The National Agricultural Law Center

University of Arkansas · System Division of Agriculture
NatAgLaw@uark.edu · (479) 575-7646

An Agricultural Law Research Article

Multicellular Vertebrate Mammals as "Patentable Subject Matter" Under 35 U.S.C. § 101: Promotion of Science and the Useful Arts or an Open Invitation for Abuse?

by

Michael B. Landau

Originally published in DICKINSON LAW REVIEW
97 DICKINSON L. REV. 203 (1993)

www.NationalAgLawCenter.org

ARTICLES

Multicellular Vertebrate Mammals as "Patentable Subject Matter" Under 35 U.S.C. § 101: Promotion of Science and the Useful Arts or an Open Invitation for Abuse?*

Michael B. Landau**

Things are getting "curiouser and curiouser!"[1]

I. Introduction

In April of 1988, the United States Patent and Trademark Office (PTO) issued U.S. Patent No. 4,736,866 on an invention developed by scientists affiliated with Harvard University.[2] This patent, however, was not just another of the almost five million patented inventions issued by the PTO at that time. The issuance of this patent was extraordinary, for the patented invention was for "transgenic

* Copyright 1993 by Michael B. Landau. An earlier version of this Article appeared in 4 Animal Law Report (ABA) 2 (1991).

** Visiting Professor of Law, Dickinson School of Law; J.D. 1988 University of Pennsylvania.

1. LEWIS CARROLL, ALICE'S ADVENTURES IN WONDERLAND ch. 2 (1865).

2. The inventors are Philip Leder of Chestnut Hill, MA and Timothy Stewart of San Francisco, CA. The invention was assigned to Harvard. Although the patent was issued in the name of Leder, I will refer to it in this article as "The Harvard Mouse."

non-human mammals," i.e., genetically altered multicellular vertebrate mammals. On April 12, 1988, the United States government issued a patent on a *mouse*! In December of 1992, after almost five years without granting any patents on animals, the PTO issued three more mouse patents.[3]

What ensued was a great debate among lawyers, legislators, scientists, ethicists and animal rights proponents over the proper scope of the patent laws, and on the potential abuses and dangers of further encouraging genetic engineering. This article will present the legislative history, statutory background and precedential cases which led to the PTO's decision to allow patentability of animals. The article will then discuss the pros and cons of expanding the patent laws to cover this new category of "patentable subject matter."[4]

---

3. On December 29, 1992, the PTO issued the following patents: (1) U.S. Pat. No. 5,175,383 is a patent on a mouse that was genetically engineered to develop benign prostatic hypertrophy (*i.e.*, enlargement of the prostate gland). The patent was issued to Harvard University for an invention developed by Harvard researchers, one of whom was Philip Leder, the inventor of the original "Harvard Mouse;" (2) U.S. Pat. No. 5,175,384 was issued to GenPharm for a mouse that has been genetically engineered to not be able to develop mature T-cells. The lack of such T-cells causes the immune system of the mouse to be deficient. The mouse was invented by Paulus J.A. Krimpenfort of Amsterdam and Antonius J.M. Berns of Spaarndam. The mouse will be used to perform research on autoimmune disorders; (3) U.S. Patent No. 5,175,385 was issued to Ohio University for a mouse strain that produces a low level of beta interferon, a protein that attacks viri and helps to prevent infection. The mouse was invented by Thomas Wagner and Wiao-Zhou Chen. The mouse was invented by injecting mouse embryos with a human gene that promotes interferon secretion. Ohio University holds the patent on the technique used to create the mouse. *See PTO Issues Three Patents for Genetically Engineered Mice*, 45 Pat. Trademark & Copyright J. (BNA) at 159 (Jan. 7, 1993). The mice, by way of their short gestation periods and rapid growth, would be able to serve as aids in what is essentially "time lapse" research regarding certain diseases.

4. *See* 35 U.S.C. § 101. At present, the United States is the only country that grants full patent protection to animals. Patent protection was attempted to be gained for the Harvard Mouse in Europe. The application had a tortured history. The Examining Division of the European Patent Office refused to grant a patent for the Harvard Mouse on July 14, 1989 because the invention was construed as being an "animal variety" under Article 53(b) of the European Patent Convention (EPC). Article 53(b) also excludes "purely biological processes." In addition, the Examining Division failed to grant the patent owing to the applications failure to comply with Article 83 of the EPC. Article 38 provides: "The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." (Article 83 of the EPC is similar to Section 112 of the United States Patent Act (35 U.S.C. § 112)). The Examining Division was of the opinion that the invention could not be reproduced by one with skill in the art from the express language on the face of the application. The Examining Division also had questions related to Article 53(a) of the EPC, which relates to inventions that are contrary to the "ordre public" or morality. Article 53 of the EPC provides:

> European patents shall not be granted in respect of:
>
> (a) inventions the publication or exploitation of which would be contrary to the 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law in some or all of the Contracting States;
>
> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or products thereof."

II. Statutory Background

The Constitution grants Congress broad power to legislate to

Issues considered were:

1) Might it not be better to perform cancer tests of this kind on non-animal models;

2) The purpose of the invention was not to improve particular features, but to produce tumors in the mice;

3) Animals were regarded as objects;

4) Descendants of the animals might escape into the environment and spread malignant foreign genes through mating;

5) Was evolution not being drastically interfered with?

Decision of EPO's Technical Board of Appeal in "Harvard Mouse" Application, 4 World Intell. Prop. Rep. (BNA) at 285 (Dec. 1990). The inventors appealed the decision to the European Patent Office Board of Technical Appeals (Board). The Board remanded the application back down to the Examining Division and ordered reconsideration of the exceptions to patentability under Article 53(b) of the EPC, as well as the ethical questions raised under Article 53(a). The Board further noted that while the EPC excludes certain categories of animals from patentability, there is no general exclusion covering all animals. *Id.* Finally, the patent was approved, but on February 11, 1993, the European Parliament voted 178 to 19, with 27 abstentions to instruct the European Patent Office to revoke the patent and stop any further animal patents until the legal uncertainties have been clarified. The Parliament went on to find that the patent contravenes the European Patent Convention . . . .

Id. at 286. As of the time of the writing of this article, the issue had not yet been resolved in Europe.

