 85% of all laboratory animals. *Id.* Farm animals used in research are also unprotected. *Id.* Another weakness of the AWA is that it does not place any limitation on the amount of pain that researchers may inflict upon laboratory animals. *Id.*

A considerable amount of transgenic research, however, is governed by administrative guidelines set forth by the National Institutes of Health (NIH), which were created to govern laboratory containment and experimental practices in recombinant DNA research. *See infra*

patenting as exacerbating a pre-existing problem.[109]

2. Small farmers

From an economic viewpoint, animal patents are predicted to have the heaviest impact on the agricultural industry, raising concerns that corporate control of this technology will threaten the survival of family farms in this country.[110] Small farmers fear that they will be unable to compete with the larger producers and that they will eventually be forced out of business.[111] The family farmers are worried that the larger farms, which can afford to pay the royalty and licensing fees for patented animals, will reap all of the benefits of this technology.[112] As a result, many farmers feel that the PTO's 1987 policy will concentrate the farming industry, much like what has already happened in the seed and poultry industries, allowing a relatively small number of large corporations to gain control of the market for transgenic animals.[113]

One major source of concern for the farmers with respect to the introduction of patented transgenic animals into the industry is that, under the present patent laws, the intentional breeding of patented

---

notes 262-70 and accompanying text (discussing purpose, coverage, and overall effectiveness of NIH guidelines for transgenic animal research).

109. *See Hearings on H.R. 1556, supra* note 1, at 110 (statement of John A. Hoyt, President, Humane Society of the United States) (suggesting that animal welfare laws are insufficient and that commercial lure of animal patenting exploits this insufficiency through increased application of biotechnology to animals).

110. *See* 133 CONG. REC. 13,915 (1987) (statement of Sen. Hatfield) (predicting that agricultural industry would feel most immediate economic effect of patenting of animals); *Patent Hearings, supra* note 42, at 108 (statement of Rep. Rose) ("The survival of the family farm could well hang in the balance.").

111. *See* 134 CONG. REC. 2677 (1988) (statement of Sen. Hatfield) (voicing concern over future of family farms in United States as result of biotechnological advances).

112. *See* 133 CONG. REC. 13,915 (1987) (statement of Sen. Hatfield) (expressing concern that patenting of animals will allow major chemical, biotechnology, and pharmaceutical companies to take over animal husbandry, thereby "creating the possibility of corporate monopoly over the genetic code of animals. . . ."); *see also Patent Hearings, supra* note 42, at 312 (statement of Stewart Huber, President of Wisconsin Farmers' Union Milk Marketing Cooperative) (relating fear that development of transgenic animals will shift profit motive in agriculture from family farmers, who have long employed classical breeding methods, to large corporations, that can afford to benefit from transgenic research).

113. *See* Dresser, *supra* note 14, at 417-18 (articulating concerns of small farmers that large agricultural corporations will corner market on genetically altered animals); *Patent Hearings, supra* note 42, at 318 (statement of Dennis Jelle, President, National Farmers Organization of Wisconsin) (indicating that seed and poultry industries have been virtually taken over by large corporations); *id.* at 312 (statement of Stewart Huber, President of Wisconsin Farmers' Union Milk Marketing Cooperative) ("To grant monopoly protection to a few corporations would . . . have a chilling effect on traditional family livestock farms . . . . It will certainly speed the process toward vertical integration where individual farmers will merely become wards of Wall Street and the biotechnology establishment."). *But see infra* note 259 (setting forth claims by biotech companies that farmers will be able to benefit from biotechnology because free market will produce equitable results for both biotech companies and farmers).

animals arguably constitutes infringement.[114] Under the PTO's 1987 rule, the law would require a farmer to pay a royalty to the patent owner for each offspring produced during the breeding process.[115] Congress has paid considerable attention to the plight of the family farm in the face of this new technology and has introduced bills aimed at remedying the situation, including a farmer's exemption from the payment of royalties for patented transgenic animals.[116]

III. *ANIMAL LEGAL DEFENSE FUND V. QUIGG*

The controversy surrounding transgenic animal patents set the stage for *Animal Legal Defense Fund v. Quigg*.[117] The plaintiffs in *ALDF*, animal rights groups, farming groups, and individual farmers, challenged the issuance of animal patents by attacking the validity of the PTO's 1987 rule. The Federal Circuit, however, did not reach the issue of whether the rule constituted valid law, as it held that the plaintiffs did not have standing to bring the suit.[118] This important issue must therefore await resolution until another day and will most likely be decided in a different forum.[119]

A. Factual Background and Procedural History

In April 1987, the PTO issued its rule ("the Rule") stating that it "considers nonnaturally occurring, nonhuman multicellular orga-

---

114. *See* Merges, *supra* note 41, at 1068 (considering practical impact current patent laws are likely to have on farming industry); Hlavinka, *supra* note 42, at 317 (discussing problems associated with proving that any given animal is progeny of transgenic animal bought from patent owner). Hlavinka suggests, however, that, through the process of "DNA fingerprinting," patent owners could accurately prove such infringement. *Id.* at 317-18. For further information, see *id.* at 318-19 (indicating that results of DNA fingerprinting process have already been effective in establishing paternity in family law cases and providing evidence in sexual assault cases).

115. *See* Robert L. King, *The Modern Industrial Revolution: Transgenic Animals and the Patent Law*, 67 WASH. U. L.Q. 653, 655, 658 (1989) (describing impact of PTO's rule on farmers seeking to breed patented animals).

116. *See infra* notes 253-61 and accompanying text (examining proposed legislation on farmer's exemption and raising arguments both in opposition to, and in support of, exemption).

117. 932 F.2d 920 (Fed. Cir. 1991).

118. This Note is not intended to review the *ALDF* decision in exhaustive detail. Rather, the Note uses the case as a vehicle to discuss the underlying controversy surrounding animal patents and to examine the implications of the case in terms of the future direction of the controversy. This Note is primarily concerned with the issue not reached by the Federal Circuit in *ALDF*: whether transgenic animals are patentable subject matter. For a discussion of *ALDF* that focuses on the 1987 rule as it relates to the APA notice and comment requirement, see David Burke, Animal Legal Defense Fund v. Quigg: *Renewed Challenge to Animal Patents*, 59 UMKC L. REV. 409 (1991) (predicting outcome of *ALDF* and thoroughly discussing APA's notice and comment requirement as it relates to Rule).

119. *See infra* notes 221-25 and accompanying text (urging that Congress, and not judiciary, is proper forum for resolution of issue).

nisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101" (the U.S. patent statute).[120] The PTO did not publish the Rule in the Federal Register prior to its promulgation, nor did it invite public comment.[121] The controversy in *ALDF* originated when the plaintiffs challenged the Rule on both procedural and substantive grounds.[122]

The plaintiffs filed suit in the District Court for the Northern District of California alleging that Donald Quigg, then Commissioner of Patents and Trademarks, issued the Rule in violation of the public notice and comment period requirement of the Administrative Procedure Act (APA).[123] The plaintiffs sought to enjoin the PTO from approving or issuing any patents on multicellular living orga-

---

120. 1077 OFF. GAZ. PAT. OFFICE 24 (Apr. 21, 1987); *see supra* notes 27-40 and accompanying text (providing text of patent statute and explaining its requirements). The PTO relied on *Chakrabarty*, *Ex parte Hibberd*, and *Ex parte Allen* in deciding to issue the rule. *See supra* notes 44-76 and accompanying text (outlining progression of cases that led to PTO's expansion of patent statute to cover living organisms).

121. Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728, 729 (N.D. Cal. 1989).

122. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 922 (Fed. Cir. 1991). There were nine plaintiffs in this case: Animal Legal Defense Fund (ALDF), The American Society for the Prevention of Cruelty to Animals (ASPCA), The Marin Humane Society (MHS), Wisconsin Family Farm Defense Fund (WFFDF), John Kinsman, Michael Cannell, Humane Farming Association (HFA), Association of Veterinarians for Animal Rights (AVAR), and People for the Ethical Treatment of Animals (PETA). *Id.* at 920. The named defendants in the case were Donald Quigg, then Commissioner of Patents and Trademarks, and C. William Verity, then Secretary of Commerce. *Id.* at 922.

123. *ALDF*, 710 F. Supp. at 729. As a federal administrative agency, the PTO is governed by the rules set forth in the APA. LIPSCOMB, *supra* note 27, § 12-74, at 320. The plaintiffs claimed that the PTO violated the public notice and comment provisions of the APA, 5 U.S.C. sections 553 (b) and (c). *ALDF*, 710 F. Supp. at 729. The APA provisions state:

> § 553. Rule making
>
> . . .
>
> (b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—
>
> (1) a statement of the time, place, and nature of public rule making proceedings;
>
> (2) reference to the legal authority under which the rule is proposed; and
>
> (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.
>
> Except when notice or hearing is required by statute, this subsection does not apply—
>
> (A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or
>
> (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.
>
> (c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

5 U.S.C. § 553(b)-(c) (1988).

nisms, including animals.[124] The plaintiffs also claimed that Quigg had violated another provision of the APA by exceeding the statutory authority granted to him under the Patent Act.[125]

The defendants filed a motion to dismiss the complaint for failure to state a claim.[126] The district court granted the defendant's motion on the grounds that the Rule was "interpretative" of prior decisional precedent and was thus expressly exempt from the notice and comment requirement of the APA.[127] Finally, the court concluded that this action neither raised the status of prior precedent nor the validity of any animal patents actually issued.[128]

The plaintiffs appealed the district court's order of dismissal to the United States Court of Appeals for the Ninth Circuit.[129] Although the Ninth Circuit recognized that the APA created the causes of action, it transferred the appeal to the United States Court of Appeals for the Federal Circuit based on the Federal Circuit's exclusive appellate jurisdiction over cases "arising under" patent law.[130]

B. The Opinion of the Federal Circuit

1. ALDF's substantive challenge to the rule

The plaintiffs' challenge of the Rule on substantive grounds alleged that the Commissioner, in issuing the Rule, exceeded the Patent Act's grant of authority.[131] Specifically, ALDF alleged that the PTO Commissioner issued the Rule in violation of section 706(2)(c) of the APA, which concerns the action a reviewing court must take

---

124. *ALDF*, 932 F.2d at 924. Chief Judge Nies of the Federal Circuit noted that the plaintiffs erred by speaking of the PTO's Rule as covering all animals, when in fact it applies only to nonnaturally occurring animals. *Id.*

125. *Id.*

126. *ALDF*, 710 F. Supp. at 729.

127. *Id.* at 730-32. Furthermore, the district court held that the Rule was clearly within the Commissioner's authority to promulgate, since it merely interpreted decisional law, neither abridging nor enlarging the rights of anyone. *Id.* at 731. The court concluded that the question in this case was whether an agency could interpret its own rules through the promulgation of new rules. *Id.* at 732. The court answered affirmatively, claiming that this is an important function of an interpretative rule. *Id.* The district court expressly assumed, without deciding, that the plaintiffs had standing. *ALDF*, 932 F.2d at 924.

128. *ALDF*, 710 F. Supp. at 732.

129. Animal Legal Defense Fund v. Quigg, 900 F.2d 195 (9th Cir. 1990).

130. *Id.* at 196. The Federal Circuit has exclusive appellate jurisdiction when the jurisdiction of the district court "was based, in whole or in part, on 28 U.S.C. Section 1338." 28 U.S.C. § 1295(a)(1) (1988). The Federal Circuit, however, does not necessarily hear all cases that involve patent law; only those cases arising under patent law are subject to section 1338 jurisdiction. *ALDF*, 900 F.2d at 197. Accordingly, after examining the plaintiffs' well-pleaded complaint, the Ninth Circuit determined that the case arose under patent law and transferred the case to the Federal Circuit. *Id.* at 196-97. Neither the parties nor the Federal Circuit challenged the legality of the Ninth Circuit's transfer. *ALDF*, 932 F.2d at 924.

131. *ALDF*, 932 F.2d at 931.

when confronted with an agency that exceeds its statutory jurisdiction.[132] The plaintiffs sought, as relief for this alleged violation, a court declaration that animals are not patentable subject matter and an injunction against the issuance of any animal patents.[133]

2. *The Federal Circuit's denial of standing to ALDF*

a. *The animal rights groups*

The five nonprofit animal rights organizations, collectively referred to as ALDF,[134] share the common purpose of participating in administrative rulemaking regarding the care and welfare of animals, including the patenting of animals.[135] As its injury, ALDF alleged that its purposes and activities, as well as those of its members, had been, and would continue to be, frustrated and adversely affected by the Commissioner's new Rule.[136] Specifically, they objected to Quigg's refusal to provide the public with notice of, and an opportunity to comment on, the Rule prior to its promulgation.[137] In addition, the organizations alleged economic injuries, claiming that they had devoted, and would continue to devote, considerable financial resources to offset the defendants' unlawful actions.[138]

Chief Judge Nies of the Federal Circuit ruled that ALDF lacked

---

132. *Id.* Section 706(2)(C) provides:

> § 706. Scope of Review
>
> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—
>
> . . .
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> . . .
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

5 U.S.C. § 706(2)(C) (1988).

133. *ALDF*, 932 F.2d at 931.

