

NOTE

BIOTECHNOLOGY AND THE PATENTING OF LIVING ORGANISMS

By
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I. INTRODUCTION

Processes, machines, manufactured products, and compositions of matter comprise the four general classes of patentable inventions in the United States.¹ The U.S. patent system also requires that the subject matter of a patent claim possess useful,² novel,³ and non-obvious characteristics.⁴ The progress of science and the development of new technologies pose continuous challenges to the adaptability of the law. However, few advances generated as much controversy as the innovations of the biotechnology industry. Late in the twentieth century, advances in genetics research confronted the patent system with the question of whether genet-

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¹ Patentability of Inventions, 35 U.S.C. §§ 100-105 (1994). "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore subject to the conditions and requirements of this title." *Id.* § 101. See also DONALD S. CHISUM, UNDERSTANDING INTELLECTUAL PROPERTY LAW 2-19 (1995).

² 35 U.S.C. § 101.

³ 35 U.S.C. § 102. "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, . . ." *Id.*

⁴ 35 U.S.C. § 103(a). "A patent may not be obtained though the invention is not identically disclosed or described as set forth in § 102 of this title [35 U.S.C. § 102], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *Id.*

ically altered living organisms qualify for patenting.⁵ The Supreme Court of the United States answered in the affirmative,⁶ and the United States Patent and Trademark Office (PTO) has promulgated a rule consistent with the decision of the Supreme Court.⁷

Focusing upon the legal rationale behind the interpretation of the patent statute, this paper analyzes the leap from the patentability of non-living things to the patentability of living things within the last twenty years.

II. CURRENT LEGAL CONTEXT

A. Case Law

Before 1980 the PTO refused to grant patent rights in a living creature without regard to the amount of bioengineering involved in its production.⁸ The federal courts often relied on the "products of nature" doctrine and the Plant Patent Acts of 1930 and 1970 as bases for rejecting patent claims covering living organisms.⁹ The "products of nature" doctrine¹⁰ is based on the premise that things which are produced by, and found in, the natural world cannot be patentable because they are not new; for example, these products cannot satisfy the novelty requirement of 35 U.S.C. § 102.¹¹ Furthermore, the PTO argued that the enactment of the Plant Patent Acts evidenced Congressional intent to exclude living things other than plants from patentability.¹² As well, the United States Court of Customs and Patent Appeals (C.C.P.A.) argued that if living things had been patentable before the enactment of the Plant Patent Acts these statutes

⁵ The patentability of plants has been addressed in the Plant Patent Act, ch. 312, § 1, 46 Stat. 376 (1930) (current version at 35 U.S.C. §§ 161-164 (1994)) and the Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (current version at 7 U.S.C. §§ 2321-2585 (1994)). However, the focus of this paper is not on plant patents but rather on the patentability of animals.

⁶ *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). "[T]he patentee has produced a new bacterium . . . accordingly it is patentable subject matter under § 101." *Id.*

⁷ *Diamond*, 447 U.S. at 311. "The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. [§] 101." 1077 OFFICIAL GAZETTE PAT. OFFICE 24 (Apr. 21, 1987).

⁸ David G. Scalise, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and The Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 95 (1995).

⁹ *Id.* (discussing *American Fruit Growers Inc. v. Brogdex Co.*, 283 U.S. 1 (1931)); see also *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979).

¹⁰ See Edmund J. Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 DRAKE L. REV. 551, 554 (1989).

¹¹ *Id.* at 556.

¹² *In re Bergy*, 596 F.2d at 978.

would be meaningless.¹³ All this changed, however, with the United States Supreme Court's decision in *Diamond v. Chakrabarty*.¹⁴

Chakrabarty sought to patent a species of bacteria capable of degrading crude oil more efficiently and to a greater extent than any other bacteria known to exist.¹⁵ He altered a species of *Pseudomonas* bacteria to give it the ability to metabolize several components of crude oil.¹⁶ Before such alteration the micro-organism proved completely incapable of metabolizing oil.¹⁷ Thus, Chakrabarty's work created a bacterium with new qualities. He sought patent protection for three elements: the bacterium itself, the process of producing the bacterium, and the combination product of the bacterium and a carrier material, such as straw, which could float on water.¹⁸ The patent examiner rejected only the first of these claims disallowing it on two grounds: 1) the bacterium was a "product of nature," and 2) living things are unpatentable subject matter.¹⁹ After the C.C.P.A. held in favor of Chakrabarty, the Supreme Court granted certiorari to rule on the dispute.²⁰