In Canada, the specific issue of a patent on an animal has not yet been addressed. Patents on life forms, in general, have not been issued for failure to comply with the disclosure requirements of Section 36(1) of the Canadian Patent Act. The major case in Canada is Pioneer Hi-Bred Ltd. v. Commissioner of Patents, 60 D.L.R. (4th) 223 (1989), a case that dealt with the patentability of a new variety of soybean developed through cross-breeding. The application itself did not disclose the specific method of genetic engineering utilized. Initially, the Patent Office rejected the application on the grounds that the new plant variety was not included in the definition of *invention* in Section 2 of the Canadian Patent Act. The Examiner stated that "the patent office regarded as non-patentable: 'Subject matter for a process for producing a new genetic strain or variety of plant or animal or a product thereof . . . .' " 60 D.L.R. (4th) at 225-26, *citing* Section 12.03.01(a) of the Patent Office Manual. The inventor appealed the case to the Patent Appeal Board. The Board affirmed the Examiner's holding that the soybeans failed to constitute patentable subject matter under Section 2. In addition, the Board stated that the Commissioner has the right to determine not only whether an invention meets the requirements of "novelty, utility and inventive ingenuity" but also whether or not an invention falls within the scope of patentable subject matter. *Id.* at 226. On Appeal to the Federal Court of Appeal, 14 C.P.R.(3d) 491 (1987), Judge Marceau opined that living organisms, in general, are not expressly excluded from the category of patentable subject matter as contemplated by Parliament. He did, however, question whether or not a soybean was within the realm of inventions so contemplated "[G]iven that plant breeding was well established when the Act was passed, it seems to me that the inclusion of plants within the purview of legislation would have led first to a definition of invention in which words such as "strain," "variety" or "hybrid" would have appeared . . . ." *Id.* at 14. In addition, Judge Pratte raised issue of Section 36 — enablement — for the first time based upon his finding that the documentation submitted by the inventors seemed to indicate that the invention was the result of much "luck" and that others would not be able to reproduce the process that led to the invention from the disclosure in the application. The Court also disagreed with the inventor's contention that the deposit of seeds with the Patent authorities constituted sufficient disclosure under the Act. *Id.* at 226-27. Section 36 of the Canadian Patent Act — the enablement statute — is similar to Article 83 of the EPC and to Section 112 of the United States Patent Act. On appeal, the Canadian Supreme Court affirmed the denial of the patent on disclosure and enablement grounds, thereby not having to decide the more difficult issue of whether or not altered living matter is patentable.

"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."[5] The federal patent laws promote this "Progress" by offering inventors exclusive rights to their inventions as an incentive for their inventiveness and research efforts.[6] The authority of Congress is exercised in the hope that "[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."[7]

The limited monopoly referred to in Article I, Section 8 of the U.S. Constitution, is a seventeen-year monopoly, during which the patent holder may exclude all others from "making, using or selling" the patented invention without authorization.[8] The patentee may also sue alleged infringers.[9] The monopoly power, and the consequent economic power have indeed been amazing incentives for invention. Since U.S. patents have first been granted, there have been over five million patented inventions. In certain recent cases, it has not been unusual for the damage award in a patent infringement case to be well into the millions of dollars. In some cases, such as *Polaroid v. Eastman Kodak*,[10] the damages may reach close to one billion dollars. It is therefore, an understatement to say that a party who invents what he believes is a commercially important invention wants to avail himself of patent protection.

> Having found that there was not sufficient disclosure of this soybean variety and that it therefore cannot be a patentable matter within the meaning of the [Canadian] Patent Act, it is neither necessary nor desirable for the reasons already given to consider in this appeal whether this new soybean variety can be regarded as an invention within the meaning of s.2. I would accordingly dismiss the appeal.

60 D.L.R.(4th) at 238. At present, the general issue of the patentability of animals has not yet been adjudicated in Canada, and *Pioneer Hi-Bred Ltd.* is the major obstacle to obtaining patent protection for life forms, plant or animal.

5. U.S. CONST. art. I, § 8, cl. 8.

6. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974); Universal Oil Co. v. Globe Co., 322 U.S. 471, 484 (1944).

7. *Kewanee, supra* note 6, at 480.

8. 35 U.S.C. § 154.

9. 35 U.S.C. § 271(a).

10. 641 F. Supp. 828, 228 U.S.P.Q. 305 (D. Mass. 1986), *aff'd*, 789 F.2d 1556, 229 U.S.P.Q. 561 (Fed. Cir.), *cert. denied* 479 U.S. 850 (1986) (liability portion of trial); *see also The Battle Raging Over Intellectual Property*. BUSINESS WEEK, May 22, 1989. In Polaroid Corp. v. Eastman Kodak Co., 16 U.S.P.Q.2d 1481, (D.Mass 1990), the plaintiff was awarded $909,457,567.00 in damages for infringement of its instant photography patents. The case was later settled for approximately $925 million in cash and short term securities.

III. Requirements for Patentability

Section 101 of the Patent Act of 1952 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.[11]

In order for a patent to be obtained, the statutory criteria listed in Section 101, newness and usefulness, must be met by the inventor. The newness or "novelty" requirement means that one may not receive a patent for an invention that is essentially the same as an invention that preceded it. The requirements for "novelty" are listed in Section 102 of the Patent Act. The invention is evaluated in light of the previously commercialized or used inventions, and publications which describe previous inventions.[12] Section 102 also includes certain statutory bars to patentability that relate to delays on the part of the inventor to file, after he or she has commercialized or publicized the invention.[13]

---

11. 35 U.S.C. § 101. Patents are granted for inventions in the following categories under 35 U.S.C. § 101: processes, machines, manufactures, or compositions of matter. The categories have been defined as follows: "A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of act, performed upon the subject matter, to be transformed and reduced to a different state or thing." Cochran v. Deener, 94 U.S. 780, 788 (1877). A machine is "every mechanical device or combination of mechanical powers and devices to perform some function and produce a given effect or result." Corning v. Burden, 56 U.S. 252, 267 (1853). A "manufacture" is "the production of articles for use from raw or prepared materials by giving these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." American Fruit Growers v. Brogdex, Corp., 283 U.S. 1, 11 (1931). A "composition of matter" is "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, 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).

12. 35 U.S.C. § 102.

13. 35 U.S.C. § 102 provides:

> A person shall be entitled to a patent unless—
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
>
> (c) he has abandoned the invention, or
>
> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
>
> (e) the invention was described in a patent granted on an application

In the context of forms of animal life, the traditional view was that "naturally occurring life forms" could not be patented because they were not "novel" or "new."[14] Prior to the Supreme Court's *Chakrabarty* decision, patents on forms of "living organisms" were not issued whether they occurred naturally or not.

In addition, in order to be protected by a patent, an invention must be "non-obvious." Under Section 103 of the Patent Act[15] an invention is "obvious," and therefore unpatentable, even though not literally the same as a preceding invention, if an inventor is able to make minor modifications to another invention, whether patented or not, which would have been obvious to a person with "ordinary skill in the art" at the time of his invention. The "ordinary skill in the art" differs according to the field of the invention. In the case of animal patents, the person with "ordinary skill in the art" would probably be a genetic engineer. The "obviousness" requirement eliminates from the field of patentability inventions with trivial changes over the prior art.