134. *See supra* note 122 (identifying all nine plaintiffs).

135. *ALDF*, 932 F.2d at 926. ALDF's other purposes and activities include the distribution of information to members, the general public, and governmental agencies. *Id.* Furthermore, they advocate the interests of members in promoting the care and welfare of farm, research, and wild animals. *Id.* The ALDF also review any rules, policies, acts, or omissions which cause or permit physical pain, behavioral stress, suffering, debilitation, and/or death to animals. *Id.* ALDF also has an interest in participating in any rulemaking proceeding regarding the patenting of animals, in providing information and documentation to the defendants, and in providing its members and the public with information about any proposed rule to patent animals. *Id.*

136. *Id.*

137. *Id.*

138. *Id.*; *see supra* notes 105-09 and accompanying text (providing more detailed discussion of arguments advanced by animal rights groups in opposition to animal patenting).

standing, calling its allegations "patently insufficient under controlling precedent."[139] Although the court recognized that, for the purposes of standing, a plaintiff's injury need not be economic in nature, it concluded, as the Supreme Court held in *Sierra Club v. Morton*,[140] that the APA does not permit organizations or individuals to use the judicial system to vindicate their own value preferences.[141] The Federal Circuit held that ALDF's claim that it would expend more money on its activities as a result of the Rule failed to distinguish ALDF from any other member of the public with a particular concern for protecting animals.[142]

---

139. *Id.* at 936 (citing Valley Forge Christian College v. Americans United for Separation of Church and State, Inc., 454 U.S. 464, 472 (1982)). The standing requirement, imposed by Article III of the United States Constitution, requires that a party invoking a court's authority, at an "irreducible minimum," show: (1) an actual or threatened personal injury as a result of the defendant's allegedly illegal conduct (injury-in-fact); (2) that the injury reasonably flows from the action (causation); and (3) that the injury is likely to be redressed by a favorable decision (effective relief or redressability).

A further limitation of standing, known as the "zone of interests" test has been established by the Supreme Court. Air Courier Conference v. American Postal Worker Union, 111 S. Ct. 913, 917 (1991); *see infra* note 161 (summarizing Federal Circuit's discussion of "zone of interest" in *ALDF*).

140. 405 U.S. 727 (1972).

141. *ALDF*, 932 F.2d at 936 (citing Sierra Club v. Morton, 405 U.S. 727, 734-35 (1972) (holding that injury to "aesthetic and environmental well-being" could constitute injury-in-fact to environmental group as result of construction of recreation area in national forest)). Two of the organizations, ASPCA and MHS, cited certain police powers (to protect and care for animals) that had been delegated to them by the state in an attempt to distinguish themselves from the "value preference" category. *Id.* at 936-37. They alleged that, due to the increased animal experimentation encouraged by the potential for patent protection, they would need to increase their budgets and enforcement staff. *Id.* at 936.

The government rebutted this argument by "uncontroverted assertions" that state statutes impose no such duties on these organizations. *Id.* The court agreed with the Government, stating that any action the organizations might take would be voluntary, and, therefore, no different from the action of any other public citizen concerned with protecting animals. *Id.* For the purposes of standing, the plaintiff's injury must be concrete and not merely a generalized grievance that all United States citizens share. *See* Schlesinger v. Reservists to Stop the War, 418 U.S. 208, 220 (1974) (holding that plaintiffs' status as United States citizens was not sufficient to confer standing and that injury must be more individualized).

The Federal Circuit recognized, however, that other courts have found the type of injury alleged by ASPCA and MHS to be sufficient. *ALDF*, 932 F.2d at 936. In support of their position, the ALDF cited Washington Util. & Transp. Comm'n v. FCC, 513 F.2d 1142, 1154 n.17 (9th Cir. 1975) (holding that federal statute imposing voluntary obligation on association of regulatory utility commissioners was sufficient to distinguish association from members of general public) and Humane Soc'y of Rochester v. Lyng, 633 F. Supp. 480, 485 (W.D.N.Y. 1986) (granting standing to animal rights group because it was specifically authorized under state law to prosecute violations of animal cruelty laws). The court in *ALDF* presumed that these allegations were sufficient to meet the injury requirement for standing. *ALDF*, 932 F.2d at 936.

142. *ALDF*, 932 F.2d at 936 (quoting *Sierra Club*, 405 U.S. at 739) (suggesting that real interests of organizations cannot be distinguished from interests of individuals, so groups should not be allowed to litigate where individual members cannot); *see* Simon v. Eastern Ky. Welfare Rights Org., 426 U.S. 26, 40 (1976) (reiterating that established precedent makes clear that organization's abstract concern with subject that could be affected by adjudication is insufficient for concrete injury requirement).

Recently, other courts have denied standing to animal rights groups on the grounds that the groups did not allege an injury sufficiently distinct from that of the general public. *See*

Since the district court granted the defendants' motion to dismiss for failure to state a claim, the Federal Circuit had to assume the truth of the injury, even though the alleged injury of the animal rights groups was clearly insufficient to achieve standing.[143] Turning then to the element of causation, the court determined that the injury alleged by the animal rights groups was not "fairly traceable" to the Commissioner's interpretation of section 101.[144] The court reasoned that the need for the independent actions of third parties to invent and prosecute animal patent applications severs any link between ALDF's injury and the Commissioner's action.[145] The court determined that the animal rights groups must be denied standing because the alleged injury required the additional acts of third parties.[146]

b. The farmers

Individual farmers and farming associations comprised another group of plaintiffs in *ALDF*.[147] The farmers alleged that the Commissioner's interpretation of section 101 caused them economic injuries by forcing them to pay increased costs in the form of royalties on patented transgenic animals and by decreasing their profits due

---

International Primate Protection League v. Administrators of the Tulane Educ. Fund, 895 F.2d 1056, 1060 (5th Cir. 1990) (denying animal rights group standing, finding that sincere commitment to care and welfare of animals is insufficient to distinguish group from other members of public); Animal Lovers Volunteer Ass'n v. Weinberger, 765 F.2d 937, 939 (9th Cir. 1985) (refusing to grant animal rights group standing because of failure to distinguish its concern from general public's distaste for cruelty to animals).

143. *ALDF*, 932 F.2d at 922, 925. The district court, pursuant to Federal Rule of Civil Procedure 12(b)(6), granted the defendants their motion to dismiss. *Id.* Both the trial and reviewing courts must, for the purposes of ruling on a motion to dismiss for want of standing, "accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party." *Id.* (quoting Warth v. Seldin, 422 U.S. 490, 501 (1975)).

144. *Id.* at 937. The court also held that ASPCA and MHS failed to allege a "fairly traceable" causal connection between their alleged injury and the Commissioner's action. *Id.*

145. *Id.*

146. *Id.* In addition, the court rejected the ALDF's claim that the potential for patent protection would lead to increased animal cruelty. *Id.* The court maintained that for increased experimentation to lead to increased cruelty, ALDF would have had to allege either that the existing animal cruelty laws are insufficient or that the granting of animal patents would "encourage" researchers to disobey animal cruelty laws. *Id.* The court refused to speculate that the Commissioner's Rule would cause researchers to disregard existing applicable animal protection laws. *Id.*

The Supreme Court has repeatedly denied standing to litigants in cases where the link between the alleged injury and the asserted cause of that injury required the Court to anticipate the actions of third parties. *See id.* (citing Los Angeles v. Lyons, 461 U.S. 95, 102-03 (1983) (denying plaintiff standing to seek an injunction against future use of "choke holds" by Los Angeles Police); O'Shea v. Littleton, 414 U.S. 488, 496-97 (1974) (holding that plaintiff lacked standing where alleged injury was anticipated of prosecution for planned violation of lawful criminal statutes)).

147. These plaintiffs included the Wisconsin Family Farm Defense Fund (WFFDF), the Humane Farming Association (HFA), as well as individual farmers, John Kinsman, and Michael Cannell. *ALDF*, 932 F.2d at 931-32.

to their inability to compete in the production of such animals.[148] As with the animal rights groups, the court had to assume the truth of the farmers' claims, thus establishing that the farmers suffered a judicially cognizable personal injury.[149]

In attempting to establish causation, the farmers cited cases recognizing that an injury could result from government action affecting the acts or decisions of a third party who then either caused, or threatened to cause, injury to the plaintiff.[150] In response to this claim, the defendants contended that the plaintiffs' injury was speculative, as it depended upon the independent actions of third parties and was therefore not controlled by government action.[151] The court agreed with the defendants and found that the alleged injury was not "fairly traceable" to the defendants' actions.[152]

The court also rejected as speculative the farmers' claim that they

---

148. *Id.* at 932. Specifically, the farmers alleged that the high price of "patented" animals would be beyond their economic reach, relegating them to the production of genetically inferior, less profitable "unpatented" animals. *Id.* Additionally, they argued that the increase in livestock productivity and decrease in herd size would cause a significant reduction in the number of small farms, negatively impacting their communities and accelerating farm consolidation. *Id.* The farmers claimed that the development of patented animals would eventually drive them out of business altogether. *Id.*; *see supra* notes 110-16 and accompanying text (providing more detailed discussion of farmers' opposition to transgenic animal patents).

149. *ALDF*, 932 F.2d at 932.

150. *Id.* The plaintiffs cited two Supreme Court cases in support of this point: Blum v. Yaretsky, 457 U.S. 991, 996 n.6, 999-1001 (1982) (holding that Medicaid patients in skilled nursing facility had standing to sue state because of utilization review committee's decision to transfer plaintiffs to lower level of care in health-related facility) and United States v. SCRAP, 412 U.S. 669, 686-90 (1973) (holding that environmental group's claim that higher railroad freight rates would result in increased use of nonrecyclable containers and more litter in Washington-area parks had standing to sue to keep railroad charges low). *ALDF*, 932 F.2d at 932.

The Federal Circuit, however, claimed that *Blum* and *SCRAP* did not in fact support the plaintiffs' position on standing. *Id.* at 935. The court distinguished the alleged injury in *Blum* from the injury at issue in *ALDF* by stating that the injury in *Blum* was certain, only delayed, as opposed to the mere speculative possibility of injury alleged in *ALDF*. *Id.* The court in *ALDF* maintained that although the injury in *SCRAP* was indirect, the complaint in *SCRAP* alleged specific harm flowing from the agency action of approving a freight rate increase.

151. *ALDF*, 932 F.2d at 932. In support of their point, defendants relied on *Simon v. Eastern Kentucky Welfare Rights Organization*, in which the Court rejected the plaintiffs' standing argument because their alleged injury required "speculative inferences" to connect it to the challenged governmental action. Simon v. Eastern Ky. Welfare Rights Org., 426 U.S. 26, 45 (1976).

152. *ALDF*, 932 F.2d at 932-33. In addition, the farmers advanced a second causation argument. They argued that their injuries could be "fairly traced" to the encouragement of third party research and development due to the availability of patent protection. *Id.* at 934. The court rejected this argument, concluding that such "encouragement" was entirely speculative. *Id.* (citing *Simon*, 426 U.S. at 44) (denying standing to litigants when "unadorned speculation" was required to link alleged injury to defendant's action)). In reaching this conclusion, the court emphasized the indirect nature of the farmers' alleged injuries. *See id.* at 933 (highlighting that, at minimum, farmers' injuries depended on issuance of patent requiring: inventor's development of novel, transgenic, nonnaturally occurring animal (specifically, farm animal); inventor's decision to file for patent application for animal, rather than, for example, maintaining discovery as trade secret; and ultimate successful prosecution of such patent).

would be forced to pay increased royalties as a result of the availability of animal patents.[153] The court reasoned that farmers could not be forced to purchase the transgenic animals and pay royalties on them.[154] Similarly, the court rejected the plaintiffs' contention that their costs of operation would increase as a result of such royalties as equally speculative.[155] The court noted that the ability of a market participant to affect the price of patented animals depends upon whether competitive patented or unpatented animals are available.[156] Because the court would need to engage in this type of market speculation to link the plaintiffs' injury to the defendant's action, the court held that the farmers failed to show a sufficient line of causation for the purposes of standing.[157]

In addition, the court determined that the farmers' claims had redressability problems.[158] Judge Nies explained that the farmers' alleged injury from increased competition could only result from the development and commercialization of transgenic animals, not merely from the grant of a patent.[159] Therefore, the court reasoned that enjoining the issuance of animal patents would not prevent their development.[160] Finally, the court denied the plaintiffs' standing because they failed to meet the standing requirements imposed under Article III of the United States Constitution.[161]

---

153. *Id.* at 934.

154. *Id.*

155. *Id.*

156. *Id.* (citing inter alia, A.I. Root Co. v. Computer/Dynamics, Inc., 806 F.2d 673, 676 (6th Cir. 1986) (explaining that patent owner has no market power if close substitutes exist for patented product in relevant market)).

157. *ALDF*, 932 F.2d at 934-35 (asserting, in addition, that there is no legal right to be free from market competition with improved animals).

158. *Id.* (arguing that refusal to grant patents for improved animals will not eliminate risk of increased competition); *supra* note 139 (indicating that plaintiffs' showing of redressability of injury is necessary element of standing under Article III of Constitution).

159. *ALDF*, 932 F.2d at 935.