Chief Justice Burger, writing for a five-justice majority, stated the issue narrowly. Rather than approach the dispute as a question of the patentability of living organisms, he defined the controversy as whether Chakrabarty's invention "[c]onstitute[d] a 'manufacture' or a 'composition of matter' within the meaning of the statute."²¹ Before deciding the issue, Justice Burger admonished the lower courts not to "read into the patent laws limitations and conditions which the legislature has not expressed."²² Echoing the legislative history from the patent statute of 1952, Justice Burger stated that "Congress intended statutory subject matter to include anything under the sun that is made by man."²³ This broad interpretation of the universe of patentable subject matter includes new bacterium such as the one invented by Chakrabarty.²⁴

The Court rejected the argument that the Plant Patent Acts demonstrate Congressional intent to withhold patentability from all living things

¹³ *In re Merat*, 519 F.2d 1390, 1393 (C.C.P.A. 1975). In this case the Court of Customs and Patent Appeals held that a chicken under controlled propagation was not a "manufacture" within the meaning of the patent statute. The CCPA further stated, "If Section 101 of Title 35 were interpreted as broadly as appellants would have us interpret it; i.e., to include processes for the breeding of things occurring in nature to improve their qualities; it would be broad enough to include breeding plants also. Thus obviating the need for 35 U.S.C. [§] 161. This we do not feel the Congress intended us to do." *Id.*

¹⁴ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

¹⁵ *Id.* at 305 n.2.

¹⁶ *In re Bergy*, 596 F.2d at 969.

¹⁷ *Id.* at 970.

¹⁸ *Diamond*, 447 U.S. at 305-06.

¹⁹ *Id.* at 306.

²⁰ *Id.*

²¹ *Id.* at 307.

²² *Id.* at 308 (quoting *United States v. Dublier Condenser Corp.*, 289 U.S. 178, 199 (1933)).

²³ *Id.* at 309 (quoting S. Rep. No. 82-1979, at 5 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2399).

²⁴ *Id.*

except plants.²⁵ After examining the legislative history of the Plant Variety Protection Act of 1970 the Court found no persuasive evidence of such an intent by Congress.²⁶ In addition, the court was undeterred by the fact that Congress could not have contemplated the ability to create new living organisms in the laboratory when the patent statute was enacted.²⁷ "This Court has frequently observed that a statute is not to be confined to the 'particular application[s] contemplated by the legislators.'"²⁸

One striking aspect of the majority opinion in *Chakrabarty* is its length. In just sixteen pages the Supreme Court ruled on this issue of first impression, interpreting a federal law with far-reaching implications for both business and science.²⁹ The earlier decision of the C.C.P.A., affirmed by the Supreme Court's *Chakrabarty* decision, offers a more detailed contemplation of the arguments involved.³⁰ The C.C.P.A. consolidated *Chakrabarty's* case with the claims of Malcolm Bergy.³¹ Bergy sought patent rights in a purified culture of a micro-organism known as *Streptomyces vellosus*.³² The PTO rejected Bergy's claim to the micro-organism itself, but allowed claims to the process of preparing an antibiotic by utilizing the purified culture of *Streptomyces vellosus*. Thus, the C.C.P.A. found that the cases of both *Chakrabarty* and *Bergy* involved the "same single question of law."³³

In its decision, the C.C.P.A. first addressed the question of whether Congress intended to include within the universe of patentable subject matter the unforeseeable products of technology.³⁴ The court answered:

To insist on specific Congressional foresight in construing § 101 would be the very antithesis of the Constitutional and Congressional purpose of stimulating the creation of new technologies by their very nature unforeseeable and their progressive development The present recital of categories in [35 U.S.C.] § 101, . . . has been the same ever since the Patent Act of 1793, For the nearly 200 years since, those words have been liberally construed to include the most diverse range imaginable of unforeseen developments in technology.³⁵

After setting forth the reasons for a broad interpretation of patentable subject matter, the C.C.P.A. considered whether to treat living and non-living subject matter differently under the patent statute. The Court noted

²⁵ *Id.* at 311.