Moreover, in order for a patent to issue, the invention must also

---

for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of Section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

14. *See Chakrabarty*, discussed *infra*; *see also In re* Bergy, 563 F.2d 1031 (CCPA 1977), *vacated* (in light of Parker v. Flook, 437 U.S. 584 (1978)), 438 U.S. 902 (1978), 596 F.2d 952 (CCPA 1979), *dismissed as moot* 444 U.S. 1028 (1980). The question of what happens to the progeny of non-sterile non-naturally occurring life forms is a different subject and has not been addressed by the court.

15. Section 103 of the Patent Act of 1952 provides as follows:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 of this title if the differences between the subject matter sought to be patented and the prior art are such at that the subject matter as a whole would have been obvious to a person with ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person which qualifies as prior art only under subsection (f) or (g) of Section 102 of this title shall not preclude patentability under this Section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103.

be "useful." In patent law, an invention is "useful" if it possesses some functional utility apart from basic research.[16] There have been situations in which "new" and "non-obvious" processes and/or products have been invented, only to not have patents issued on them, because at the time of the application there was no known use for the invention. As was stated in *Brenner v. Manson*:

> Unless and until a process is refined and developed to [the] point where specific benefit exists in currently available form there is insufficient justification for permitting an applicant to engross what may prove to be a broad field . . . . [A] patent is not a hunting license. A patent is not a reward for search, but compensation for its successful completion. "[A] patent system must be related to the world of commerce, rather than to the realm of philosophy."[17]

In the case of the "Harvard mouse," the usefulness requirement was met, for the mouse was invented to be used as an aid in cancer research. Because the mice were engineered to be more susceptible to cancer, scientists would be able to more quickly monitor the growth and spread of the disease. The mouse would provide "time-lapse" cancer research.[18] Unlike the unpatentable steroid in *Brenner v. Manson*, the patented transgenic mice were found to be "useful" at the time of their invention.

As previously mentioned, the major statutory requirement in question in cases involving living organisms is "novelty or newness." Can a living organism be considered new? This issue was dealt with by the Supreme Court a decade ago in *Diamond v. Chakrabarty*.[19]

IV. Precedent Setting Cases

A. Diamond v. Chakrabarty

Diamond v. Chakrabarty allowed for the legalized patenting of "living organisms."[20] In *Chakrabarty*, an inventor filed a patent application with the PTO for a human-made, genetically engineered

16. *See, e.g.*, Brenner v. Manson, 383 U.S. 519 (1966) (patent on new process for manufacturing steroid with no known use not issued for lack of "utility").

17. *Id.* at 535-36 (quoting Application of Rushig, 343 F.2d 965, 970 (C.C.P.A. 1965).

18. The 1992 patented mice, too, will act as "time lapse" aids for disease research. U.S. Pat. No. 5,175,383 was engineered to develop an enlarged prostate gland; U.S. Pat. No. 5,175,384 was engineered to not be able to develop mature "t-cells"; U.S. Pat. No. 5,175,385 was engineered to develop a low level of beta interferon, a protein that helps to fight viri and prevents infections. 45 Pat. Trademark & Copyright J. (BNA) at 159.

19. 447 U.S. 303 (1980).

20. *Id.*

new strain of bacteria from the genus *Pseudomonas*, which was capable of breaking down the multiple components of crude oil. No other species of bacteria had this unique ability.[21] The invention was "useful," because it could be utilized in efforts to break down and clean up oil spills, and was viewed to be a useful improvement over other bacteria or other processes previously used to dissolve oil spills.[22]

During the prosecution of the Chakrabarty patent application, the Patent Examiner rejected the application on the grounds that bacteria constituted living organisms, and since "microorganisms cannot qualify as patentable subject matter [under § 101], the invention was unpatentable."[23] The inventor appealed the PTO's decision to the Patent Board of Appeals, which affirmed the PTO's rejection. On further appeal, the Court of Customs and Patent Appeals (CCPA) reversed, holding that "the fact that microorganisms . . . are alive . . . [is] without legal significance for purposes of the patent law."[24]

The Supreme Court affirmed the decision of the CCPA and allowed the issuance of the patent in question. The Court, in its 5 to 4 decision, analyzed the general legislative history of the patent law, and of the Patent Act of 1952, by considering writings going all the way back to the original Patent Act of 1793. These writings included Thomas Jefferson's definition of patentable subject matter, i.e., "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereon," as well as the language in the House Report that accompanied the drafting of the Patent Act of 1952.[25] The Court stated: "The Committee Reports accompanying the 1952 Act inform that Congress intended statutory subject matter to 'include *anything under the sun that is made by man.*' "[26]

The Supreme Court did, however, add the clarification that not everything is patentable; a patentable invention must be *created by man*, instead of merely discovered:

> [A] new mineral discovered in the earth or a new plant

21. *Id.* The applicant claimed "a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway." *See also* 1 DONALD S. CHISUM, PATENTS § 1.02[7][d].

22. *Id.* at 305 n.2.

23. *Id.* at 305 n.2.

24. *Id.* at 306.

25. *Id.* at 308 (quoting Act of Feb. 21, 1793, § 1, 1 Stat. 319).

26. CHISUM, *supra* note 21, at 309 (quoting H.R. Rep. No. 1923, 82nd Cong., 2d Sess., 6 (1952) (emphasis added)).

> found in the wild is not patentable subject matter. Likewise, Einstein could not patent his ultimate law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations . . . of nature, free to all men and reserved exclusively to none.[27]

Because the bacteria in *Chakrabarty* did not naturally occur in nature, and was clearly created by man, it was considered to be a new and useful "composition of matter." The Court, therefore, allowed the patent on the bacteria to issue.

Although the issue in *Chakrabarty* was the patentability of a simple bacterium, the language indicated that "living organisms" were patentable, not just bacteria. The *Chakrabarty* decision, therefore, opened up the field for the patentability of other forms of life and ignited the spark that set off the present controversy.[28]

B. Ex Parte Hibberd

Shortly after the United States Supreme Court decided *Chakrabarty*, the Patent Office was faced with another case involving a patent on living matter. In *Ex Parte Hibberd*,[29] the Board of Patent Appeals and Interferences (BPAI) extended the scope of "patentable subject matter" by holding that nonnaturally occurring, man-made multicellular plants fell within the scope of Section 101.[30] The invention in question was a corn plant (maize) that was developed to contain an increased level of the amino acid tryptophan. In its initial examination in the PTO, the Examiner rejected the application on the grounds that the exclusive scheme for protection for newly made plants was under the Plant Variety Protection Act[31] and not under the Patent Act.[32] On appeal, the BPAI relied on *Chakrabarty* and held that Congress did not intend for the plant patent statutes to be the exclusive means of protecting plants that otherwise met the requirements of patentability as set forth in Sec-

27. *Id.* at 303 (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

28. Since *Chakrabarty*, there have been over 200 patents granted on bacteria. *See* Robert B. Kambic, Note, *Hindering the Progress of Science: Regulate Research on Genetically Altered Animals*, 16 FORD. URB. L.J. 441, 442-43 (1988).