160. *Id.* (citing Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980) ("The grant or denial of patents . . . is not likely to put an end to genetic research or its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown . . . ."). *See generally infra* note 197 and accompanying text (expanding on argument that transgenic animal patent opponents' objection to animal patents is misplaced, as it actually concerns objections to biotechnological research itself).

161. *ALDF*, 932 F.2d at 939. In addition to the three well-established requirements for standing, the Supreme Court has further limited standing to those parties within the "zone of interests" of a particular statute. *See* Lujan v. National Wildlife Fed'n, 110 S. Ct. 3177, 3186 (1990) (citing Clarke v. Securities Indus. Ass'n, 479 U.S. 388, 396-97 (1987)) (holding that plaintiff must establish that injury complained of falls within "zone of interests" sought to be protected by statutory provision whose violation forms legal basis of complaint). The plaintiffs in *ALDF* claimed that they fell within the "zone of interests" protected by either the APA or the patent laws generally. *ALDF*, 932 F.2d at 937. First, the plaintiffs argued that section 706(2)(C) of the APA itself was the "relevant statute" under section 702 of the APA. *Id.* Section 702 of the APA gives standing to any person "adversely affected or aggrieved by an

3. *How the Federal Circuit interpreted the APA notice requirement in* ALDF

One count of the plaintiffs' complaint alleged that the Commissioner of the PTO violated the APA by failing to comply with the notice and comment provisions before adopting the 1987 Rule.[162] Furthermore, the plaintiffs argued that upon notice of the Rule's issuance, the Commissioner failed to state the basis and purpose of the Notice for the proposed Rule within the parameters of the APA.[163] The Federal Circuit held that the Rule was "interpretative," and thus exempt from the APA's public notice and comment requirements.[164] The court reasoned that the "genesis and effect"

---

agency action within the meaning of the relevant statute." 5 U.S.C. § 702 (1988). The court in *ALDF* rejected this argument, looking to Supreme Court cases for guidance on the meaning of "relevant statute" in section 702 of the APA. *See ALDF*, 932 F.2d at 937 (citing *Lujan*, 110 S. Ct. at 3187 (rejecting plaintiff's attempt to rely on section 706 as "relevant statute" and defining relevant statute as "the statute whose violation is the gravamen of the complaint")). *See also* Air Courier Conference of Am. v. American Postal Workers Union, 111 S. Ct. 913, 918-20 (1991) (suggesting that, in determining meaning of "relevant statute," courts should look to Congress' intent in enacting statute and history of legislation).

Second, the plaintiffs claimed that they fell within the "zone of interests" of section 553 of the APA (notice and comment provision). *ALDF*, 932 F.2d at 937-38. The court rejected this argument as well, relying on Capitol Legal Foundation v. Commodity Credit Corp., 711 F.2d 253, 260 (D.C. Cir. 1983), which held that the plaintiffs were not injured by not having the benefit of section 553 notice and comment. *ALDF* at 937-38. The court in *Capitol Legal Foundation* reasoned that if it was to accept the plaintiff's claim of injury,

> every asserted violation by an agency of its own regulations could be recharacterized as '*de facto* rulemaking' outside the APA, and therefore arguably open to challenge as procedurally-flawed by any person who claims he, she, or it would have participated had the rulemaking occurred inside the APA. We are certain that Congress, in adopting the APA, had no such universal standing design in mind . . . ."

711 F.2d at 260.

Finally, the plaintiffs claimed that they fell within the "zone of interests" addressed by the patent laws. They argued that patents "are issued not for private benefit but for the public good" and that "[p]atent case law emphasizes the importance of the public interest and the constitutional requirement of a public benefit." *ALDF*, 932 F.2d at 938. The court fervently struck down this argument, charging that the patent statute's "zone of interests" does not envelop any member of the public who anticipates harm from an issued patent. *Id.* The court emphasized that the "zone of interests" of the patent is not nearly as broad as the plaintiffs claimed it to be. *Id.* The court urged that if it accepted this overly broad interpretation of the "zone of interests" of the patent statute, it would be "opening the door to collateral attack" on the validity of all issued patents, which it refused to do. *Id.* The court noted that if it did adopt such a sweeping interpretation, any competitor could simply file suit against the Commissioner, challenging a patent's validity. *Id.* Thus, the court held that because none of the plaintiffs fell within the "zone of interests" of any "relevant statute," they lacked standing to bring the suit. *Id.* at 938-39.

162. *ALDF*, 932 F.2d at 925, 926-27.

163. *Id.*; *see supra* note 123 (setting forth provisions of APA regarding notice and comment requirements for agency rulemaking.

164. *ALDF*, 932 F.2d at 927. In responding to this particular claim, the court did not distinguish between the two different kinds of plaintiffs (animal rights groups and farmers), but rather treated all nine litigants as one group. *Id.* at 926. In contrast, the court addressed each of the two groups separately for the purpose of determining whether the plaintiffs had standing. *Id.* at 931-39; *see supra* notes 134-61 and accompanying text (detailing court's discussion of standing for animal rights groups and farmers, respectively).

Rules that are deemed "substantive" are subject to the requirements of the notice and com-

of the notice demonstrated that it represented no change in the law and was, in fact, merely "interpretative" of prior decisional precedent.[165] In arriving at this conclusion, Chief Judge Nies traced the progressive expansion of section 101 to encompass nonnaturally occurring, nonhuman, multicellular organisms, including animals.[166] She found that the Rule clearly corresponds to the interpretations of section 101 as set forth by the Board in *Ex parte Hibberd*[167] and *Ex parte Allen*,[168] in reliance upon *Diamond v. Chakrabarty*,[169] and, therefore, constituted no change in the law by the Commissioner.[170]

ALDF argued that the Rule was "substantive" because it reversed the PTO's long standing policy of considering animals as outside the parameters of patentable subject matter.[171] The court rejected this argument, claiming that it failed to recognize the actions of the Patent Appeals Board as independent from those of the Commissioner.[172] Judge Nies explained that the plaintiffs sought to tie the

---

ment provisions of the APA. Powderly v. Schweiker, 704 F.2d 1092, 1098 (9th Cir. 1983). Rules which are "interpretive," however, are exempt from these provisions. 5 U.S.C. § 553(b)(A) (1988).

In determining whether a rule is interpretive or substantive, two factors must be considered. *See* W.C. v. Bowen, 807 F.2d 1502, 1504 (9th Cir. 1987) (setting forth analysis used in distinguishing interpretative from substantive rules). The first factor is whether the rule modifies existing rights, law, or policy. *Id.*; *see* Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979) (asserting that substantive rule "affect[s] individual rights and obligations"); *Powderly*, 704 F.2d at 1098 (explaining that, if rule "effect[s] a change in existing law or policy," it is substantive). If, on the other hand, the rule is only indicative of the agency's "clarif[ication] or expla[nation] of existing law or regulations," it is interpretive. *See* Alcaraz v. Block, 746 F.2d 593, 613 (9th Cir. 1984) (quoting *Powderly*, 704 F.2d at 1098). Second, the source of the rule must be taken into account. *See Bowen*, 807 F.2d at 1504 (maintaining that, if agency does not exercise delegated legislative power to promulgate rule, it is interpretative); Cubanski v. Heckler, 781 F.2d 1421, 1426 (9th Cir. 1986) (concluding that if rule is promulgated pursuant to statutory direction or under statutory authority, it is substantive), *vacated as moot*, 485 U.S. 386 (1988). For a more detailed discussion of the "interpretative/substantive" distinction, see Burke, *supra* note 118, at 420-26.

165. *ALDF*, 932 F.2d at 927.

166. *Id.*

167. 227 U.S.P.Q. 443 (Bd. Pat. App. & Int. 1985); *see supra* notes 63-67 and accompanying text (discussing *Hibberd* and its impact on patent statute).

168. 2 U.S.P.Q.2d 1425 (Bd. Pat. App. & Int. 1987); *see supra* notes 68-76 and accompanying text (outlining *Allen* decision).

169. 447 U.S. 303 (1980); *see supra* notes 44-59 and accompanying text (describing *Chakrabarty* holding in detail).

170. *ALDF*, 932 F.2d at 927-28 (pointing out that, in first paragraph of Rule, Commissioner summarizes decisional law of these cases, specifically tracking history and language of *Allen*).

171. *Id.* at 928.

172. *Id.* at 928-29. Judge Nies vigorously attacked this contention:

> This argument at best merely ignores the Board's intervening interpretation of section 101 made in its *Allen* and *Hibberd* decisions and at worst treats the Board as the alter ego or agent of the Commissioner which it is not. If this were the case, the Board's decision in *Allen* would effectively be a decision by the Commissioner, and the Commissioner could not properly consider the Notice as "interpretative" of that decision.

Id. at 928.

Board's authority to adjudicate issues of patentability to the Commissioner's statutory grant of rulemaking.[173] To the contrary, the court found that the Board's authority to review section 101 issues rests on an independent federal statutory grant and does not arise from the Commissioner's power to promulgate regulations.[174] Judge Nies concluded, therefore, that although the Commissioner may interpret a PTO ruling, the Board's authority is distinct and independent from the Commissioner's.[175]

ALDF further contended that the Rule is "substantive" because it cuts off the agency's discretion to deny applications for animal patents during prosecution.[176] The plaintiffs argued that, under *W.C. v. Bowen*,[177] substantive rules are rules that significantly limit an agency's discretion.[178] In this case, the plaintiffs claimed, the agency is "significantly limited" as the Rule binds agency personnel while removing the discretionary powers of the PTO examiners to reject an animal patent application.[179] The court rejected this argument, maintaining that the plaintiffs read *Bowen* too broadly.[180] Judge Nies explained that a limitation of discretion is not sufficient to make an agency action "substantive."[181] Rather, she explained that the dispositive characteristic of a substantive rule is a resultant limitation on an individual's rights and obligations.[182] The court claimed, therefore, that the relevant question in this case was whether any limitation on an examiner's ability to reject patent applications, based on section 101, would adversely affect any individual's existing rights and obligations.[183]

The court found that ALDF failed to raise any adverse effects to

---

173. *Id.*

174. *Id.* at 929 (citing 35 U.S.C. § 7(b) (1988)). The statute provides in relevant part: "The Board of Patent Appeals and Interferences shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents and shall determine priority and patentability of invention in interferences declared under section 135(a) of this title." 35 U.S.C. § 7(b) (1988). In addition, the court stated that the Commissioner, when sitting on the Board, has no greater voice than any other Board member. *ALDF*, 932 F.2d at 929 n.10 (citing 35 U.S.C. § 7(a) (1988)).

175. *ALDF*, 932 F.2d at 929.

176. *Id.*

177. 807 F.2d 1502 (9th Cir. 1987).

178. *ALDF*, 932 F.2d at 929 (quoting W.C. v. Bowen, 807 F.2d 1502, 1505 (9th Cir. 1987)).

179. *ALDF*, 932 F.2d at 929.

180. *Id.*

181. *Id.*

182. *Id.* (citing *Bowen*, 807 F.2d at 1505). The court in *Bowen* found that because a limitation on the discretion of the Secretary of Health and Human Services in reviewing various Administrative Law Judge decisions adversely affected certain individuals' asserted rights to Social Security disability benefits, the rule was substantive. *Id.*

183. *ALDF*, 932 F.2d at 929. The APA provides the framework to determine the requirement of an "adverse affect" to a party. *Id.* at 930 (citing 5 U.S.C. §§ 552a, 702).

any individual's rights stemming from the patent statute.[184] ALDF contended that the general public has an interest in the statutory limitations to patentability.[185] According to the court, the plaintiffs were asserting a right, as members of the public concerned with the welfare of animals, to bring suit to prevent an unwarranted interference with the discretionary judgment of an examiner.[186] The court rejected this argument, stating that the determination of whether animal patents will be issued is not a matter of discretion, but is a matter of law.[187] The court did not, therefore, deem the Rule to be substantive, as it did not adversely affect the existing rights and obligations of any individual.[188]

---

184. *ALDF*, 932 F.2d at 929.

185. *Id.*

186. *Id.*

187. *Id.* (citing Graham v. John Deere Co., 383 U.S. 1, 17 (1965) ("[U]ltimate question of patent validity is one of law . . ."); *see* A & P Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 155 (1950) (asserting that standard of patentability is constitutional standard governed by law). Accordingly, in *ALDF*, the Federal Circuit concluded that the Commissioner's Rule has no bearing on the final validity of any patent. *ALDF*, 932 F.2d at 929-30. The court stated that the patent examiner merely determines whether a given subject matter fits within the scope of patentable subject matter. *Id.* at 930. Thus, the court concluded that the individual discretion of the examiner does not factor into the process. *Id.*

188. *ALDF*, 932 F.2d at 929-30 & n.11 (concluding that patent validation process, with hierarchy of review, does not substantially affect any individual's rights). Nor did the court find that the Rule "affect[ed] existing rights and obligations" of patent applicants. *Id.* at 930. The court interpreted the effect of the Notice, if mandatory, to mean that examiners will abstain from issuing a section 101 rejection, but that the examiner's decision not to reject a proposed patent would not "adversely affect" the patent applicants. *See id.* (explaining that, if examiner does not file rejection on patent, patent issues and final outcome of invalidity of claims is postponed until challenged in court and also reasoning that such deferral of determination of patent's validity does not adversely affect legal rights of applicant).