²⁶ *Id.* at 312.

²⁷ *Id.* at 316. "Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable." *Id.*

²⁸ *Id.* at 315 (quoting *Barr v. United States*, 324 U.S. 83, 90 (1945)).

²⁹ See Thomas Traian Moga, *Transgenic Animals as Intellectual Property (or the Patented Mouse that Roared)*, 76 J. PAT. [& TRADEMARK] OFF. SOC'Y 511 (1994). "In a sweeping summary, of the type which often begs a question, the Court observed that the 'subject matter of patents is to include anything under the sun that is made by man.'" *Id.* at 515.

³⁰ *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979).

³¹ *Id.*

³² *Id.* at 967.

³³ *Id.* at 955.

³⁴ *Id.* at 973.

³⁵ *Id.* at 973-74.

that throughout history, humans employed processes utilizing live micro-organisms in the production of bread, cheese, wine, and other products.³⁶ In addition, the Court noted that the chemical industry also has a long history of using micro-organisms.³⁷ Furthermore, the Court stated, "In fact, we see no legally significant difference between active chemicals which are classified as 'dead' and organisms used for their chemical reactions which take place because they are 'alive.' Life is largely chemistry. We think the purposes underlying the patent system require us to include micro-organisms and cultures within the terms 'manufacture' and 'composition of matter' in § 101."³⁸

The foregoing passage appears as a bold assertion rather than reasoned analysis. Why do the purposes underlying the patent system demand that living organisms be patentable? And how many statutory interpretations can be premised on the truism that "life is largely chemistry?" The decision leaves these questions unanswered.

The C.C.P.A. went on to address the PTO's arguments against patentability for living organisms. According to the C.C.P.A., the PTO's basis for excluding living organisms from the universe of patentable subject matter derived from the misinterpretation of dicta in two cases, *Guaranty Trust Co. of New York v. Union Solvents Corp.*,³⁹ and *In re Mancy*.⁴⁰ *Union Solvents* involved a dispute over a patent for a fermentation process utilizing bacteria.⁴¹ While the court held in favor of the patentability of the process, some question exists as to whether the court would have supported the patentability of a claim to the bacteria used in the fermentation process. The PTO focused on the following passage of the C.C.P.A.'s decision: "Were the patent for bacteria *per se*, a different situation would be presented. As before stated, the patent is not for bacteria *per se*. It is for a fermentation process employing bacteria. Undoubtedly there is patentable subject-matter in the invention."⁴² The PTO, in its 1977 Bergy decision, interpreted this language to allow the patenting of processes employing bacteria, but not the patenting of the bacteria itself.⁴³ However, in the view of the C.C.P.A. in the *Bergy-Chakrabarty* decision, the above quoted passage "is a trite observation of minimal magnitude as precedent dealing with a non-issue on which no opinion was expressed."⁴⁴ The C.C.P.A. found more pertinent the fact that the *Union Solvents* deci-

³⁶ *Id.* at 975 (citing Harvey W. Edelblute, *Microbiological Applications and Patents*, in THE ENCYCLOPEDIA OF PATENT PRACTICE AND INVENTION MANAGEMENT 1, 567 (R. Calvert ed. 1964)).

³⁷ *In re Bergy*, 596 F.2d at 975.

³⁸ *Id.*

³⁹ *Guaranty Trust Co. of N.Y. v. Union Solvents Corp.*, 54 F.2d 400, 12 USPQ 47 (D. Del. 1931), *aff'd*, 61 F.2d 1041, 15 USPQ 237 (3rd Cir. 1932).

⁴⁰ *In re Mancy*, 499 F.2d 1289 (C.C.P.A. 1974).

⁴¹ *Guaranty Trust Co.*, 54 F.2d at 401.

⁴² *Id.* at 410.