29. 227 U.S.P.Q. 443 (B.P.A.I. 1985).

30. *Id.* at 447.

31. The Plant Variety Protection Act (PVPA) is codified in 7 U.S.C. § 2402 *et seq.* The PVPA provides protection to certain sexually reproduced plants, however, it excludes bacteria from its scope. *See Chakrabarty*, 447 U.S. at 310-11. Protection for asexually reproduced plant forms is provided under the Plant Protection Act (PPA). The PPA is codified in 35 U.S.C. § 161.

32. 227 U.S.P.Q. at 446.

tions 101, 102 and 103.[33]

Although *Ex Parte Hibberd* dealt with a patent for a plant, and not an animal, it stands for the proposition that Congress, the Supreme Court, and the Patent Office all intended "patentable subject matter" under Section 101 of the Patent Act to be construed quite broadly.

C. *Ex Parte* Allen

Following the *Chakrabarty* and *Ex Parte Hibberd* decisions, there was a case involving the patentability of another type of living organism, oysters. In *Ex Parte Allen*[34] the patent applicants developed a method for producing a new variety of sterile polyploid oysters of the *Crassostrea gigas* species. The argued advantage of the oysters being sterile is that they would remain edible throughout the entire year, instead of only during the "R" months.[35]

During the prosecution of the patent, the Patent Examiner, allowed the method claims, but rejected the "product-by-process" claims under Section 101, stating that the new variety of oyster was "controlled by the laws of nature and not a manufacture by man that is patentable."[36] The PTO also rejected the application on the grounds of Section 103 of the Act, "obviousness," stating that the process used to produce the oysters in question would have been obvious, from other similar experiments and processes, to the scientist possessing skill in the art.[37] The inventor appealed the PTO's final determination.

The Board of Patent Appeals and Interferences reversed the holding of non-patentability under Section 101, reiterating the legislative history cited in *Chakrabarty*, "that Congress intended statutory subject matter 'to include anything under the sun that is made by man.' "[38] Because this type of oyster had not existed before, and was clearly the result of man's creative scientific efforts, the court held that the organism qualified as "patentable subject matter" under Section 101.

The patent, however, did not issue on the other grounds for

33. *Id.* Shortly after *Ex Parte Hibberd* was decided, the PTO announced that it would examine applications for utility patents on plants, plant tissues, seeds, and plant cells. *See* 1060 OFF. GAZ. PAT. OFFICE 4 (Oct. 8, 1985).

34. 2 USPQ 2d 1425 (BPAI 1987), *aff'd sub nom, In re* Allen, 846 F.2d 77 (Fed. Cir. 1988).

35. Normally, oysters are inedible during the summer breeding months.

36. *Id.*; *see* 35 U.S.C. § 102.

37. 2 U.S.P.Q. 2d at 1428.

38. *Id.*

which it was found unpatentable, i.e., "obviousness."[39] The BPAI agreed with the Patent Examiner that the methods used to produce the oysters would have been "obvious" to one skilled in the art at the time. On further appeal, the Federal Circuit affirmed both the BPAI's "patentable subject matter" and "obviousness" determinations.[40] Although the patent did not issue, the case reinforced the proposition that newly created genetically altered "living organisms" fall within the category of "patentable subject matter" under Section 101.

D. The PTO "Rule"

In April of 1987, shortly after the BPAI decided *Ex Parte Allen*, the United States Patent and Trademark Office promulgated a rule (the "Rule") allowing for the patenting of animals:

> The Patent and Trademark Office now considers non-naturally 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.[41]

The "Rule" set the stage for the first patent on a multi-cellular vertebrate life form — The Harvard Mouse.

V. The Harvard Mouse

On April 12, 1988, the PTO issued a utility patent, U.S. Patent No. 4,736,866 to a "transgenic non-human mammal" — i.e., a genetically engineered mouse. The invention was described in the patent's abstract as:

> A transgenic non-human eukaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal, or an ancestor of the animal, at an embryonic stage.

Scientists at Harvard were able to isolate a gene that causes cancer in mammals, including humans. The gene was then injected

---

39. 35 U.S.C. § 103.

40. *In re* Allen, 846 F.2d 77 (Fed. Cir. 1988).

41. Printed at 1077 OFF. GAZ. PAT. OFFICE 24 (Apr. 21, 1987) (emphasis added). The word "claim" referred to in the "Rule" relates to the claims of a patent. In every patent, it is only the claims — which appear at the end of the patent document, that define the scope of the invention. Although there may be a detailed description in the abstract or specification, it is only the claim that governs the scope of the patent itself. *See* 35 U.S.C. § 112.

into already fertilized mouse ova.[42] Approximately one-half of the female mice produced this way developed breast cancer within ten months of their birth.[43] These mice are extremely prone to known carcinogens and "will develop cancer if exposed to only small amounts" of the carcinogens.[44] By being so sensitive to carcinogens, the mice act as "time lapse" "cancer detectives,"[45] and enable scientists to monitor both the course of the disease and its causes. In addition, the patented mice are supposedly fertile, so the cancer susceptibility could be traced from generation to generation. It is reported that the progeny will exhibit the same characteristics as their parents.[46] Questions of whether or not exposure of one generation to carcinogens would affect the progeny could also be studied. Therefore, a creature of this type might be able to detect second generation cancer, such as with the drug DES, where the daughters of mothers who took DES during pregnancy developed cancer.

The usefulness of the "transgenic non-human mammal" is set forth in the description section of the patent itself:

> The animals of the invention can be used to test a material suspected of being a carcinogen, by exposing the animal to the material and determining neoplastic growth as an indicator of carcinogenicity. This test can be extremely sensitive because of the propensity of the transgenic animals to develop tumors. This sensitivity will permit suspect materials to be tested in much smaller amounts than the amounts used in current animal carcinogenicity studies, and thus will minimize one source of criticism of current methods, that their validity is questionable because the amounts of the tested material used is greatly in excess of amounts to which humans are likely to be exposed. Furthermore, the animals will be expected to develop tumors much sooner because they already contain an activated oncogene. The animals are also preferable, as a test system, to bacteria (used, e.g., in the Ames test) because they, like humans, are vertebrates, and because carcinogenicity, rather than mutagenicity, is measured.
>
> The animals of the invention can also be used as tester animals for materials, e.g., antioxidants such as beta-carotene or Vitamin E, thought to confer protection against the development

42. *Id.*; Note, *Altering Nature's Blueprints for Profit: Patenting Multicellular Animals*, 74 U. VA. L. REV. 1327, 1356 (1988); *see also* N.Y. TIMES, Apr. 13, 1988, at A12, col. 5.