ALDF advanced another argument that rules promulgated pursuant to a statutory grant have a "legislative" effect, since they "carry the force and effect of law," and are therefore "substantive" for the purposes of section 553. *Id.* Based on this theory, ALDF asserted that the Rule must have been promulgated by the Commissioner under his authority in 35 U.S.C. § 6 to "establish regulations." *ALDF*, 932 F.2d at 930. The court rejected this argument, claiming that the Commissioner did not invoke his statutory grant of section 6 authority in issuing the Rule. *See id.* (pointing out that authority granted in section 6 is directed to "conduct of the proceedings" before Office and not "establishment of regulations," as plaintiffs alleged). The court continued by arguing that the Commissioner's "substantive declaration" on the patent statutes is distinct from typical agency interpretation of statutes. *Id.*; *see* General Elec. Co., Inc. v. Gilbert, 429 U.S. 125, 141-42 (1976) (holding that agency need not have statutory authority to issue guidelines, but guidelines do not have force of law); H. Walmsley, *The Rulemaking Power of the Commissioner of Patents and Trademarks (Part 2)*, 64 J. PAT. OFF. SOC'Y 539, 541 (1982) (maintaining that notices published in PTO's weekly *Official Gazette* are not deemed to have "force and effect of law").

The court rationalized that even if the Commissioner did issue the Rule under section 6 authority, it does not automatically follow that the Rule is "ipso facto 'substantive'." *ALDF*, 932 F.2d at 931. The court reasoned that accepting this argument of the plaintiffs' would mean that every action taken by an agency pursuant to statutory authority would be subjected to section 553's public notice and comment requirement. *Id.* Such a result, the court claimed, would invalidate the statutory exceptions in section 553 and would eliminate the "interpretative" exception. *Id.* The court, therefore, refused to endorse this interpretation of section 553. *Id.* (citing Colautti v. Franklin, 439 U.S. 379, 392 (1979)) (reiterating well-established rule of statutory interpretation that one section of statute must not be interpreted so as to

Having rejected all of ALDF's arguments regarding the notice requirement, the court held that the Commissioner's Rule was "interpretative" of prior precedent, and thus fell within the exception to the notice and comment requirements of the APA.[189] In light of this determination, the court concluded that the plaintiffs did not have standing to assert the "procedural harm" portion of their claim.[190]

IV. IMPACT OF THE FEDERAL CIRCUIT'S OPINION

A. Validity of Plaintiffs' Claims

1. The claim of the animal rights groups

The Federal Circuit's denial of standing to the animal rights groups in *ALDF* was warranted because the groups offered no factual basis for their claim that the issuance of patents would result in increased animal suffering.[191] In fact, the patenting of animals fails to raise any novel animal cruelty issues.[192] Animal patent advocates contend that potential harmful elements of animal patenting already

---

render any part inoperative). The court in *ALDF* stated that even if the basis for the agency action arose from a statutory grant, it would not be compelled to conclude that the notice is "substantive." *ALDF*, 932 F.2d at 931.

189. *ALDF*, 932 F.2d at 931. Additionally, the court noted that the plaintiffs were attempting to intervene as third parties in the prosecution of all animal patent applications. *Id.* at 930. The court stated that no law would give the plaintiffs the right to intervene in the prosecution of another's patent. *Id.* (citing Syntex (U.S.A.) Inc. v. United States Patent and Trademark Office, 882 F.2d 1570, 1574-75 (Fed. Cir. 1989)) (concluding that to infer that Congress intended to grant third parties right to judicial review of PTO's final reexamination decisions is "wholly unwarranted," and refusing to infer right or remedy in third party to challenge result favorable to patent owner after ex parte prosecution because it would be unprecedented); Yuasa Battery Co. v. Commissioner of Patents and Trademarks, 3 U.S.P.Q.2d 1143, 1144 (D.D.C. 1987) (urging that statutory provisions for reexamination do not provide for judicial review of decision rendered in reexamination proceeding for any party other than patent owner). In light of the precedent cited above, the court in *ALDF* concluded that the mere fact that the plaintiffs were making a "broadside attack gives no greater right of intervention against all than against one." *ALDF*, 932 F.2d at 930; *see also infra* notes 217-18 and accompanying text (exploring ramifications of this argument on questions of standing of future litigants challenging validity of animal patents).

190. *ALDF*, 932 F.2d at 931 (determining that court's conclusion that Rule was "interpretative" necessarily moots any further question of standing as to plaintiff's procedural claim).

191. *See id.* at 936 (holding that ALDF did not show that PTO's 1987 rule, which allowed issuance of transgenic animal patents, would likely serve to increase animal cruelty); *see also Hearings on H.R. 1556*, *supra* note 1, app. 2 at 477 (emphasizing lack of proof brought forth by animal rights groups in arguing that patenting of animals will lead to increased animal suffering); *supra* note 89 (presenting claims by animal patent advocates that advances in transgenic research will actually serve to decrease animal suffering, by engineering animals that are resistant to disease).

192. *See Patent Hearings*, *supra* note 42, at 120 (statement of Dr. A. Ann Sorensen, Assistant Director, Natural & Environmental Resources Division) (acknowledging that, while manipulation of animal life is troubling moral issue, it is not new problem); *cf.* King, *supra* note 115, at 657 n.31 (attacking argument of animal rights groups against animal patenting, on grounds that there is no logic behind assertion that patented animals will be mistreated more frequently than nonpatented animals).

exist in traditional breeding methods used in agriculture.[193] Realistically speaking, our society determined long ago that it is acceptable to sacrifice the welfare of animals in order to obtain benefits for human beings.[194] Moreover, humans have long treated animals as personal property by buying them, selling them, and keeping them as pets.[195] The moral reasons that these animal rights groups set forth should not, therefore, prevent the patenting of animals.

As the Federal Circuit realized in *ALDF*, transgenic research is bound to proceed, regardless of whether animal patents are issued.[196] Thus, the animal rights groups' objections are not directed specifically to the issue of whether patents should be granted for transgenic animals, but bear on the much broader issue of whether transgenic research should be allowed at all.[197] Prohibiting animal patents, therefore, is an ineffective approach to protecting the welfare of animals.[198]

a. Patent laws should not be used to express moral views

Although the protection of animal welfare is an important issue, it

193. *See* Dresser, *supra* note 14, at 423 (stating that animals have traditionally been bred to express certain desired traits to their detriment, such as turkeys with breasts so large they cannot mate and veal calves that are confined for their entire lives in tiny stalls that greatly inhibit their movement); *see also Patent Hearings*, *supra* note 42, at 303 (statement of Michael S. Ostrach, Senior Vice President and General Counsel, Cetus Corp.) (maintaining that transgenic research does not present issues more contentious or different than those already implicated in traditional breeding practices).

194. *See* Lauroesch, *supra* note 23, at 114 (stressing that people have traditionally used animals to benefit themselves for food, transportation, labor, and testing of potentially harmful drugs); *Patent Hearings*, *supra* note 42, at 525 (statement of Iver P. Cooper, Patent Counsel, The Association of Biotechnology Companies) (stressing that it is "hypocritical" to object to patenting of animals while society traditionally exploits animals).

195. *See* Lauroesch, *supra* note 23, at 115 (stressing that it would be inconsistent to deny "intellectual property rights" over transgenic animals when personal property rights have historically been recognized in naturally occurring animals); Dresser, *supra* note 14, at 413 (declaring that humans have long "objectified" animals); Raines, *supra*, note 22, at 68 (remarking that nobody has yet distinguished difference between owning patented animal and unpatented animal). *See generally* Pierson v. Post, 3 Cai. R. 175 (N.Y. Sup. Ct. 1805) (holding that one can acquire property rights in wild animals by taking exclusive possession).

196. *ALDF*, 932 F.2d at 936; *see supra* note 160 (stating that in *Chakrabarty*, Court argued that grant or denial of patents for microorganisms is not likely to halt genetic engineering research); *see also* Bradford Chaucer, Note, *Life, the Patent Office and Everything: Patentability of Lifeforms Created Through Bioengineering Techniques*, 9 U. BRIDGEPORT L. REV. 413, 440 (1988) (asserting that critics of genetic engineering are mistaken in believing that lack of patent protection will halt research in field).

197. *See* Kulseth, *supra* note 100, at 709 (stressing that transgenic experimentation and not animal patenting is real focus of opposition in present controversy); Kambic, *supra* note 61, at 459 (asserting that animal patent opponents' concerns about process stem from potential repercussions of biotechnological research and not patenting process).

198. *See Patent Hearings*, *supra* note 42, at 437-40 (statement of Geoffrey M. Karny, Esq.) (urging that concerns about animal welfare would best be addressed by regulation and not by moratorium on animal patents); *supra* notes 139-46 and accompanying text (setting forth court's assessment in *ALDF* of causation problems for standing purposes inherent in animal rights groups' arguments).

does not belong in the patent law forum. Patent laws have not typically been amended to answer any of the kinds of ethical or moral concerns voiced by the animal rights groups.[199] Instead, the United States patent system hinges on a principle of neutrality, whereby the system neither supports nor discriminates against technologies.[200] Patents for transgenic animals should not be prohibited simply because they may entail risk.[201] Patents have issued for many inventions, including guns, slot machines, cattle prods, and abortion-related instruments, despite the fact that they arguably may be immoral.[202] Policymakers control the risks associated with any particular technology through regulation, not patent law.[203] Moreover, the goals of the patent system differ from the goals of regulation concerned with technological risks.[204] Congress created the patent system to promote technological research and innovation for the

---

199. *See, e.g.*, PATENT REFORM ACT, *supra* note 8, at 62 (providing House Judiciary Committee's conclusion that animal welfare laws, not patent laws, are best suited to protect animals); *Hearings on H.R. 1556*, *supra* note 1, at 71 (statement of Steven Holtzman, Vice President for Corporate Development, DNX, Inc.) (noting that patent system has traditionally not been forum for airing philosophical and moral objections to patents); Merges, *supra* note 41, at 1067-68 (charging that patent forum is not appropriate place to address moral concerns about developing technologies); Kulseth, *supra* note 100, at 710 (asserting that Congress' purpose in enacting patent statute does not embrace morality, but originality of inventions). The PTO was never intended to enforce ethical principles other than deterring applicant fraud on the PTO. *See* 35 U.S.C. §§ 31-33 (1988) (regulating conduct of agents and attorneys before PTO).

200. *See, e.g., Hearings on H.R. 1556*, *supra* note 1, at 96 (statement of Donald S. Chisum, Professor, University of Washington School of Law) (emphasizing that patent system does not establish distinct guidelines to promote any one technology or industry, and that this objectivity is consistent with system's goals of promoting research and disclosure of information); *Patent Hearings*, *supra* note 42, at 182 (testimony of Robert P. Merges, Professor, Columbia School of Law) (claiming that patent system is not correct forum for weighing technologies); Kulseth, *supra* note 100, at 710 (arguing that patent system should remain ethically neutral). *But see infra* notes 207-12 and accompanying text (discussing Congress' prohibition of patents for nuclear weapons technology).

201. *See* Dresser, *supra* note 14, at 404 (interpreting decision in *Chakrabarty* as expressing judicial refusal to allow potential dangers found in invention to restrict granting of patent and suggesting that patent law is predicated on concept that technological advances are for public good).

202. *See Hearings on H.R. 1556*, *supra* note 1, at 71 (statement of Steven Holtzman, Vice President for Corporate Development, DNX, Inc.) (commenting that government does not forbid patenting of other morally suspect inventions). *See generally* Merges, *supra* note 41, at 1062-66 (tracing history of patenting of "immoral" inventions). Merges emphasizes that society's moral norms, as well as the courts' perceptions of those norms evolve and relax over time. *Id.* at 1064. He cites society's reaction to birth control devices as illustrating this point. *Id.* For instance, birth control devices, once considered illegal, have reached a position of widespread acceptance as a means to control population growth. *Id.* at 1064-65. Merges thus reasons that "in determining 'utility' based on public mores, the courts should apply a test which will not penalize an inventor who may be prescient enough to be anticipating basic needs of a society changed by forces yet unrecognized by the general public. . . ." *Id.* at 1065 (quoting R. CHOATE, CASES AND MATERIALS ON PATENT LAW 76 (3d ed. 1987)).

203. *See* Raines, *supra* note 22, at 67 (asserting that Congress did not design patent system to replace regulatory system); *see also* PATENT REFORM ACT, *supra* note 8, at 62 (urging that Patent Office not be asked "to act as a health and safety regulatory agency").