⁴³ *In re Bergy*, 563 F.2d 1031, 1036 (C.C.P.A. 1977). "The statement the examiner relied on, 'Were the patent for bacteria *per se*, a different situation would be presented,' is a trite observation of minimal magnitude," *Id.*

⁴⁴ *In re Bergy*, 596 F.2d 952, 977 (C.C.P.A. 1979).

sion supported the disputed issue, patentability of the process claim. The Court said that it would be illogical to allow "process" patents but not "manufacture" or "composition of matter" patents in situations involving living organisms.⁴⁵ However, there exist many instances where processes are patentable, but the separate components used in the processes, in and of themselves, lack patentability.⁴⁶

In re Mancy involved a controversy over the patentability of a process for manufacturing an antibiotic from a micro-organism known as *Streptomyces bifurcus*.⁴⁷ Again the C.C.P.A. held the process patentable and again the PTO focused on statements regarding the patentability of the bacteria itself.⁴⁸ The C.C.P.A. stated:

Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature.'⁴⁹

The PTO interpreted this language as a manifestation of the C.C.P.A.'s presumption that all bacteria lack patentability because as living creatures they are "products of nature."⁵⁰ To the contrary, however, the *Bergy-Chakrabarty* Court explained that the quoted passage referred to the C.C.P.A.'s belief that the bacteria at issue simply lacked novelty.⁵¹ "[W]e now make it explicit that the thought underlying our presumption that Mancy could not have obtained a claim to the strain of microorganism he had described was simply that it *lacked novelty*."⁵² It seems curious, however, that the judges on the C.C.P.A. in 1931 called Mancy's bacteria a "novel strain" while purporting to believe that it lacked novelty for purposes of the patent statute.

Finally, the *Bergy-Chakrabarty* Court addressed the surplusage argument based on the Plant Patent statutes. The PTO argued that the Plant

⁴⁵ *Id.* "It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not affect their status under § 101." *Id.*

⁴⁶ See Diane Kay McDonald, *The Patentability of Living Organisms Under 35 U.S.C. § 101: In Re Bergy*, 58 NEB. L. REV. 303, 319-20 (1979). "[P]atent case law does distinguish between the patentability of the tools of the process and the process itself, . . ." *Id.* (noting *Cochrane v. Deener*, 94 U.S. 780, 788 (1876)).

⁴⁷ *In re Mancy*, 499 F.2d 1289, 1290 (C.C.P.A. 1974).

⁴⁸ *Id.* at 1294.

⁴⁹ *Id.*

⁵⁰ McDonald, *supra* note 46, at 307. "The Examiner rejected the claim to patent the microorganism on the basis of the product of nature rule. As authority for the rejection on that basis, the Examiner cited the supportive dicta of *In re Mancy*: . . ." *Id.*

⁵¹ *In re Bergy*, 596 F.2d 952, 976 (C.C.P.A. 1979).

⁵² *Id.* "We were thinking of something preexisting and merely plucked from the earth and claimed as such, a far cry from a biologically pure culture [such as Bergy's] produced by great labor in a laboratory and so claimed." *Id.*

Patent Acts of 1930⁵³ and 1970⁵⁴ would be completely unnecessary if section 101 of the patent statute already included living organisms within the scope of patentable subject matter.⁵⁵ The C.C.P.A., however, found this reasoning unpersuasive.⁵⁶ Neither the Congress that enacted the Plant Variety Protection Act of 1930, nor the Congress that enacted the Plant Patent Act of 1970, was responsible for the enactment of 35 U.S.C. § 101 which defines the scope of patentable subject matter.⁵⁷ The C.C.P.A. believed that the PTO erred when it looked to the legislative history of the Plant Patent Act for Congressional intent.⁵⁸ They quoted the Supreme Court's language in unrelated cases: "[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one."⁵⁹ This last statement appears result-oriented when considered in combination with what the C.C.P.A. said about its confidence in its own knowledge of the presumption residing in the minds of the C.C.P.A. judges of 1931. Yet these inconsistencies do not jeopardize the soundness of the C.C.P.A.'s ultimate decision in *Bergy-Chakrabarty*.

The last piece of evidence mentioned in favor of the patentability of living organisms saves the C.C.P.A.'s majority decision from error. Quoting from a student paper in a legal journal, the C.C.P.A. noted that in the past the PTO granted patents on cultures of yeasts (including one granted to Louis Pasteur in 1873) and bacteria.⁶⁰ Without an act of Congress, liv-

⁵³ The Plant Patent Act, ch. 312, § 1, 46 Stat. 376 (1930) (current version at 35 U.S.C. §§ 161-164 (1994)).