43. *Altering Nature's Blueprints for Profit, supra* note 42 at 1356.

44. *Id.*

45. *Id.*

46. *Id.* This leads to an interesting question. Should the progeny be unpatentable because they would be "naturally occurring?"

of neoplasms. An animal is treated with the material, and a reduced incidence of neoplasm development, compared to untreated animals, is detected as an indication of protection. The method can further include exposing treated and untreated animals to a carcinogen prior to, after, or simultaneously with treatment with the protective material.

The animals of the invention can also be used as a source for cell culture. Cells from the animals may advantageously exhibit desirable properties of both normal and transformed cultured cells; i.e., they will be normal or nearly normal morphologically and physiologically, but can, like cells such as NIH 3T3 cells, be cultured for long, and perhaps indefinite, periods of time. Further, where the promoter sequence controlling transcription of the oncogene sequence is inducible, cell growth rate and other culture characteristics can be controlled by adding or eliminating the inducing factor.[47]

By patenting the mouse, the patent holder, in this case, the Assignee, Harvard, has a statutory seventeen year monopoly on the mouse, and its cells.[48] Should a company or other institution wish to do additional research on the mouse, or on its cells, or replicate the procedure described in the patent to create another cancer susceptible genetically altered organism, a license or other grant of authorization would be necessary in order to avoid patent infringement. The commercial potential is immediately evident.

It should be noted, however, that although the preferred embodiment described in the invention is a mouse, the independent claim, claim 1, covers "non-human" life forms. Therefore, technically, under this patent, other forms of similarly altered animals, such as rats or cats, would probably infringe.

VI. Promotion of Science and the Useful Arts?

Many will argue that the patentability of animals is the "promot[ion] of Science and the useful Arts" as is called for in the Constitution. Many inventions which were not within the realm of thought or within the imaginations of the framers of the Constitution have been patented, such as the television, computer chips, lasers, etc. It could be argued that genetically engineered animals are part of the natural progression of science and should therefore be afforded patent protection. As science grows, and as our desire to un-

47. U.S. Patent No. 4,736,866.
48. The patent will expire in April, 2005.

derstand and conquer disease grows as well, a solid argument could be made that patent protection for genetically altered creatures will create additional incentives to create, which will ultimately reward society.

With the carrot of seventeen years of royalties waived in front of them, inventors and researchers may be additionally motivated. However, a great deal of valid and valuable research occurred during the years before animals were patentable. The over five million patents and the huge research and development budgets of research oriented companies that existed before patents on animals were issued is evidence of this. How much of an increase in genetic engineering activity will be spurred by the allowance of the patenting of animals remains to be seen.

> The grant or denial of patents on microorganisms is not likely to put an end to genetic research or to 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 any more than Canute can command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.[49]

VII. Invitation to Abuse?

Although the topic has been discussed quite actively since *Chakrabarty*, since the promulgation of the "Rule" by the PTO in April 1987 allowing the patentability of living organisms, and certainly since the issuance of U.S. Patent No. 4,736,866 on the "Harvard Mouse," even at the time of the *Chakrabarty* decision, scientists, academics, and animal rights proponents expressed concern over potential dangers of allowing the patentability of animals.

In *Chakrabarty*, the Supreme Court discussed the amicus briefs filed by the animal rights interested parties:

> The briefs present a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told

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

> that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at time, human ingenuity seems unable to control fully the forces it creates—that, with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of."[50]

Many inventions that have ultimately been patented have been the result of accidents. The vulcanization of rubber or even the familiar "Post-it"™ immediately come to mind. If inventors are able to receive the benefits of the seventeen-year patent monopoly on genetically altered animals, there is no telling to what certain scientists might subject their animal subjects, in attempts to "create" a "new, useful, and non-obvious" creature, i.e., a patentable invention. In a climate of increased sensitivity to the rights of animals among many students, scientists and academics, the patenting of animals may be an invitation to additional abuse. The Harvard mouse, itself, has been criticized as an abusive invention, for the patented invention is a living animal that was deliberately created to be susceptible to cancer. The three new strains of mice covered by the patents issued in December of 1992 were also specifically engineered to be more susceptible to disease.

Congress, too, has recognized this concern over what may happen should there not be any limitations on the patenting of "living organisms." In each session of Congress since the PTO passed the "Rule" in 1987, Senator Mark Hatfield (Rep. Ore.) has introduced legislation to place a moratorium on animal patents.[51] None of the prior bills were acted upon. This year, in response to the PTO's issuance of the three new mouse patents, and in response to the National Institute of Health (NIH) applying for patents on hundreds of human DNA gene sequences,[52] Senator Hatfield once again intro-

---

50. *Chakrabarty*, 447 U.S. at 316.

51. *See Animal and Gene Patent Moratorium Bill is Reintroduced*, 45 Pat. Trademark & Copyright J. (BNA) at 347 (Feb. 25, 1993).

52. *See* Cong. Rec. 2/18/93, p.S1792, reprinted in *Animal and Gene Patent Moratorium Bill (S 387) and Floor Debate on NIH Authorization Legislation*, 45 Pat. Trademark & Copyright J. (BNA) at 355-59 (Feb. 25, 1993). The NIH filed patent applications on behalf of its researchers for hundreds of complementary DNA fragments or "express sequence tags" to be used to identify full gene sequences. Last September, NIH Director, Bernadette Healy, told the Senate Subcommittee on Patents, Trademarks that the PTO had rejected the NIH gene patenting claims for failure to demonstrate novelty, nonobviousness, and utility. However, she indicated that the NIH would "continue to deal with the PTO" on its patent applications which she said were filed as an "interim policy" to protect United States interests and to "hold

duced legislation to temporarily restrict patents on animal life forms, in order to give Congress time to thoroughly consider the matter. The Animal and Gene Patent Moratorium Bill (S.387) proposed the enactment of a new section 106 of the Patent Act.[53] The proposed statute would provide as follows:

> § 106 Prohibition on Patentability of Certain Inventions or Processes
>
> (a) IN GENERAL.—No human being, human organ, organ subpart (genetically engineered or otherwise) or genetically engineered animal shall be considered patentable subject matter under this title.
>
> (b) SUSPENSION.—Except as otherwise provided in this section, during the 2-year period beginning on the date of enactment of this section, no —
>
> (1) human tissue, fluid, cell, gene, gene sequence (genetically engineered or otherwise); or
>
> (2) animal or animal organism (genetically engineered or otherwise) shall be considered patentable subject matter under this title. The prohibition under this section may continue after such 2-year period pursuant to Section 381(f) of the Public Health Service Act.
>
> (c) EXCEPTION.—Subsection (b) shall not apply to patents issued prior to the date of enactment of this section.
>
> (d) PATENT STATUS OF OTHERS.—Notwithstanding any other provision of law, with respect to those individuals who have applied or will apply for a patent to which this section applies, this section shall not be construed to detrimentally affect the rights of such individuals, but rather to maintain such rights until the expiration of the 2-year period described in subsection (b).
>
> (e) DEFINITIONS.—As used in this section, the term "genetically engineered" means the formation of new combinations of genetic material by the insertion of nucleic acid mole-

---

our place" internationally. *See Animal and Gene Patent Moratorium Bill is Reintroduced, supra* note 51, at 347. Ms. Healy pointed out that dumping the rights to the NIH gene sequences into the public domain would forfeit rights to them in both the United States and abroad. *Id.* This was good advice from Ms. Healy, for under 35 U.S.C. § 102, a patent may not be obtained for an invention that had been offered for sale or described in a printed publication more than one year prior to the filing of a patent application. Filing, even when the standards are unclear, preserves the rights to the inventions and prevent any of the Section 102 statutory bars from preventing patentability.

53. Former legislation proposed a new Section 105. This year's bill proposes Section 106 because in October of 1992, President Bush signed into law a bill creating 35 U.S.C. § 105, "Patents in Space." In addition, this year's legislation is far more encompassing than prior legislation. The 1993 bill contains a moratorium on "human tissue, fluid, cell, gene, or gene sequence." Previous moratorium bills were aimed only at the patenting of animals.

cules into the host organism's somatic or germline cells so as to allow the incorporation of new genetic material into the genetic material of the host organism."

In proposing the moratorium, Senator Hatfield stated:

> I am not here to object to the research that is being conducted using these creatures. No Senator is more committed to the advancement of scientific research than is this one. Nor have I come to the floor to attack the motives of the Patent and Trademark Office to issue these patents, primarily the 1980 Supreme Court decision in Diamond against Chakrabarty.
>
> Let me make my position clear. Despite the legal issues that swirl outside the walls of this great building, Congress has a solemn duty to ensure that the serious ethical issues related to the patenting of living creatures is raised and dealt with. The idea of issuing patents for living creatures that have been altered in minor ways by man raises many profound ethical issues that I believe should be carefully explored.[54]

The House, too, has its moratorium proponent. Each year, usually in tandem with Senator Hatfield's proposal, Rep. Benjamin Cardin (Dem. Md.) has proposed similar legislation.[55] At the time that this article was written, Rep. Cardin had not yet introduced the House Counterpart to S.387. If, however, past history is any indicator, Cardin is expected to act in the near future. As stated earlier, none of the previously introduced bills has passed. There is no reason to expect that Congress will actually act this time. Hatfield's and Cardin's proposals may be more symbolic than legislative.

It should be noted that the failure of Congress to pass legislation that restricts or prohibits the patenting of animal life forms is not owed to inactivity in the intellectual property arena. Since the first bills restricting animal patents have been introduced, Congress has passed numerous laws related to intellectual property, including but not limited to "The Visual Artists Rights Act of 1990,"[56] "The Copyright Remedy Clarification Act,"[57] "The Patent Remedy Clari-

54. *Animal and Gene Patent Moratorium Bill (S 387) and Floor Debate on NIH Authorization Legislation*, 45 Pat. Trademark & Copyright J. (BNA) at 355 (Feb. 25, 1993).

55. Rep. Cardin previously introduced the following bills regarding patents on transgenic or genetically engineered animals: H.R. 3247 (1989) and H.R. 4989 (1992).

56. The Visual Artists Rights Act of 1990 created Section 106A of the Copyright Act. Section 106A provides artists with protection against alteration or mutilation of "works of visual art" as defined in Section 101 of the Act. In addition, Section 106A enables an artist to receive attribution for works created for him or her.

57. The Copyright Remedy Clarification Act, enacted November 15, 1990, eliminated state sovereign immunity under the Eleventh Amendment of the United States Constitution in copyright infringement actions. After the Supreme Court decided *Atascadero State Hospital*

fication Act,"[58] "Patents in Space,"[59] "The Home Audio Recording Act,"[60] and "The Process Patent Reform Act."[61] In addition, laws amending Section 107 of the Copyright Act regarding unpublished works and fair use[62] and legislation adding Section 271(e) to the Patent Act to allow an exemption for the manufacture and use of patented drugs and medical devices for FDA approval,[63] have also been enacted. Congress' reluctance to enact specific legislation limiting or restricting animal patents, therefore, appears to be the result

---

v. Scanlon, 473 U.S. 234 (1985), courts construed the term "anyone" in Section 501 of the Copyright Act as not being specific enough to empower plaintiff to sue a state in federal court. Because federal courts are the exclusive jurisdiction in copyright infringement cases under 28 U.S.C. § 1338, plaintiffs were left without a remedy in the event that it was a state who had infringed the patent. *See BV Engineering v. University of California, Los Angeles*, 858 F.2d 1394 (9th Cir. 1988), *cert. denied*, 489 U.S. 1033 (1989); *see also Richard Anderson Photography v. Brown*, 852 F.2d 14 (4th Cir. 1988), *cert. denied*, 489 U.S. 1090 (1989). The Copyright Remedy Clarification Act expanded the definition of "anyone" in Section 501 to specifically include "states," "state employees," and "instrumentalities of states." In addition, Section 511 was added to expressly provide that "Any State, employee of a State, or instrumentality of a State acting in his or her official capacity, shall not be immune, from suit in federal court by any person, including a governmental entity, for a violation of any of the exclusive rights of a copyright owner." 17 U.S.C. § 511, Pub. L. 101-553 (1990). *See generally* Michael B. Landau, *Sovereign Immunity and U.S. Patent and Copyright Law*, 7 INT'L PROP. J. 204 (1992).