204. *See Patent Hearings*, *supra* note 42, at 433 (statement of Geoffrey Karny, Esq.) (stating

benefit of society.[205] Regulation, however, is designed to control the risks of technological innovation by monitoring the introduction of patented inventions into society.[206]

The legislature has on one occasion, however, excluded a form of otherwise patentable subject matter when, in 1954, Congress enacted a prohibition on the patenting of nuclear weapons technology.[207] Congress believed that patent availability for nuclear weapons technology posed grave danger to national security and thus necessitated the enactment of the prohibition.[208] Animal rights opponents have tried to draw analogies between the threatened dangers of transgenic research and those of nuclear weapons technology.[209] This argument lacks merit, however, as the inherent risks of the two technologies differ dramatically. Nuclear weapons technology has direct, proven dangers, whereas transgenic research, at present, creates only speculative risks.[210] National security was the main motivation behind Congress' prohibition of patenting nuclear weapons technology, not morality.[211] Moreover, biotechnology has many beneficial uses and the implementation of regulatory measures could adequately control its risks.[212]

---

that goal of patenting is to "stimulate technological advancement," while goal of regulation is to safeguard public interest).

205. *See supra* notes 25-39 and accompanying text (setting forth goals of patent system and requirements of patent statute).

206. *See Patent Hearings*, *supra* note 42, at 433-35 (statement of Geoffrey Karny, Esq.) (maintaining that regulatory agencies focus on amount of danger particular product may pose to public and, if perceived risks of product are unacceptable or greater than product's benefits, regulatory system will prohibit or restrict release of product).

207. 42 U.S.C. § 2181(a) (1988).

208. *See* Dresser, *supra* note 14, at 404 (discussing underlying motivation of nuclear weapons patent prohibition and explaining that Congress decided to take such action after concluding that public would not benefit, but would probably be harmed, if patent protection was afforded to this technology); *see also* Sease, *supra* note 84, at 571 (claiming that prohibition on patents for nuclear weapons technology has effectively reduced threat of misuse of nuclear weapons research in private industry). *But see In re* Brueckner, 623 F.2d 184, 187 (C.C.P.A. 1980) (holding that prohibition is to be interpreted narrowly, only applying to nuclear technology innovations that have no function other than as atomic weapons); Sease, *supra* note 84, at 571 (recognizing that nuclear technology has beneficial uses and that limited patents in this area, namely for nuclear energy, are granted).

209. *See* Dresser, *supra* note 14, at 404 (commenting that opponents of animal patents find potential dangers gene-manipulation technology as great as threat posed by nuclear weapons).

210. *See* S. MCAULIFFE & K. MCAULIFFE, LIFE FOR SALE 180 (1981) (quoting Zsolt Harsanyi of the Office of Technology Assessment) (asserting that dangers associated with two technologies are substantially different, in that nuclear research has "demonstrable hazard" of radiation while biotechnology has only "conjectural risks").

211. *See* Merges, *supra* note 41, at 1067 (distinguishing Congress' reason for placing prohibition on nuclear weapons technology from rationale to enact similar prohibition against biotechnological innovations).

212. *See* Dresser, *supra* note 14, at 404 (rebutting arguments in favor of prohibiting animal patents and arguing that risks associated with transgenic research would be more easily curbed through regulatory system than could risks of nuclear weapons technology); *see also*

2. The claim of the farmers and farm groups

Although the farmers' and the farm groups' claim of economic injury was stronger and more tangible than that of the animal rights groups, it was still highly speculative. Therefore, the court's determination that the farmers' injury was inadequate for purposes of standing was correct.[213] Considering that a patent is yet to be issued for a transgenic farm animal,[214] the timing of *ALDF* was premature for the farmers. Recent congressional action aimed toward enacting a farmers' exemption from paying royalties for breeding patented animals lends credence to the farmers' claims that they will suffer economic injuries once patents for these animals are granted.[215] Lobbying Congress for the enactment of such legislation is a better solution for the farmers than is seeking relief through the judiciary, due to the lack of ripeness and concrete injury that the court addressed in *ALDF*.[216]

B. After ALDF: *Who Could Have Brought the Suit?*

One logical question remains after *ALDF*: who would have standing to challenge the PTO's 1987 rule? Under the Federal Circuit's reasoning in the *ALDF* case, it is difficult to imagine any situation in which the plaintiffs could achieve standing. One reading of the decision is that ALDF did not have the right to intervene in the prosecution of another's patent and that only an owner of an animal patent would have standing to challenge the Rule.[217] As neither animal rights groups nor farmers are likely to ever own an animal patent, these groups will probably never be able to achieve standing to challenge the validity of transgenic animal patents. The irony of the situation created by the *ALDF* holding is that the only people who would have standing to challenge the validity of animal patents (i.e., researchers and biotech companies) would have no incentive to do

---

infra notes 262-70 and accompanying text (discussing regulatory effort of NIH in establishing guidelines for transgenic research).

213. *See supra* notes 150-61 and accompanying text (describing farmers' claim of injury as too speculative for grant of standing).

214. *See Hearings on H.R. 1556*, *supra* note 1, at 232-34 (letter from Jack Doyle, Director, Agriculture and Biotechnology, Friends of the Earth/Environmental Policy Institute to Rep. Kastenmeier, Chairman, Subcommittee on Courts, Intellectual Property and the Administration of Justice (Sept. 14, 1989)) (listing examples of farm animals developed through transgenic research, though patent for transgenic animal has only been given to "Harvard mouse").

215. *See infra* notes 253-54 and accompanying text (discussing support of proposed legislation for farmers' exemptions).

216. *See supra* notes 150-61 and accompanying text (outlining Federal Circuit's assessment of claims made by farmers).

217. *See supra* note 189 (setting forth court's argument that law did not allow ALDF to intervene, as third party, in prosecution of others' patents).

so, as they are the beneficiaries of the Rule.[218] Thus, *ALDF* illustrates an impasse for animal patent opponents attempting to obtain relief through the judiciary.

C. *What the* ALDF *Decision Did Not Do*

Since the plaintiffs were denied standing, the Federal Circuit's decision in *ALDF* did not resolve whether the PTO's 1987 policy permitting the patenting of transgenic animals is valid law. The case merely determined that the plaintiffs did not have standing to challenge the Rule and that the Rule was not subject to the public notice and comment requirements of the APA.[219] Thus, due to these procedural obstacles, the case did not reach the merits of the controversy. The question of whether transgenic animals should be patented implicates broad policy issues, rather than the narrow procedural issue of statutory interpretation of the APA that the court in *ALDF* addressed.[220]

The judiciary, however, is not the appropriate body to confront this issue.[221] In *Chakrabarty*, the Supreme Court recognized that Congress has the ultimate authority to determine what constitutes patentable subject matter.[222] Although the majority of the Court held that microorganisms were patentable subject matter, it realized

---

218. *See Hearings on H.R. 1556, supra* note 1, at 258 (statement of Steven M. Wise, President, Animal Legal Defense Fund) (suggesting that future case reaching merits of *ALDF* could arise when one biotech company infringes on another's animal patent, and when infringing company is subsequently sued, it can allege that patent was never valid because transgenic animals are not patentable subject matter). Realistically, however, a biotech company is not likely to bring such a suit. A court decision invalidating an issued patent in this scenario would deny either company the future benefit of patent protection for transgenic animals. *See generally supra* notes 97-101 and accompanying text (discussing advantages provided by availability of patent protection to researchers and biotech companies).

219. *ALDF*, 932 F.2d at 920, 922.

220. *See* Diamond v. Chakrabarty, 447 U.S. 303, 322 (1980) (Brennan, J., dissenting) (recognizing that issue of whether innovations in biotechnology should be patentable subject matter "uniquely implicates matters of public concern").

221. The Federal Circuit's denial of standing to the plaintiffs in *ALDF* could be interpreted as the court's acknowledgment that it is not the proper forum in which to resolve this issue. Although the biotech companies are not likely to bring generalized suits attacking the validity of an animal patent on subject matter grounds, there are bound to be infringement actions in which an animal patent's validity will be challenged on other more specific grounds, such as obviousness.

222. *Chakrabarty*, 447 U.S. at 317 ("The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. . . ."). The Court declared itself to be incompetent to make the value judgments that would determine the limits of patentability and acknowledged Congress' responsibility in this area. *Id.* at 317-18. The Court emphasized that its role was limited to interpreting what Congress intended to include within the scope of patentable subject matter. *Id.*; *see supra* notes 44-58 and accompanying text (examining *Chakrabarty* decision).

that Congress could override its decision.[223] In dissent, Justice Brennan took the argument one step further, strenuously charging that the majority misinterpreted Congress' intent for the scope of patentability and that the Court should never have decided the issue.[224] Thus, Congress, and not the courts, should determine whether transgenic animals should be patented.[225]

Nor should the PTO address the issue of the patentability of transgenic animals.[226] Article I of the United States Constitution gives Congress the broad power to enact laws pertaining to patents.[227] In contrast, the statutory duty of the PTO is limited to applying the legislative scheme that Congress enacts.[228] Specifically, the PTO is vested with the authority to grant and issue patents.[229] This duty is limited to examining patent applications "to determine if they meet requirements of law for the issuance of patents."[230] The PTO does not possess the authority to decide that transgenic animals are patentable subject matter.[231] In issuing the 1987 rule, therefore, the PTO usurped Congress' responsibility to enact patent laws and exceeded its statutory grant of authority.[232]

---

223. *See Chakrabarty*, 447 U.S. at 318 (acknowledging that Congress was free to amend section 101 so as to exclude biotechnological innovation from scope of patentability).

224. *Id.* at 320-21 (Brennan, J., dissenting).

225. *See* Burke, *supra* note 118, at 431 (expressing danger of judicial system becoming "political battleground" for special interest groups attempting to employ courts, rather than Congress, to make policy determinations regarding patent system and regulation of technology); *cf.* De Bré, *supra* note 1, at 254 (urging that Congress is more appropriate body than judiciary to determine whether humans should be patentable).

226. *Cf.* Lane, *supra* note 24, at 90 (arguing that decision to patent animals should occur in wider forum than in patent offices).

227. U.S. CONST. art. I, § 8, cl. 8 ("To 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.").

228. Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

229. 35 U.S.C. § 6a (1988).

230. *See* 48 Fed. Reg. 14,735 (1983) (providing patent granting authority and power of Commissioner of PTO to establish regulations for PTO proceedings, perform functions that are "necessary and proper" in exercise of authority delegated to office, and establish policies and regulations pertaining to administration of patent laws). This role, however, does not extend to making laws that define the scope of patent protection. *See* De Bré, *supra* note 1, at 251 (emphasizing limited authority of PTO).

231. *See, e.g., Hearings on H.R. 1556*, *supra* note 1, at 102 (statement of Donald S. Chisum, Professor, University of Washington School of Law) (contending that it is not up to PTO to decide what constitutes patentable subject matter, although PTO has correctly perceived *Chakrabarty*'s implications); 133 CONG. REC. 13,914 (1987) (statement of Sen. Hatfield) ("Such a monumental decision about the fate of animal life should not be left only to the Patent Office."); De Bré, *supra* note 1, at 252 (arguing that deciding how life should be altered is "well beyond" competence or authority of PTO).

232. *See* 137 CONG. REC. S7818 (daily ed. June 13, 1991) (statement of Sen. Hatfield) (charging that PTO's 1987 Rule represents "deeply troubling usurpation" of congressional authority). Senator Hatfield argues that, by leaving animal patenting decisions to the PTO, Congress has "effectively abandoned the responsibility to deal with the results of genetic . . . engineering." *Id.*; *see Hearings on H.R. 1556*, *supra* note 1, at 264, 271 (statement of Andrew Kimbrell, Policy Director, Foundation on Economic Trends, on behalf of the Coalition on

Although over five years have passed since the PTO issued its 1987 rule, Congress has yet to make a determination regarding the validity of transgenic animal patents.[233] Congress' silence on the issue could be interpreted in several ways. On the one hand, it could be construed as tacit approval of the Supreme Court's *Chakrabarty* decision and of the granting of transgenic animal patents.[234] A decision as important as allowing patents to be granted for genetically altered animals, however, arguably merits some express response from Congress.[235] Another possible interpretation of Congress' silence is that Congress is unwilling to be held politically accountable for the present controversy surrounding animal patents.[236] Congress must take action on this issue immediately so that the patent laws may keep pace with the rapid technological advancements in transgenic research.[237]

D. Proposed Legislation

Although Congress has attempted to react to the arguments against animal patenting through the introduction of various bills,

---

Animal Patenting) (maintaining that PTO's usurpation of congressional authority by issuing 1987 Rule has led to disaster and has denied American people traditional legislative process for protection of their rights); *see also Patent Hearings*, *supra* note 42, at 112 (statement of Rep. Rose) (asserting that decision to patent animals should not be made solely by Patent Office without any direction from Congress).

233. *See Hearings on H.R. 1556*, *supra* note 1, at 245 (statement of Steven M. Wise, Esq., President, Animal Legal Defense Fund) (pointing out that legality of PTO's decision to permit transgenic animal patenting remains unresolved).

234. *See Patent Hearings*, *supra* note 42, at 302 (statement of Michael S. Ostrach, Senior Vice President and General Counsel, Cetus Corp.) (theorizing reasons behind lack of definitive congressional action on issue of transgenic animal patents); *see also Hearings on H.R. 1556*, *supra* note 1, at 15-16 (statement of Kevin W. O'Connor, senior analyst, Office of Technology Assessment, U.S. Congress) (noting various options available to Congress and indicating that taking no action would be interpreted as congressional approval of PTO policy). *But see Hearings on H.R. 1556*, *supra* note 1, at 184 (statement of Rep. Kastenmeier) (charging that *Chakrabarty* addressed only microorganisms and noting there is "quite a quantum leap to a mammal and a vertebrate").