⁵⁴ The Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (current version at 7 U.S.C. § 2321 (1994)).

⁵⁵ *In re Bergy*, 596 F.2d at 978.

⁵⁶ *Id.* "In analyzing the issue in this way, the PTO has made several errors." *Id.*

⁵⁷ *Id.* at 979. "The PTO has engaged in pure speculation in using the Plant Patent Act of 1930 as evidence of the intent of a preceding Congress despite the total absence in that act's legislative history of any support for such a position. Such speculation cannot tell us what Congress intended by the terms 'manufacture' or 'composition of matter' when they were reenacted in 1874 into R.S. § 4886 (now in 35 U.S.C. § 101)." *Id.*

⁵⁸ *Id.* at 978. "The principal mistake of the PTO was to look to the legislative history of the Plant Patent Act for evidence of the intent of a previous Congress, . . ." *Id.*

⁵⁹ *Id.* (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). The Court went on to quote Justices Jackson and Frankfurter regarding the improper use of legislative history: "[Courts should reach their decisions] by analysis of the statute instead of by psychoanalysis of Congress." *In re Bergy*, 596 F.2d at 979 (quoting *United States v. Pub. Util. Comm'n of Cal.*, 345 U.S. 295, 319 (1953)). *But see McDonald, The Patentability of Living Organisms Under 35 U.S.C. § 101: In re Bergy*, 58 Neb. L. Rev. 303, 325 (1979). "[I]t is reasonable to assert that while the Congress in 1930 believed that the intent of the patent statute was not to include plants or other living organisms, the initial lawmakers may very well have intended the statute to provide protection for such inventions. If the spirit of the constitutional provision and the statute is to encourage inventions that are for the benefit of society, it may be argued that the significant benefits of microorganisms secured to the public do just that; . . ." *Id.* at 325, *construed in Edelbute, Microbiological Applications and Patents*, in *THE ENCYCLOPEDIA OF PATENT PRACTICE AND INVENTION MANAGEMENT* 567 (R. Calvert ed. 1964).

⁶⁰ *In re Bergy*, 596 F.2d at 985. "The existence of patents drawn to living organisms and cultures used in foods, insecticides, et cetera, is indicated in [the list contained in footnote 36]." *Id.* (quoting Donald G. Daus et al, *Microbiological Plant Patents*, 10 *IDEA* 87, 94 (1966)).

ing organisms, once patentable, do not lose that status. Furthermore, the fact that Congress acquiesced in the earlier patent grants undercuts any argument suggesting legislative hostility to the patentability of microorganisms.

Whatever the merits of the C.C.P.A.'s decision, the Supreme Court affirmed.⁶¹ In 1987 the PTO Board of Patent Appeals and Interferences (BPAD) faced claims covering polyploid Pacific Oysters in the case of *Ex parte Allen*.⁶² The term "polyploid" refers to the fact that the oysters in question possess more than the normal two sets of chromosomes.⁶³ In this case the oysters covered by the patent claims were "triploid"—they had three sets of chromosomes.⁶⁴ Here again the patent examiner rejected the inventor's claims,⁶⁵ because living organisms such as oysters lacked patentability.⁶⁶ In addition, the examiner found the oysters to be "obvious" in light of an earlier publication discussing the "induction of polyploidy in oysters as a way to increase growth."⁶⁷ The BPAI agreed with the examiner that the invention, in light of the publication, failed to meet "non-obvious" criteria.⁶⁸ However, the BPAI's opinion repudiated the examiner's contention that living oysters lack patentability.⁶⁹ Citing the Supreme Court's *Chakrabarty* decision, the BPAI held that man-made living organisms do qualify as patentable subject matter.⁷⁰

Regarding the oysters at issue in the case, the BPAI noted: "[T]he examiner has presented no evidence that the claimed polyploid oysters occur naturally without the intervention of man," ⁷¹ Here the BPAI's reasoning could be characterized as the "reverse products of nature" doctrine. Because the oysters were not found to occur naturally they were, therefore, novel. Ultimately the oysters failed to meet the non-obviousness requirement of section 103.⁷² The important point remains that

⁶¹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁶² *Ex Parte Allen*, 2 USPQ 2d (BNA) 1425 (Apr. 3, 1987).