58. The Patent Remedy Clarification Act, enacted October 28, 1992 was similar in intent to the Copyright Remedy Clarification Act, in that it was meant to correct the same problem with respect to patent law. Prior to its enactment, states were immune from liability for patent infringement under the Eleventh Amendment of the United States Constitution. See *Chew v. California*, 893 F.2d 331 (Fed. Cir., *cert. denied*, 111 S. Ct. 44 (1990); The Patent Remedy Clarification Act created a new Section 296 to Title 35. The language of 35 U.S.C. § 296 tracks the language of 17 U.S.C. § 511. In addition, the Patent Remedy Clarification Act amended Section 501 of the Patent Act (35 U.S.C. § 501) to expand the definition of "whoever" to include States, employees of States, and instrumentalities of States.

59. *See* 35 U.S.C. § 105 which provides that an invention made, used or sold on a space vehicle under United States jurisdiction shall be covered by United States patent laws.

60. The Home Audio Recording Act, enacted October 28, 1992, provides for the sale and importation of Digital Audio Media. The Act imposes a royalty on digital tapes and recorders, and, for the first time, expressly states that it is not an act of infringement for one to make an audio copy for home personal use.

61. *See* 35 U.S.C. § 271(g).

> Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted on account of the non-commercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of the product. A product which is made by a patented process will for purposes of this title, not be considered to be so made after —
>
> (1) it is materially changed by a subsequent process; or
>
> (2) it becomes a trivial and non-essential component of another product.

Id.

62. Section 107 of the Copyright Act, "Fair Use" was amended on October 28, 1992, to include language providing that the unpublished nature of a work shall not preclude a finding of fair use.

63. *See* 35 U.S.C. § 271(e) which was amended in response to *Roach v. Bolar*.

of a deliberate decision on the part of Congress to endorse the *status quo* — allowing animals to be patented.

Although Congress is taking a step in the direction of temporarily curbing the patenting of animals, pending more thorough debate, Congress' proposal only partially addresses many of the animal rights proponents' concerns. Congress has not attempted to impose a moratorium on process or methods used to create the genetically engineered animals. Therefore, even if the patents on the animals themselves are temporarily restricted or curtailed, genetic engineers would still be able to obtain patents on "new," "useful," and "non-obvious" processes used on the animals, or their ova. If the concern truly is establishing limits on genetic experimentation on animals, then the issuance of process or method patents which lead to genetically altered organisms should be curtailed, pending further consideration, as well.

VIII. Litigation Challenging the PTO "Rule"

As stated above, in April of 1987, the PTO issued a statement that it "considers nonnaturally occurring, non-human multicellular organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101."[64] The "Rule" was not published in the Federal Register prior to promulgation. The PTO also did not invite public comments prior to promulgation of the "Rule".[65] The Animal Legal Defense Fund (ALDF) and other plaintiffs[66] mounted a hyper-technical attack challenging the PTO's Rule on both procedural and substantive grounds.[67] The plaintiffs alleged that the PTO was not empowered to make such a ruling with respect to patentability and that the PTO issued the Rule in violation of the public notice and comment requirements of Section 553 of the Administrative Procedures Act (APA).[68]

64. In promulgating its Rule, the PTO relied on *Chakrabarty*, *In re Hibberd*, and *Ex Parte Allen*. The Rule was published at 1077 OFF. GAZ. PAT. OFFICE 24 (Apr. 24, 1987).

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

66. In addition to ALDF, the following groups and individuals were also plaintiffs in the action: 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 the People for the Ethical Treatment of Animals (PETA).

67. Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728 (N.D. Cal. 1989). The named defendants were Donald J. Quigg, the Commissioner of Patents and Trademarks and C. William Verity, the former Secretary of Commerce.

68. 5 U.S.C. § 553. Section 553 provides in pertinent part:

> (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

The defendants filed a motion to dismiss for failure to state a claim arguing that the "Rule" was not a new statute or regulation, but was merely "interpretive" of precedent, namely *Chakrabarty* and *Ex Parte Allen* and did not abridge or enlarge anyone's rights. The Northern District of California agreed with the defendants, held that the Rule was exempt from the notice and comment requirements of the Administrative Procedure Act, and granted defendants' motion to dismiss.[69] The ALDF appealed the case to the Court of Appeals for the Ninth Circuit.[70] On appeal, the Ninth Circuit did not address the merits of the case, but transferred the case to the Court of Appeals for the Federal Circuit, pursuant to 28 U.S.C. § 1631, because, in its opinion, the case "arises under the patent law."[71]

When the Federal Circuit heard the case in 1991,[72] it, too, did not address the merits of ALDF's argument with respect to the PTO's authority to promulgate the "Rule." Instead, the Federal Circuit held that the defendants lacked standing to seek a declaration that animals were not patentable subject matter and an injunction against the issuance of other animal patents.[73]

---

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;

(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 interpretive 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 into 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.

Id.

69. 710 F. Supp. at 730-32.

70. 900 F.2d 195 (9th Cir. 1990).

71. *Id.* at 197. The Court of Appeals for the Federal Circuit, created in 1982, has exclusive jurisdiction for all patent appeals, regardless of the district court in which the case originates.

72. 932 F.2d 920 (Fed. Cir. 1991).

73. *Id.* at 938.

> The standing allegations of the animal protection associations are patently insufficient under controlling precedent. As the various appellants correctly point out, the alleged injury need not be economic in nature to constitute "injury" for the purposes of standing. The interests alleged to have been injured "may reflect 'aesthetic, conservational, and recreational, as well as economic values. But broadening the categories of injury that may be alleged in support of standing is a different matter from abandoning the requirement that the party seeking review must himself have suffered an injury . . . [A]s the Supreme Court held in *Sierra Club*,[74] the APA does not authorize judicial review at the behest of organizations or individuals who seek to do no more than vindicate their own value preferences through the judicial process." [Appellants] assert only a general interest in preventing cruelty to animals. That these appellants allege they will spend more dollars on organizational activities and expenses as a result of the Notice does not serve to distinguish them from any member of the public with a particularized conviction about protecting animals. Thus [appellants] have failed to allege any cognizable injury.[75]

The court continued.