235. *See Hearings on H.R. 1556*, *supra* note 1, at 245 (statement of Steven M. Wise, Esq., President, Animal Legal Defense Fund) (arguing that Congress should not allow decision to grant animal patents to be made by implication or by default); *id.* at 7 (statement of Rep. Cardin) (urging Congress to retain responsibility for determining whether plants and animals are patentable).

236. *See* Kambic, *supra* note 61, at 460 n.171 (interpreting reasons for Congress' inaction on issue of transgenic animal patent validity); Thomas D. McGarity & Karl O. Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 538 (1983) (suggesting that Congress' sluggishness in responding to issue may be due to either lack of public demand for legislation and/or low public perception that transgenic animals will lead to disastrous results).

237. *See* Seibold, *supra* note 24, at 99 (charging that Congress must take action quickly on biotechnology patent issues because as biotechnology revolution progresses, current inadequacies in patent law will likely become more apparent); *see also id.* at 90 (advocating that it is time for Congress to accept "*Chakrabarty* challenge," and to evaluate existing patent law in light of issues and problems raised by animal patents).

no such bill has yet received enough support to be enacted. To date, the proposed congressional response to animal patents entails: (1) a moratorium on the issuance of animal patents; and (2) bills providing farmers an exemption from the payment of royalties for breeding patented animals. One effect of *ALDF* may be to encourage animal patent opponents to work harder in lobbying Congress to enact such bills, because it is unlikely, after *ALDF*, that these groups will obtain adequate relief through the judiciary.

1. Moratoria on animal patents

In response to the mounting public opposition to transgenic research, Congress has proposed several moratoria on animal patents.[238] The purpose of enacting such a moratorium is to halt the issuance of animal patents long enough for Congress to assess the implications of animal patenting.[239] The strongest support for this action comes from religious leaders and animal rights activists who are morally opposed to the issuance of animal patents.[240]

---

238. On August 5, 1987, Representative Rose introduced H.R. 3119, a bill amending the patent laws by prohibiting the patenting of animals for two years. 133 CONG. REC. 22,588 (1987) (announcing introduction of bill and referral to Judiciary Committee). The bill also revoked previously granted patents for genetically altered animals. H.R. 3119, 100th Cong., 1st Sess. (1987). The Judiciary Committee defeated the bill by a 2-to-1 vote. 134 CONG. REC. 23,565 (1988) (statement of Sen. Kastenmeier) (reviewing history of committee action on animal patenting).

On February 29, 1988, Senator Hatfield introduced S. 2111, a bill proposing to amend the patent statute by prohibiting the patenting of transgenic animals and to revoke any previously granted patents. 134 CONG. REC. 2676-77 (1988). The bill added a section to 35 U.S.C., containing the following language:

> Vertebrate or invertebrate animals, modified, altered, or in any way changed through genetic engineering, shall not be considered matter within the confines of patentability and shall not be patentable within the meaning of section 101 or section 102 or any other provision of this title. No such patent shall be granted and any patent previously granted for any such animals is hereby revoked.

S. 2111, 100th Cong., 2d Sess. (1988). S. 2111 died when the 100th Congress adjourned.

On June 13, 1991, Senator Hatfield introduced S. 1291, a bill proposing that a five-year moratorium be placed on animal patents (vertebrate and invertebrate). 137 CONG. REC. S7817 (daily ed. June 13, 1991) (statement of Sen. Hatfield). The bill is still pending in the Senate Judiciary Committee.

239. *See* 137 CONG. REC. S7817 (daily ed. June 13, 1991) (statement of Sen. Hatfield) (explaining that purpose of moratorium would be to stop race for animal patents long enough for Congress to examine effect animal patents will have on world). Senator Hatfield, the main advocate of a moratorium, claims that it is "irresponsible and imprudent" to grant patents on all types of animals suddenly and unconditionally. He urges that "this kind of research . . . cries out for some modicum of ethical oversight." *Id.* at S7818.

240. *See Hearings on H.R. 1556*, *supra* note 1, at 114 (statement of John A. Hoyt, President, Humane Society of the United States) (expressing Humane Society's support for the enactment of moratorium); *id.* at 266 (statement of Andrew Kimbrell, Policy Director, Foundation on Economic Trends, on behalf of the Coalition on Animal Patenting) (declaring that organization, which includes 17 animal protection groups and 26 religious leaders, supports legislative moratorium on animal patenting); *see also supra* notes 102, 105-09 and accompanying text (outlining arguments of animal rights activists and religous groups against animal patenting). In addition to animal rights groups and religious leaders, environmental groups also support

Animal patent advocates argue that a moratorium should not be placed on transgenic animals because it would have the effect of stifling important research, thereby preventing society from reaping all of the benefits that transgenic animals stand to offer.[241] Specifically, animal patent supporters claim that a moratorium would frustrate developments in biotechnology by slowing the investment of money in rDNA technology.[242] Proponents of animal patents also contend that a moratorium would severely harm the American biotechnology industry, by diminishing its position as the current worldwide leader in the field.[243] Animal patent supporters also note that several countries have begun to follow the lead of the United States and are granting patent protection for transgenic animals, thereby increasing this country's pressure to keep its competitive edge in the biotechnology industry.[244] In addition to warning that moratoria will adversely affect research, patent supporters argue

---

the enactment of a moratorium on animal patents. *See Hearings on H.R. 1556, supra* note 1, at 237 (statement of Dr. Margaret Mellon, Director, National Biotechnology Center, National Wildlife Federation) (declaring NWF support for moratorium until federal regulatory system is implemented).

241. *See Patent Hearings, supra* note 42, at 467-69 (statement of Dr. Alan Smith, Vice-President of Integrated Genetics) (arguing that moratorium on animal patents would hinder beneficial health care developments); *see generally supra* notes 84-95 and accompanying text (describing contributions genetically altered animals are expected to make to society).

242. *See* Manspeizer, *supra* note 84, at 450 (discussing negative consequences of moratorium on transgenic research).

243. *Hearings on H.R. 1556, supra* note 1, at 70 (statement of Steven Holtzman, Vice President for Corporate Development, DNX, Inc.) ("I can think of no better way to throw a bucket of cold water on America's high-tech industries than to suggest that scientists and inventors cannot count on our patent system until Congress debates whether the new technology should qualify for patent protection. . . ."); *see also id.* at 146 (statement of Donald J. Quigg, Commissioner, PTO) (expressing opposition to moratorium on animal patents, as it will substantially harm competitive position of United States in worldwide biotechnology industry); *Patent Hearings, supra* note 42, at 265 (statement of Richard D. Godown, President, Industrial Biotechnology Association) (arguing that moratorium would discourage American companies from engaging in transgenic research, while foreign competitors would continue to find new ways to compete with United States).

244. *See Patent Hearings, supra* note 42, at 148 (statement of William H. Duffey, Director, Intellectual Property Owners, Inc.) (commenting that Japanese government has officially targeted biotechnology as major national priority, foreshadowing that it will become "formidable global presence" in biotechnology industry). European governments are under increasing pressure from domestic biotech industries to modernize their patent laws using current U.S. practice as a model. *Id.* at 136. Accordingly, the Examining Division of the European Patent Office (EPO) recently granted a patent for the Harvard mouse, making it the first patented transgenic nonhuman mammal in Europe. *Examining Division Allows Patent for Genetically Altered Mouse*, PAT. TRADEMARK & COPYRIGHT LAW DAILY (BNA), Jan. 8, 1992, *available in* WESTLAW, BNA-PTD File (1992). The EPO's decision to grant the patent followed an initial rejection of the patent and a drawn out debate over the ethical issues involved in patenting animals. *Id.* at 49. The EPO ultimately decided that the utility of the Harvard mouse in fighting cancer outweighed concerns about the suffering of animals or possible environmental risks, and thus compelled the issuance of a patent for the animal. *Id.* Before the EPO granted a patent for the Harvard mouse, Australia was the only country other than the United States to grant a patent for a transgenic animal. *See* Lane, *supra* note 24, at 90, 98 (commenting on Australia's first issuance of animal patent for trangenic pig patent in October 1990).

that such measures are unnecessary[245] and unprecedented.[246]

Furthermore, animal patent supporters claim that a moratorium on animal patents would be inimical to the patent system's purpose of encouraging the disclosure of information of new technologies. This would result in inventors concealing important information from competitors to protect their discoveries and investments.[247] Under the laws of trade secrecy,[248] an inventor guards important information about the invention to prevent duplication by competitors.[249] If scientists engaged in transgenic research are forced to turn to trade secrecy, the public and scientific world will be robbed of the widespread disclosure that the patent system ensures.[250] Another concern associated with trade secrecy is that it provides the inventor less protection against infringement than does patenting.[251]

---

245. *See* H.R. REP. No. 960, 101st Cong., 2d Sess., pt. 1, at 27-28 (1990) (concluding that moratorium is unnecessary, given fact that PTO has not issued animal patent since April 1988). The report argued, therefore, that it is clear that the PTO is already exercising appropriate care and discretion in the granting of these patents. *Id.* at 28.

246. *See* Kambic, *supra* note 61, at 465 (asserting that Congress has never before proposed legislation aimed at interfering with Patent Office policy decision).

247. *See Patent Hearings*, *supra* note 42, at 260 (statement of Richard D. Godown, President, Industrial Biotechnology Industry) ("The moratorium on animal patents would be a moratorium on scientific knowledge."); Manspeizer, *supra* note 84, at 450 (claiming that moratorium will hinder public disclosure of information, which is contrary to goal of United States patent system). *See generally supra* notes 25-26 and accompanying text (discussing purpose and goals of United States statutory patent system).

248. Under common law tort doctrines, an inventor might sue for damages for disclosure or use of a trade secret if discovery of the secret is improper or use results from breach of confidence. RESTATEMENT OF TORTS § 757 (1939). Comment b in the Restatement defines "trade secret" to be:

> any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula or chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device . . . .

RESTATEMENT OF TORTS § 757 cmt. b (1939). For a discussion of trade secrets, see generally ROGER M. MILGRIM, MILGRIM ON TRADE SECRETS (1967) and MELVIN F. JAGER, TRADE SECRETS LAW (1991) (discussing law of trade secrets in greater detail).

249. *See* Montgomery, *supra* note 10, at 254 (explaining how inventors use trade secrecy).

250. *See Patent Hearings*, *supra* note 42, at 209 (statement of Leo Walsh, Dean, College of Agriculture, University of Wisconsin) (predicting that, if transgenic researchers follow trade secret route, industry would share less information than if patents are granted). Because the biotechnology industry is still in its infancy, advancements in the field are dependent upon the disclosure of research results. *See* Reid G. Adler, *Biotechnology as an Intellectual Property*, 224 SCIENCE 357, 361 (1984), *reprinted in Patent Hearings*, *supra* note 42, at 655 (explaining that as present and former university researchers play key roles in developing basic research needed to commercialize biotechnology, publication of research results is usually expected).

251. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 489-90 (1974) (describing trade secret protection as being more limited than patent protection, as it only protects against certain types of unfair intentional discovery (not including discovery by independent creation or reverse engineering), whereas patent law protects against both innocent and intentional infringement); *see also id.* at 490 (explaining that trade secrecy remains effective only as long as invention is kept secret and that anyone who independently discovers secret may use it);

2. Farmer's exemption

Congress has drafted legislation in response to the pleas of farmers that they will suffer adverse economic effects in the face of animal patenting.[252] In 1989, Representative Kastenmeier introduced two bills, H.R. 1556 and H.R. 1557, that are sensitive to these concerns.[253] This legislation exempts farmers from the payment of royalties, allowing farmers to reproduce patented transgenic farm animals through breeding for use in the farming operation or for sale.[254] The farmer's exemption would not apply, however, if the germ cells, semen, or embryos of the patented transgenic animal were sold without the permission of the patent owner.[255] The ex-

---

Raines, *supra* note 22, at 66-67 (noting that trade secrecy is often insufficient in preventing competitors from pirating innovation).

252. *See generally supra* notes 110-16 and accompanying text (articulating economic concerns of farmers with respect to animal patenting).

253. 135 CONG. REC. H830 (daily ed. Mar. 22, 1989) (statement of Rep. Kastenmeier) (introducing H.R. 1556, 101st Cong., 1st Sess. (1989) and H.R. 1557, 101st Cong., 1st Sess. (1989)). These bills were virtually identical to two bills introduced in the previous Congress, Transgenic Animal Patent Reform Act, H.R. 4970, 100th Cong., 2d Sess. (1988) and The Transgenic Animal Regulatory Reform Act, H.R. 4971, 100 Cong., 2d Sess. (1988).

H.R. 1556, the Transgenic Animal Patent Reform Act, is intended to serve four basic purposes:

> First, it recognizes that the Patent Office has determined that genetically altered animals are patentable subject matter. Second, the bill clarifies that human beings are not patentable subject matter. Third, the bill authorizes the Commissioner of the Patent and Trademark Office to issue any regulations necessary to regulate the deposit of biological materials. Finally . . . the bill addresses the thorny question of the scope of a patent on patented transgenic farm animals.