⁶³ *Sease*, *supra* note 10, at 563.

⁶⁴ *Id.*

⁶⁵ *Ex Parte Allen*, 2 USPQ 2d at 1425.

⁶⁶ *Id.* at 1426. "In support of his rejection under 35 U.S.C. § 101, the examiner states that polyploid oysters are held to be living entities and do not fall within the statutory subject matter of 35 U.S.C. 101." *Id.*

⁶⁷ *Id.* at 1427.

⁶⁸ *Id.* "With respect to the rejection under 35 U.S.C. § 103 [the non-obviousness requirement] . . . we will affirm this rejection." *Id.*

⁶⁹ *Id.* at 1426. "The examiner's position that the claimed polyploid oysters are 'held to be living entities' is not controlling on the question of whether the claims are drawn to patentable subject matter under 35 U.S.C. § 101" *Id.*

⁷⁰ *Id.* "[T]he Supreme Court made it clear in its decision in *Diamond v. Chakrabarty* . . . that section 101 includes man-made life forms. The issue, in our view, in determining whether the claimed subject matter is patentable under section 101 is simply whether that subject matter is made by man." *Id.*

⁷¹ *Id.* at 1427. "The record before us leads to no conclusion other than that the claimed polyploid oysters are non-naturally occurring manufactures or compositions of matter within the confines of patentable subject matter under 35 USC § 101." *Id.*

⁷² *Id.*

the basis of the rejection rests on a requirement other than lack of novelty.⁷³

B. Position of the PTO

Shortly after the BPAI handed down its decision in *Ex parte Allen*, the PTO released a notice expressing its intent to comply with the Supreme Court's holding in *Chakrabarty*: "The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. [§] 101. 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."⁷⁴

This ruling arrived fortuitously for co-inventors Philip Leder and Timothy Stewart who were awarded the first patent for a genetically engineered mouse in 1988.⁷⁵ The PTO assigned the patent to Harvard⁷⁶ and the subject of the patent became known as the "Harvard mouse."⁷⁷ While an embryo, alteration of the mouse's genetic material made it highly susceptible to the development of cancerous tumors.⁷⁸ The offspring of this mouse also carried the extra sensitivity to cancer.⁷⁹ Possible uses of the mice included testing potential carcinogens and evaluating the therapeutic effect of certain materials thought to protect against cancer.⁸⁰

Commentators observed that the PTO defined the patent grant covering the Harvard mouse in broad terms.⁸¹ The patent abstract described the invention 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."⁸² Thus, the Harvard patent presumably gave the patent-holder exclusive rights over other similarly genetically engineered non-human ani-

⁷³ *Id.* at 1426.

⁷⁴ 1077 OFFICIAL GAZETTE PAT. OFFICE 24 (April 21, 1987). The notice stated further that "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation 'non-human' to avoid this ground of rejection." *Id.*

⁷⁵ Patent No. 4,736,866, issued April 12, 1988.

⁷⁶ Sease, *supra* note 10, at 565.

⁷⁷ *Id.*

⁷⁸ 35 PAT. TRADEMARK & COPYRIGHT J. (BNA) 503, April 14, 1988.

⁷⁹ *Id.*

⁸⁰ See Michael B. Landau, *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?*, 97 DICK. L. REV. 203, 214-15 (1993). The description section of the patent explains the potential uses of the genetically altered mice. After exposing the animal to a certain material the incidence of subsequent cancer growth will indicate the carcinogenicity of the material. Alternatively, the mice could be treated with a substance that is thought to shield against cancer. The incidence of tumor development in the group of treated mice would then be compared to the incidence in a similar group of untreated mice. *Id.*

⁸¹ See Moga, *supra* note 29, at 521. "[T]he examples of the Harvard patent specification relate only to experiments on mice, although the scope of the claims covers any animal." *Id.*

⁸² Landau, *supra* note 80, at 213 (quoting U.S. Patent No. 4,736,866).

mals.⁸³ In contrast to the Harvard mouse patent, however, more recent patents on transgenic animals grant more narrow coverage. "The patents issued subsequent to the Harvard patent have been limited to the laboratory-produced examples set forth in the specification and to the specific animals used."⁸⁴