> "A party bringing suit must fall within the 'zone of interest' addressed by the substantive provisions of the law they seek to invoke."[76] Appellants baldly claim that they fall within the "zone of interests" addressed by the patent laws because patents "are issued not for private benefit, but for the public good . . . ." We cannot agree that the "zone of interest" of the patent laws is so broad. Under such an interpretation, we would, for example, be opening the door to collateral attack on the validity of issued patents; any competitor could simply file suit against the Commissioner challenging a patent's validity. The structure of the Patent Act indicates that Congress intended only the remedies provided therein to insure that the statutory objectives would be realized.[77]

---

74. 405 U.S. at 740.
75. 932 F.2d at 935.
76. 932 F.2d at 937.
77. *Id.* The court went ont to list numerous sections of the Patent Act and the proceedings authorized thereunder. *See, e.g.*, §§ 35-82 (in civil action for infringement, validity of patent can challenged as a defense); § 145 (civil action to obtain patent); § 146 (civil action in case of interference); § 135 (interference action); §§ 301-02 (reexamination proceedings). Essentially, after the Federal Circuit's opinion, the ALDER and the other plaintiffs were caught "between a rock and a hard place." The Federal Circuit held that the plaintiffs did not have standing to sue the Commissioner to challenge the validity of the patent, or of animal patents in general. The plaintiffs were not competitors, alleged infringers, or other inventors claiming priority of invention. Federal court was, therefore, not available to them. Plaintiffs also proba-

The ALDF was, therefore, unsuccessful in its challenge to the PTO's ruling that animals are patentable subject matter. At present, the issue has not been decided by a federal court. Following the logic of ALDF, it appears as though the only parties that would be within the "zone of interest" in order to have standing would be competing genetic researchers. Those parties would not want to challenge the "Rule" that creates considerable monetary rewards for the fruits of their labor. It is, therefore, doubtful that the issue will ever be decided by a federal court.[78]

One might ask, was the "Rule" by the PTO "interpretation" or was it new law? Section 101 provides: "[w]hoever invents or discovers any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[79] Each and every day, the PTO decides on an *ad hoc* basis which inventions constitute patentable subject matter. Determinations with respect to "novelty," "nonobviousness," and "utility" of individual inventions must be made. What is the difference between the PTO making numerous individual rulings with respect to each animal application that animals fall within the scope of patentable subject matter or the PTO making the blanket ruling that "non-human, nonnaturally occurring multicellular organisms, including animals constitute patentable subject matter?" In any event the result is the same; non-naturally occurring animals are patentable. Would there have been public outcry had the PTO ruled: "The United States Patent and Trademark Office considers lightbulbs which meet the requirements for novelty, nonobviousness and utility under Section 101 of the Patent Act to be considered to be patentable subject matter?" As the statute and case law stand, the category of "patentable subject matter" is broad. Section 101 does not contain the limiting language "excluding animals." If there is to be a change, it is up to Congress.

---

bly would have been unsuccessful in asking for a reexamination of the Harvard Mouse patent. Any reexamination or protest would have been decided by the PTO. Because it was the PTO which promulgated the "Rule" being challenged, it could probably be assumed that the result would not be any different in a subsequent proceeding before the PTO. Moreover, the only challenge to the patent that could be asserted by the ALDER and the other plaintiffs is that animals, *per se*, do not fall within the scope of "patentable subject matter." The ALDF was not challenging the validity based upon any newly discovered prior art that was not previously before the Examiner.

78. The issue cannot be decided by a state court, for the federal courts are the exclusive jurisdiction for all cases "arising under the patent law." 28 U.S.C. § 1338(a).

79. 35 U.S.C. § 101.

IX. Federal Preemption of State Animals Rights Laws

A potential problem with the April 1987 PTO Rule that allows "non-naturally occurring, non-human multicellular animals, including animals to be patentable subject matter within the scope of 35 U.S.C. Section 101, *et seq.*,"[80] the resultant mouse patent, and the inevitable other genetically altered animal patents to come, is that the inventions are protected under federal patent law. Therefore, any other animal, including primates may legally be experimented upon and genetically altered in the names of "science" and "promot[ion] of the useful Arts" under federal law, and may not be able to be regulated under state law.

Whenever a state law attempts to take away rights or conflict with rights granted under the patent laws, the state law is usually preempted.[81] Because of federal preemption of state laws in the patent area, a scientist conducting abusive experiments may not be prevented from doing so by state law. Were a state to enact strong "anti-vivisection" laws, or attempt to regulate what it deemed to be abusive or unnecessary experimentation on animals, the scientist, or should I say his lawyers, would claim that the state laws were preventing the scientist from doing what he is encouraged to do under the United States Constitution, and entitled and empowered to do under Title 35 — *i.e.*, invent. As the Supreme Court held in *Bonito Boats*:[82]

> [O]ur past decisions have made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws. The tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources is constant. Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second guess.[83]

Although this particular issue of state regulation of animal experimentation has not yet been tested in court, the preemption argument is a legal argument of which those who favor the rights of animals should be aware.

---

80. Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728, 729 (N.D. Cal. 1989), ordered transferred to Fed. Cir., 900 F.2d 195 (9th Cir. 1990).

81. *See, e.g.*, Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225 (1964); Compco Corp. v. Day Bright Lighting, Inc., 376 U.S. 234 (1964); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141 (1989).

82. 489 U.S. 141 (1989).

83. *Id.* at 147.

X. Conclusion

The patentability of animals raises serious, ethical, moral and legal issues, which require much thought and responsible legislation. In *Chakrabarty*, the Supreme Court realized that the decision of whether or not to allow animals to be patented was a difficult and complex one. However, as the Supreme Court often does, it left the ultimate decision to Congress.

> [The] process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives . . . . Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering . . . . But, until Congress takes such action, this Court must construe the language of § 101 as it is. The language of that section fairly embraces respondent's invention.[84]

Congress should give serious thought to this important issue, carefully consider all sides of the controversy, balance the competing values of promoting science and research with protecting the rights of animals, and enact legislation that carefully and expressly sets forth the limitations on the patenting of genetically engineered organisms or on the processes used to create such organisms.

Congress has often, in the past, changed or amended the patent laws to provide for unforeseen situations, to correct its ambiguous drafting, or in direct response to unpalatable Federal Circuit or Supreme Court opinions.[85] It is up to Congress to amend the Patent Act once again to set forth what it believes the proper limits on animal experimentation and genetic engineering should be. Until that time, however, *Chakrabarty*, *Ex Parte Allen*, the PTO "Rule" and the Harvard Mouse are the law.

---

84. *Chakrabarty*, 447 U.S. at 318; *see also* Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 530 (1972).

85. For example, in earlier versions of the patent law, "processes" were not patentable; in addition, several amendments of the 1952 Act were passed in response to certain court decisions to either impose or eliminate liability for infringement for certain acts. 35 U.S.C. § 271(f) (imposing liability on exporters or importers of essential component parts — in response to *Deepsouth, supra*); 35 U.S.C. § 271(e) (exempting from infringement the submission of drugs and medical samples, prior to patent expiration, for FDA Approval — in response to Roche Products, Inc. v. Bolar Pharmaceuticals Co., 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984)); *see also* 35 U.S.C. § 271(g) (imposing liability on parties who sell products made overseas by processes protected under U.S. Patents preventing the result in University Patents v. Questor, 517 F. Supp. 676 (D. Colo. 1981)).