135 CONG. REC. H830 (daily ed. Mar. 22, 1989) (statement of Rep. Kastenmeier).

The Transgenic Animal Regulatory Reform Act, also introduced by Representative Kastenmeier, aimed to establish a Biotechnology Science Coordinating Committee. H.R. 4971, 100th Cong., 2d Sess. § 102 (1988). The BSCC was to have five functions:

> (1) to serve as a coordinating forum for addressing scientific problems, sharing information, and developing consensus with respect to methods for evaluating potential risks to human health and the environment which are or may be caused by genetically engineered animals, (2) to promote uniformity in the development of review procedures and assessments for evaluating such risks, (3) to facilitate continuing cooperation among Federal agencies on emerging scientific issues related to such animals and such risks, (4) to identify gaps in scientific knowledge with respect to such animals and such risks, and (5) to develop guidelines to govern good laboratory and good manufacturing practices in the biotechnology sciences.

Id. § 102(a)1-5. Neither of these bills were enacted, however.

254. H.R. 1556, 101st Cong., 1st Sess. (1989). Section 2, of H.R. 1556, entitled "Infringement of Patent," would amend 35 U.S.C. § 271 (1988) by adding the following subsection:

> (h)(1) 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.

H.R. 1556, 101st Cong., 1st Sess. § 2 (1989).

255. H.R. 1556, 101st Cong., 1st Sess. § 2 (1989). H.R. 1556 adds the following to 35 U.S.C. § 271:

> (2) Notwithstanding the provisions of paragraph (1), it shall be an act of infringement for a person to sell the germ cells, semen, or embryos of a patented transgenic farm animal.

emption is modeled after the provisions of the farmer's crop exemption of the Plant Variety Protection Act of 1970, the only patent statute in American law that has ever dealt with the problems associated with self-reproducing subject matter.[256]

Farmers have welcomed this legislation, believing that it will make the process of purchasing patented animals more convenient and affordable and allow them to compete more easily with larger producers in the transgenic farm animal market.[257] Opponents argue, however, that the farmer's exemption will actually harm the farmers it is designed to help.[258] They claim that the loss of royalty fees derived from the breeding process will cause biotech companies to inflate the sale price of transgenic farm animals.[259] Animal patent

---

(3) for purposes of paragraphs (1) and (2) —
(A) the term "transgenic farm animal" means a farm animal whose germ cells contain genetic material originally derived from another animal other than the parent of the farm animal; and
(B) the term "farm animal" means any animal used or intended for use as food or fiber.

Id.

Other commentators have suggested a similar exemption to the farmer's exemption for researchers. *See* Merges, *supra* note 41, at 1072-74 (discussing researcher's exemption and advocating its enactment); *see also Hearings on H.R. 1556*, *supra* note 1, at 104 (statement of Donald S. Chisum, Professor, University of Washington School of Law) (claiming that research exemption is implicit in case law).

256. *See* Merges, *supra* note 41, at 1070-71 (providing detailed discussion of PVPA and its treatment of self-reproducing subject matter and claiming that it provides useful starting point to look for solutions to practical problems breeding of patented animals will pose to farmers); *id.* (explaining that PVPA essentially exempts farmers from having to pay royalties on seeds obtained from patent owners after farmers make initial purchase). *But see Hearings on H.R. 1556*, *supra* note 1, at 149 (statement of Donald J. Quigg, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks) (claiming that although there are conceptual similarities between farmer's exemption in H.R. 1556 and provisions in PVPA, there are "significant differences between technology related to new plant varieties and new transgenic animals"). Quigg explained that the protection that the PVPA provides is much narrower than that afforded by the general patent law. *Id.* He asserted that the PVPA applies only to a single type of plant, whereas a patent can protect an innovation applicable to numerous varieties of an animal. *Id.* Moreover, Quigg pointed out that Congress enacted the PVPA to address a problem that existed in a relatively mature industry, as contrasted to the very young field of transgenic animal research. *Id.* at 150. For a more thorough discussion of the PVPA, see Czarnetzky, *supra* note 41, at 1351-54.

257. *See* Merges, *supra* note 41, at 1072 (citing potential benefits of farmer's exemption as: (1) reducing need for farmers to engage in extensive recordkeeping; (2) eliminating risk that farmers would be forced to assume role of patent enforcers; (3) diminishing farmers' uncertainty of law with respect to infringement of transgenic animal patents; and (4) preventing patentees from using threat of patent infringement to extract major concessions from farmers negotiating licensing agreements).

258. *See Hearings on H.R. 1556*, *supra* note 1, at 281-82 (explaining that bill will ultimately harm farmers, by reducing availability of transgenic animals to small farms).

259. *See Hearings on H.R. 1556*, *supra* note 1, at 72 (statement of Steven Holtzman, Vice President for Corporate Development, DNX, Inc.) (claiming that enactment of bill would have ironic effect of making animals exclusively available to small number of larger integrated producers); *Patent Hearings*, *supra* note 42, at 303-04 (statement of Michael S. Ostrach, General Counsel, Cetus Corp.) (stating that exemption would make cost of patented animals abnormally high, due to resultant lost sales of offspring).

The biotechnology industry has suggested that the farmers' fears about the economic ef-

advocates argue further that the enactment of a farmer's exemption would reduce the incentives for researchers to develop such animals and, thus, destroy the market for transgenic animals.[260] Moreover, opponents of the farmer's exemption argue that the patent system is not the proper forum to address the farmers' concerns that large corporations will monopolize the market for transgenic farm animals.[261]

E. Administrative Regulations: The NIH Guidelines

In response to concerns about the use of transgenic animals in the laboratory, the National Institutes of Health's Recombinant Advisory Committee issued "Guidelines for Research Involving Recombinant DNA Molecules" to provide an oversight mechanism for transgenic experimentation.[262] The guidelines establish levels of

---

fects of patenting transgenic farm animals are misplaced. *See Hearings on H.R. 1556*, *supra* note 1, at 72 (statement of Steven Holtzman, Vice President for Corporate Development, DNX, Inc.) (claiming that farmer's exemption is not necessary because biotech companies, in order to succeed in selling transgenic animals, have incentive to reach mutually beneficial arrangement with farmers to sell transgenic animals).

260. *See Hearings on H.R. 1556*, *supra* note 1, at 195 (statement of Dr. Philip Leder, Dep't of Genetics, Harvard Medical School) (voicing concern that exemption would hurt biotech industry and create major funding uncertainties for research and development). The farmers refute this argument, claiming that the phenomenon of "genetic drift" will make it necessary for them to continue buying animals to keep the desired genetic traits from being passed on to subsequent generations. *See* Merges, *supra* note 41, at 1071 (explaining that "genetic drift" phenomenon dictates that patented trait would appear in only maximum of 60% of offspring, making it necessary for farmers seeking to maintain patented trait in animals to periodically buy or license new ones); *see also id.* (indicating that genetic drift has had similar effects on genetic traits of seeds, such that PVPA has not harmed inventors' incentives in seed industry). *But see Hearings on H.R. 1556*, *supra* note 1, at 299 (statement of Vance A. Smith, President, Licensing Executive Society) (attacking validity of "genetic drift theory," alleging that all offspring that inherit genes inserted into animal's genetic complement will possess 100% of gene's attributes, with no "genetic drift").

261. *See Patent Hearings*, *supra* note 42, at 119 (statement of Dr. A. Ann Sorensen, Assistant Director, American Farm Bureau Federation) (countering farmers' fears and asserting that concerns regarding concentration of agricultural resources in multinational companies would be more appropriately handled by antitrust laws, not by denying patent rights); *id.* at 364 (statement of Nicholas J. Seay, Esq.) (arguing that while patent laws should not address concerns raised by farmers, it should be major objective of agricultural stations and extension services to create mechanisms whereby all farmers could enjoy benefits of biotechnology).

Another argument against the farmer's exemption is that it would establish troubling precedent and weaken this country's intellectual property laws. *See Hearings on H.R. 1556*, *supra* note 1, at 148 (statement of Donald J. Quigg, Commissioner, PTO) (claiming that farmer's exemption would establish precedent of removing from scope of patent protection activities by individuals based on their occupation); *see also id.* at 414 (letter to Rep. Kastenmeier from Thomas F. Smegal, Jr., American Bar Association) (commenting that farmer's exemption would establish precedent that may lead to other special interest group exemptions).

262. *Recombinant DNA Research Guidelines*, 41 Fed. Reg. 27,902 (1976). NIH has amended the guidelines a number of times. *See Recombinant DNA Research; Actions Under Guidelines*, 51 Fed. Reg. 16,952 (1986) (providing most recent complete guidelines).

The USDA has also proposed guidelines to govern research on and containment of genetic engineering experiments. *Advanced Notice of Proposed USDA Guidelines for Biotechnology Research*, 51 Fed. Reg. 23,367 (1986). Since the USDA is a major sponsor of livestock and food products research, its guidelines would apply to all federally funded agricultural biotechnology

approval required before certain experiments can be performed and containment levels for genetic engineering research.[263] The guidelines are useful, therefore, as a means of protecting the welfare of laboratory animals.[264]

Although compliance with the NIH guidelines is only mandatory for any researcher or institution receiving federal funding, the NIH guidelines have been adopted voluntarily throughout the biotechnology industry.[265] While the NIH guidelines serve to promote the protection of animal welfare, they have several deficiencies.[266] First, institutions that do not receive NIH funding need not comply with the guidelines.[267] In addition, NIH has difficulties in enforcing

---

research. *See* Dresser, *supra* note 14, at 426-27 (describing extent of coverage of USDA guidelines). The USDA guidelines are modeled after the NIH guidelines and, thus, have many of the same problems. *Id.*; *see infra* notes 266-70 and accompanying text (outlining shortcomings of NIH guidelines). The USDA's authority, however, extends to some commercial and private activities such as animal quarantine, interstate movement of plant pests, and veterinary biological products. Dresser, *supra* note 14, at 426. Accordingly, USDA has adopted regulations, for the transport of genetically altered organisms that are plant pests. *Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests*, 7 C.F.R. § 340 (1991).

263. *See* Diane E. Hoffmann, *The Biotechnology Revolution and Its Regulatory Evolution*, 38 DRAKE L. REV. 471, 484-86 (1990) (discussing purposes and extent of guidelines' coverage). The guidelines focus on the protection of human health and dictate methods for the construction and handling of tools, the physical containment of experiments, and the review process for the release of organisms into the environment. *Hearings on H.R. 1556*, *supra* note 1, app. II, at 471-72. In addition, the guidelines only apply to researchers receiving NIH or National Science Foundation funding. Hoffmann, *supra*, at 471. The guidelines' limited coverage has been noted in conjunction with the piecemeal way in which the federal government has regulated activities related to biotechnology products. *Id.* at 474. No single federal regulatory agency has central oversight of transgenic animals. *Id.* In addition, Hoffmann notes that commercial, health, agricultural, and environmental statutes potentially cover biotechnical activities. *Id.* at 491; *see* McGarity and Bayer, *supra* note 236, at 503-09 (discussing regulatory agencies such as Occupational Health and Safety Administration, Food and Drug Administration, and Environmental Protection Agency which have authority to regulate use and disposal of products and by-products of biotechnological research); Gregory A. Jaffe, *Inadequacies in the Federal Regulation of Biotechnology*, 11 HARV. ENVTL. L. REV. 491, 493 (1987) (explaining that growth and development of biotechnology industry has reached stage of commercial exploitation, thus implicating regulatory responsibilities of many agencies).

264. *See* Kulseth, *supra* note 100, at 713 (indicating that guidelines address lab animal welfare issues, such as animal care, housing, use, and regulation of amount of pain that may be inflicted upon research animals).

265. *See Hearings on H.R. 1556*, *supra* note 1, app. I, at 473 (commenting that most biotechnology companies voluntarily comply with NIH guidelines, and that degree of compliance is greater in private sector than in public institutions). In addition, the state of New York and a number of localities have made compliance with the NIH guidelines mandatory. *See The Potential Environmental Consequences of Genetic Engineering: Hearings Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. on Environment and Public Works*, 98th Cong., 2d Sess. 38 (1984) (statement of Dr. Bernard Talbot, Acting Director, NIH) (listing localities that have adopted guidelines).

266. *See Hearings on H.R. 1556*, *supra* note 1, at 117 (statement of John A. Hoyt, President, Humane Society of the United States) (setting forth specific deficiencies of NIH guidelines in ensuring protection of laboratory animal welfare in transgenic research).