Neither Congress nor the Judiciary officially express any opinion regarding the validity and appropriateness of the Harvard mouse patent, or the animal patents which follow it. However, the opponents of animal patenting angled to make their voices heard. After the PTO granted the Harvard mouse patent, the Animal Legal Defense Fund (ALDF) sought judicial review of the PTO rule allowing patent claims to non-naturally occurring non-human multicellular living organisms including animals.⁸⁵ ALDF argued that the promulgation of this rule violated the Administrative Procedure Act (APA) rendering it invalid.⁸⁶ They believed that the rule was of a legislative rather than interpretive nature.⁸⁷ Thus, ALDF contended that the APA's formal rule-making procedures required the PTO to engage in notice and comment prior to promulgation.⁸⁸ Unfortunately for ALDF, the federal courts dismissed the case for lack of standing before reaching the merits of their claims.⁸⁹

C. Congressional Inaction

Despite several attempts, legislation altering the status of animal patentability failed to pass in either house of Congress. The most recent attempt occurred during the 102nd Congress, when Senator Mark Hatfield of Oregon and Congressman Benjamin Cardin of Maryland introduced bills S. 1291 and H.R. 4989 in their respective houses.⁹⁰ The bills called for a five year moratorium on the issuance of animal patents.⁹¹ It was suggested that the PTO deliberately waited a few years between the grant of the first

⁸³ *Id.* at 215. "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." *Id.*

⁸⁴ Moga, *supra* note 29, at 520-21. "The trend discernable from reviewing the [recently] issued patents is a move away from the broad scope of the Harvard patent which covered any animal having a susceptibility to cancer because of the 'activated oncogene sequence.'" *Id.*

⁸⁵ David Burke, Note, *Animal Legal Defense Fund v. Quigg: Renewed Challenge to Animal Patents*, 59 UMKC L. Rev. 409 (1991).

⁸⁶ *Id.*

⁸⁷ *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 928 (Fed. Cir. 1991). "Appellants argue, nonetheless, that the notice is 'substantive' because it reverses a longstanding PTO policy whereby non-naturally occurring microorganisms were considered to fit within the definition of patentable subject matter, but the PTO 'had long considered animals not to be patentable subjects.'" *Id.*

⁸⁸ *Id.* at 923.

⁸⁹ *Id.* at 925. "[W]e conclude that none of these parties has made allegations sufficient to satisfy standing criteria with respect to either count of the complaint." *Id.*

⁹⁰ 137 CONG. REC. S7817 (daily ed. June 13, 1991).

⁹¹ 138 CONG. REC. E1117-02 (daily ed. April 28, 1992) (introduction of Legislation for a Moratorium on the Patenting of Genetically Engineered Animals).

animal patent to Harvard University in 1988 and the issuance of subsequent animal patents beginning in 1992 in order to give Congress ample time to respond.⁹² Lack of Congressional response altering or clarifying section 101 of the patent statute seems to support the interpretation of the Supreme Court and the PTO.⁹³

III. AN ALTERNATIVE ANALYSIS

Congress's expressed intention that anything under the sun, made by man, be patentable, provides a major impetus behind the Supreme Court's decision that living things are patentable.⁹⁴ The Supreme Court's *Chakrabarty* decision relies on this language for interpreting the scope of patentable subject matter.⁹⁵ However, others have focused on the word "anything" within the Congressional statement and have challenged the Court's definition of it. One commentator argued that only "things" should be patentable, and "things" excludes animals.⁹⁶ But, this argument neglects to recognize that the patent statute allows for the patentability of compositions of matter. Certainly, even living things are compositions of matter.