267. Jaffe, *supra* note 263, at 534-36 (noting limited application to projects funded by NIH and estimating that over 90% of all rDNA research is conducted privately); *see supra* notes 263-65 and accompanying text (explaining scope of authority of guidelines).

compliance with these guidelines because the withholding of research funds is currently NIH's only method of enforcement.[268] Another shortcoming of the guidelines is that the NIH definition of covered organisms, drafted over a decade ago, has failed to keep pace with the rapid advances made in the biotechnology field.[269] Despite these limitations, the NIH guidelines constitute the primary thrust of federal regulatory efforts in the biotechnology field and will, undoubtedly, continue to play an important role in the future regulation of transgenic animal research.[270]

V. RECOMMENDATIONS

A. Congress Should Amend Section 101 To Include Transgenic Animals

Transgenic animals should be patentable subject matter because they are expected to provide many benefits to society,[271] and because the risks associated with the technology are largely overstated.[272] Congress, however, must amend section 101 to accommodate the patenting of living organisms and to outwardly

---

268. *See Hearings on H.R. 1556*, *supra* note 1, at 239 (statement of Dr. Margaret Mellon, Director, National Wildlife Federation) (commenting on lack of enforcement mechanisms for guidelines); Dresser, *supra* note 14, at 426 (stating that NIH has had problems ensuring guideline compliance, even among those institutions that are clearly subject to them); Jaffe, *supra* note 263, at 535-36 (asserting that NIH does not have capacity to enforce guidelines and relies on third party reports of violations); *see also infra* notes 279-81 and accompanying text (recommending methods to ensure stricter compliance with NIH guidelines).

269. *See Hearings on H.R. 1556*, *supra* note 1, app. III, at 564 (article by Dr. Margaret Mellon, Director, National Wildlife Federation) (noting deficiencies of NIH guidelines in face of newly developed gene transfer techniques). The guidelines do not govern the use of genetic engineering methods such as microinjection, electroporation, or projectile transfer. *Id.* at 564; *See Recombinant DNA Research; Proposed Actions Under Guidelines*, 53 Fed. Reg. 12,752, 12,753 (1988) (noting that NIH's Recombinant DNA Advisory Committee (RAC) was requested to clarify which transgenic animals are covered by regulations, as some animals do not contain rDNA and technically fall outside scope of present guidelines). The RAC has considered several expanded definitions delimiting the gene transfer experiments to be covered by the NIH guidelines. *Id.* The RAC supports inclusion of experiments involving transgenic animals, but acknowledges that further study of the environmental impacts of such a change will be necessary before final implementation. *Id.*; *RAC Seeks To Govern Experiments Overseas*, BIOTECH NEWSWATCH, June 20, 1988, at 5 (quoting William J. Gartland, Executive Secretary, RAC).

270. *See* John B. Attanasio, *The Genetic Revolution: What Lawyers Don't Know*, 63 N.Y.U. L. REV. 662, 689 (1988) (emphasizing that, despite their limited impact, NIH guidelines constitute major force of federal regulatory efforts regarding genetic research); De Bré, *supra* note 1, at 256 (stating that NIH guidelines are presently only regulations governing treatment of laboratory animals used in transgenic research); Kulseth, *supra* note 100, at 711-13 (urging that implementation of administrative guidelines, like those of NIH, is best way to regulate risks associated with biotechnology). *But see* Dresser, *supra* note 14, at 430 (expressing concerns about NIH's ability to exercise appropriate oversight because it has conflicting roles as promoter and financial supporter of research it is assigned to regulate).

271. *See supra* notes 84-95 and accompanying text (describing various rewards society is expected to reap from transgenic animals).

272. *See supra* note 102 and accompanying text (discussing environmental dangers and religious objections concerning transgenetic research and rebutting these arguments).

express its approval of the PTO's 1987 rule.[273] Congress should amend section 101 as follows:

> § 101. Inventions Patentable
> Whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or *genetically altered, nonhuman living organism (unicellular or multicellular)*,[274] or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Another way in which Congress could amend the patent statute is to keep the language of the present statute, but to follow the *Chakrabarty* holding, by plainly defining either "manufacture" or "composition of matter" as encompassing genetically altered animals.[275] Of the two options, it is preferable for Congress to revamp the statute as presented in the text, however, to make it absolutely clear that section 101, on its face, includes biotechnological innovations within its scope of patentable subject matter. Moreover, Congress has the authority to enact new patent laws, whereas the structure of the federal constitutional system restricted the Court in *Chakrabarty* to determining what Congress intended to include within the scope of patentable subject matter, rather than being able to change the language of the statute.[276]

Ultimately, Congress should define what constitutes a human being, at least in terms of how much genetic material an organism must possess to qualify as human.[277] Regardless of whether humans are ever considered patentable subject matter, scientists need such a definition in order to draw a more clear-cut line in conducting transgenic experimentation. If humans remain unpatentable, researchers will need to know when an organism qualifies as human to have an appropriate stopping point in experimentation. Conversely, if, at

---

273. Congress' amendment of section 101 to include biotechnological innovations actually should have taken place twelve years ago, after the *Chakrabarty* decision. *See supra* notes 222-24 and accompanying text (explaining how, in *Chakrabarty*, Supreme Court encouraged Congress to amend patent statute).

274. The modifiers "unicellular" and "multicellular" are included in the statute so as to encompass within the scope of patentability any organism ranging from a simple unicellular bacterium to a complex multicellular mammal. The italicized portion of the statute represents the proposed change to the currently existing section 101.

275. *See supra* notes 44-61 and accompanying text (discussing *Chakrabarty* holding and its effect on interpretation of patent statute).

276. *See supra* notes 221-24 and accompanying text (contrasting role of Congress in defining limits of patentability with role of judiciary of interpreting Congressional intent of what constitutes patentable subject matter).

277. *See Patent Hearings*, *supra* note 42, at 374 (statement of Dr. Leroy Walters, Kennedy Institute of Ethics, Georgetown University) (suggesting that sustained attention should be devoted to defining appropriate boundaries between human and nonhuman organisms in areas of technological research); *see also supra* note 1 (setting forth problem that absence of definition of human will cause within biotechnology discipline, if not confronted soon).

some point, humans are deemed to be patentable, researchers will need to know when an organism becomes human, in order to know if their newly developed organism is considered animal or human. Congress should appoint a committee comprised of biotechnologists to develop this definition.[278]

B. Regulating Animal Patents

In addition to drafting a new patent statute, Congress should focus on regulatory measures. One major goal of Congress should be to strengthen those regulatory methods already in existence in the biotechnology industry. Specifically, NIH should update its guidelines so as to embrace new transgenic techniques.[279] During this process, NIH should revise the definition of covered experiments and techniques to account for recent developments in the field of biotechnology.[280] Furthermore, NIH should begin conducting random on-site inspections in those labs receiving federal funding in order to monitor and enforce compliance with the guidelines more effectively.[281]

1. Moratoria

Regarding the proposed legislation, Congress should not enact a moratorium on animal patents because such action would unnecessarily harm this country's fledgling biotechnology industry and impede the development of drugs to combat serious diseases and agricultural innovation.[282] Although risks accompany transgenic re-

---

278. *Cf. Hearings on H.R. 1556*, *supra* note 1, at 243 (statement of Steven Wise, Esq., President, Animal Legal Defense Fund) (acknowledging that any genetic definition of species cannot be simple, but must be technical and complex). It is beyond the scope of this Note to formulate a definition of a human being.

279. *See* Hoffman, *supra* note 263, at 543 (noting need for regulations that better respond to and anticipate new uses of biotechnology products). *See generally supra* notes 262-70 and accompanying text (discussing NIH guidelines).

280. *See supra* note 269 and accompanying text (explaining that guideline's coverage of transgenic experiments has become increasingly limited due to significant progress made in transgenic research).

281. Other commentators have advocated means of strengthening enforcement of research guidelines involving transgenic research. *See* Seibold, *supra* note 24, at 98 (recommending that granting of transgenic animal patent protection be tied to compliance with research guidelines); *see also* Note, *Designer Genes*, *supra* note 102, at 1096 (claiming that modified tort system could enhance ability of NIH to encourage safety practices of biotechnology firms and to enforce compliance with guidelines). The Note also maintains that many private biotechnology firms have voluntarily adopted NIH guidelines, in part out of the belief that they will thus be shielded from tort liability. *Id.* at 1105.

282. *See* Raines, *supra* note 22, at 64 (concluding that moratorium on animal patents would ultimately undercut competitiveness of United States agriculture and stunt progress in disease treatment). Additionally, animal patent advocates contend that enacting a moratorium on animal patents will merely result in adding to the delay that is already involved in obtaining such a patent. *See Patent Hearings*, *supra* note 42, at 261 (statement of Richard D. Godown,

search, addressing such risks falls squarely within the regulatory system, not the patent system.[283] Furthermore, Congress should not use special interest groups' moral objections as a justification for denying patent protection for transgenic animals.[284]

2. Farmer's exemption

Additionally, because it is not clear at this point exactly who would benefit from the royalty-free licensing scheme of a farmer's exemption, such an exemption should not yet be enacted.[285] This legislation may not be necessary, as it is highly questionable whether the biotech companies will find enforcement of the royalty scheme economical.[286] Congress should, therefore, delay the enactment of a farmer's exemption until its need can be conclusively proven.[287] Unless a farmer's exemption is proven necessary, Congress should not enact one, because any constraints on patenting will weaken this country's intellectual property laws and detrimentally affect the role of the United States in world trade negotiations.[288]

President, Industrial Biotechnology Association) (noting that it currently takes 25-26 months from time of initial filing of patent application until first notification of whether discovery is patentable); *see also supra* notes 241-51 and accompanying text (discussing other arguments against moratoria).

283. *See* Lane, *supra* note 24, at 95-96 (asserting that patent law should not be used as means to regulate uses of inventions); *supra* notes 203-06 and accompanying text (distinguishing goals of regulatory system from goals of patent system).

284. *See supra* notes 199-202 and accompanying text (maintaining that patent laws traditionally have not reflected moral viewpoints).

285. *See Hearings on H.R. 1556*, *supra* note 1, at 150 (statement of Donald J. Quigg, Commissioner, PTO) (emphasizing that farmer's exemption may not alleviate problems that its proponents designed it to solve).

286. *See* Raines, *supra* note 22, at 69 (explaining that enforcing royalty policy would require biotech companies to periodically send inspectors, armed with genetic screening kits, to every farm where transgenic animals have been purchased to determine which newborn animals inherited patented trait and that cost of inspection process would probably exceed value of collected royalties); *Patent Hearings*, *supra* note 42, at 123-24 (statement of Dr. A. Ann Sorensen, Director, American Farm Bureau Federation) (expressing doubt that companies will have time and money to sue individual farmers for infringement); Lane, *supra* note 24, at 92 (maintaining that enforcement of royalty collections in complex markets such as livestock industry would be difficult, due to market size and structure); *see also Patent Hearings*, *supra* note 42, at 523 (statement of Iver P. Cooper, Patent Counsel, The Association of Biotechnology Companies) (asserting that transgenic animal patent owners would only become concerned with farmers' activities if farmers themselves become producers of transgenic animals).

287. *See Hearings on H.R. 1556*, *supra* note 1, at 309 (letter from William H. Elliott, Jr., Esq., Law Offices of Synnestvedt Lechner, to Rep. Kastenmeier, Chairman, Subcommittee on Courts, Intellectual Property and the Administration of Justice (Aug. 29, 1989)) (warning that, if Congress enacts farmer's exemption without demonstrable factual showing that it is needed, Congress will never know if it was in fact needed and, in meantime, exemption will deter development of United States' biotechnology capabilities); *id.* (reasoning that Congress can revisit farmer's exemption issue if clear need for it is shown or if blatant abuse surfaces).

288. *See Hearings on H.R. 1556*, *supra* note 1, at 414 (letter from Thomas F. Smegal, American Bar Association, to Rep. Kastenmeier (Feb. 8, 1990)) (contending that enactment of farmer's exemption would frustrate attempts of United States negotiators who are trying to encourage elimination of various exemptions and exceptions from foreign patent laws).

CONCLUSION

Although *Animal Legal Defense Fund v. Quigg* did not reach the issue of the validity of transgenic animal patents, it is an important case because it illustrates the underlying issues implicated in the heated animal patent controversy. The Federal Circuit's denial of standing to the plaintiffs in the case raises questions about what type of litigant could achieve standing to challenge the validity of transgenic animal patents. *ALDF* makes it doubtful that the controversy over animal patents will be handled by the judicial system, because the groups that could possibly qualify for standing to raise the issue, namely, the biotechnology corporations, have no incentive to do so.

This Note has explained that neither the judiciary, nor the PTO is the proper forum for such a debate. Congress alone has the power to define the scope of patentable subject matter. Over the last twelve years, in a series of decisions, the Supreme Court and the Patent Office have pushed the limits of patentability. In promulgating its 1987 rule, the PTO exceeded the bounds of its authority by usurping Congress' responsibility to enact patent laws. The time has come for Congress to take the animal patenting issue into its own hands, where it belongs.[289] Specifically, Congress should amend the patent statute to accommodate for the patenting of transgenic animals and seek to strengthen the regulatory scheme currently in place in the biotechnology industry. Congress should aim to maximize the many benefits of transgenic animal patenting, while minimizing its potential risks. Because biotechnology is such a morally-charged issue, it has far-reaching implications for our entire society. Therefore, the technology must be approached with a cautious eye to the future.

289. *Cf. Patent Hearings*, *supra* note 42, at 317 (statement of Gervase Heffner, Lobbyist, National Farmers' Organization of Wisconsin) (urging that Congress not shed its responsibility to American people by expecting resolution of animal patent issue to be handled soley by PTO); *id.* at 73 (statement of Jack Doyle, Director, Agricultural Resources Project, Environmental Policy Institute) (charging that Congress now has duty to address broader social and economic questions surrounding animal patenting).