Leaving aside any debate over the metaphysical, non-material aspects of living animals, it should be noted that compositions of matter invented by the patent applicant or his assignor, qualify for patenting.⁹⁷ According to Congress, patentable subject matter includes anything under the sun made by man,⁹⁸ but some question may exist as to whether man makes living things. The Harvard mice self-reproduce; although the basis of their existence differs from that of the first genetically altered mouse.⁹⁹ How-

⁹² G. Christian Hill, *U.S. Issues Patents on Genetically Engineered Mice*, WALL ST. J., Dec. 24, 1992, at A8. "Jonathan MacQuitty, GenPharm's Chief Executive Officer, said the patent awards [for three more genetically altered mice] end a four-year hiatus by the federal agency [PTO] in issuing animal patents. He said the patent office appears to have delayed approval while Congress debated legislation that would have placed a moratorium on animal patents or restricted their use." *Id.*

⁹³ Landau, *supra* note 80, at 220-21. "Congress's reluctance to enact specific legislation limiting or restricting animal patents, therefore, appears to be the result of a deliberate decision on the part of Congress to endorse the status quo—allowing animals to be patented." *Id.*

⁹⁴ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). "[T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101." *Id.* at 310.

⁹⁵ *Id.* at 308-09.

⁹⁶ Terri Jones, *Patenting Transgenic Animals: When the Cat's Away, the Mice Will Play*, 17 Vt. L. Rev. 875, 894 (Spring 1993) (quoting Black's Law Dictionary and Webster's New World Dictionary the author shows that the words "thing" and "things" include tangible and inanimate objects and articles of property).

⁹⁷ 35 U.S.C. § 101 (1994).

⁹⁸ S. REP. NO. 82-1979, at 5 (1952) (this language is quoted by the C.C.P.A. and the Supreme Court in their respective *Chakrabarty* decisions). *See also* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979).

⁹⁹ By injecting new DNA into several fertilized mouse eggs, Leder and Stewart took part in the creation of a handful of animals.

ever, the offspring of those mice have been "made" in the same way that mice have always been made, not by man but rather by other mice.

This is not to say that humans make only those things created by their hands, but it is incorrect to say humans produce mice. If Congress based the scope of patentable subject matter on the assertion that anything under the sun, made by man, should be patentable, it follows that living animals should fall outside that mandate.

The patent statute establishes the patentability of inventions and improvements of inventions, it does not, however, contain the words "made by man."¹⁰⁰ It should be recognized that mice are not inventions. It follows that genetically engineered bacteria and mice, even though "improved" for certain purposes, are not improvements of inventions. Thus, animals do not belong within the scope of patentable subject matter.

In contrast, application of a reverse products of nature doctrine, such as the one employed by the PTO Board of Patent Appeals and Interferences in *Ex parte Allen*, allowed Harvard's mouse and Chakrabarty's bacterium to qualify as patentable.¹⁰¹ Therefore, such a doctrine conflicts with the logical interpretation of Congressional intent and language within the patent statute.

IV. CONCLUSION

An expansive interpretation of 35 U.S.C. section 101 created the basis for the inclusion of live animals within the scope of patentable subject matter under United States law. The inclusive language of section 101 which states, "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," may be patentable,¹⁰² provides the support for such an interpretation. Further support for a broad interpretation is found in the Congressional statement that patentable subject matter should "include anything under the sun that is made by man."¹⁰³

After careful consideration, however, the language of Congress and the patent statute do not compel the conclusion that living animals should be patentable. Despite the Supreme Court's holding to the contrary, *mice* produced successive generations of the Harvard mouse, not man. Furthermore, mice are not human inventions. Therefore, genetically altered mice are not improvements of human inventions. Organisms similar to Chakrabarty's bacterium and Harvard's mouse already existed in nature and man only tinkered with them. The patent statute allows patents for things humans invent, not anything humans modify. Therefore, a broad reading of section 101 does not necessarily find living animals to be patentable subject matter.

¹⁰⁰ *Diamond*, 447 U.S. at 309 (noting that this language appeared in the committee reports accompanying the recodification of the patent statutes in 1952).

¹⁰¹ See *Ex Parte Allen*, 2 USPQ 2d (BNA) 1425 (Apr. 3, 1987).

¹⁰² 35 U.S.C. § 101.

¹⁰³ *Diamond*, 447 U.S. at 309.

Neither the Supreme Court nor the Court of Customs and Patent Appeals offer a convincing rationale for the inclusion of living animals within section 101. Of course, issuance of patents on micro-organisms occurred long before Mr. Chakrabarty manipulated his first bacterium. Nonetheless, an improper construction of section 101 in the past should not validate an improper construction of the statute in the future.

