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PATENTABILITY OF GENETICALLY ENGINEERED LIFE-FORMS: LEGAL ISSUES AND SOLUTIONS

In the latter part of the 20th century man has made substantial inroads in his understanding and ultimate control of the natural, physical and life sciences. For example, in the year 1902 man had not yet perfected flight;[1] by 1969 he had walked on the moon.[2] Despite the magnitude of the hurdles which our scientists overcome, the technical obstacles seem easier to deal with than the sociological and ethical issues created by the newfound technologies. In no single endeavor of human ingenuity is this more profoundly illustrated than in the field of genetic engineering.

In addition to the ethical and moral questions[3] which we now must face, our lawmakers must also face the legal issues emanating from the patentability of higher life forms.[4] As is usually the case, legal theory has lagged behind onrushing reality. At present,

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1. 28 ENCYCLOPEDIA BRITANNICA, TRANSPORTATION 828 (1988). At 10:35 A.M., on December 17, 1903, Orville Wright successfully took off in a powered, heavier-than-air airplane.

2. 19 ENCYCLOPEDIA BRITANNICA, EXPLORATION 51 (1988). On July 20, 1969, at 2:56 A.M. GMT Neil Armstrong became the first man to step onto the moon's surface.

3. To some, including religious groups and environmental activists, the thought of genetically engineered animals is detestable. They picture an uncontrolled technology gone awry, with the sanctity of life being degraded by a race for profits. *See, e.g.*, Crawford, *Religious Groups Join Animal Patent Battle*, 237 SCI. 480 (1987). Arie R. Browner, general secretary of the National Council of Churches states that "[t]he gift of life from god, in all its forms and species, should not be regarded solely as if it were a chemical product, subject to genetic alteration and patentable for economic benefit." *Id.* at 480.

Others, as might be imagined, have disagreed. For example, to some businessmen and doctors the concept of genetic engineering is a godsend, heralding an era of cures for infectious and hereditary diseases. *See, e.g.*, Irwin Arieff, *U.S. Grants Patent to Genetically Altered Mouse*, REUTER BUSINESS REP., Apr. 12, 1988 (the genetically altered "Harvard mouse" provides researchers with a new tool to help them develop treatments for cancer, quoting R. Godown, President of the Industrial Biotechnology Association); *Mouse Patent, A First, Issued to Harvard*, N.Y. TIMES, Apr. 13 1988, at A1, col. 5 (genetically altered mouse affords scientists a new tool to efficiently test new cancer treatments).

The genetic engineering proponents also envision an increase in food production resulting from the use of genetic engineering. *See, e.g.*, Rachel E. Fishman, *Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?*, 15 AM. J.L. & MED. 461 (1989); Kevin D. DeBre, Note, *Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?*, 16 HASTINGS CONST. L.Q. 221 (1989).

4. For the purposes of this comment, "higher life forms" refers to any multicellular living organism, excluding plants.

higher life forms are clearly patentable subject matter[5] under section 101 of the Patent Act[6], which defines what type of inventions are patentable[7].

However, questions remain as to the ownership of the offspring of patented animals. Also, it is not clear as to how the requirements of section 112,[8] which mandates that an inventor describe his invention, will be fulfilled by an inventor who has genetically altered an animal. Additionally, as the field of genetic engineering matures, we will have to face the question of the constitutionality of a patent covering a human or a human/non-human hybrid.[9]

This comment highlights some of the legal issues raised by the emerging field of genetic engineering and suggests how the issues may be resolved. Part I will provide a brief exposition of the genetic engineering field. Part II will explain the judicial decisions leading up to the patentability of multicellular animals. Finally, part III will discuss some of the novel legal issues presented by the patentability of genetically altered life-forms, as well as analyze some suggestions for their resolution. Part III is further divided into three sections. The first section discusses the uncertainty regarding the ownership of the offspring of a patented farm animal. This section concludes by suggesting appropriate legislation to remedy the uncertainty in the present law. The second section addresses a shortcoming in the Patent and Trademark Office's ("PTO") procedure for determining when a deposit of a specimen of a genetically engineered organism must be included with a patent application. This section proposes a modification to the PTO's procedure to remedy the fault. Finally, the third section explains how a person's constitutionally protected right of privacy might be vio-

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5. *See infra* notes 71-74 and accompanying text for a discussion of the patentability of multicellular organisms, including animals.

6. 35 U.S.C. §§ 101-376 (1990).

7. 35 U.S.C. § 101. This section details what inventions are patentable. It states that "[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 requirement of this title." *Id.*

8. 35 U.S.C. § 112. This section states, in pertinent part, that "[t]he specification [part of the patent application] shall contain a written description of the invention." *Id.*

9. When genetic manipulation of human genes becomes feasible, scientists will be in a position to create a human/non-human hybrid animal. Such a hybrid animal has been proposed as a possibility by Dr. J.B.S. Haldane. He has suggested that genetic engineering might be employed to produce humans endowed with prehensile feet and no heels. Such genetically altered people would prove to be able astronauts because such a configuration would be particularly well suited to life in the cramped quarters and low gravity of a spaceship. DeBre, *supra* note 3, at 222 n.8 (citing Haldane, *Biological Possibilities for Human Species in the Next Ten Thousand Years, in* MAN AND HIS FUTURE 337, 354 (G. Wolstenholme ed. 1963)).

lated by the present patent system if that person possessed a patented gene. This section proposes appropriate legislation to alleviate any unconstitutional violations of privacy caused by the patent process.

I. GENETIC ENGINEERING

Genetic engineering, or recombinant DNA ("rDNA") technology, is a term incorporating various procedures within the expansive field of biotechnology.[10] It is a process in which a cell's genetic material, or DNA,[11] can be transformed or manipulated to yield a new life-form.[12]

Scientists have at their disposal numerous methods of manipulating an organism's DNA.[13] Regardless of the exact procedure involved, however, the ensuing genetically engineered organisms are proving to have more and more practical applications. As the developers of emerging rDNA technology begin to see the potential for monetary rewards for their endeavors,[14] they are inevitably seeking

10. Biotechnology is a field in which living organisms are utilized in industrial or technical processes. It is an expansive field, embodying disciplines such as applied genetics, biochemistry, chemistry, biology, microbiology, chemical engineering and industrial engineering. John M. Czarnetzky, Note, *Altering Natures Blueprints for Profit: Patenting Multicellular Animals*, 74 VA. L. REV. 1327, 1327 n.3 (1988).

11. Deoxyribonucleic acid ("DNA") in effect contains a "blueprint" of an organism. The DNA molecules are composed of two intertwined spiral bands of chemicals; the order of these chemicals, known as nucleotides, establishes the characteristics of an organism. *See id.* at 1331.

12. Because the possible number of permutations resulting from the matching of any two DNA bands is extensive, there is considerable diversity conceivable among life forms. *Id.*

13. *See* Berge Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. PAT. OFF. SOC'Y 569 (1985). The exact method of DNA manipulation utilized will depend upon the particular task. *Id.* at 572. The scientist may, for example, intend to obtain large amounts of a particular gene. *Id.* In this case, the gene would be separated and introduced into a strand of DNA taken from a host cell. *Id.* This DNA is then spliced into the host cell where it reproduces, using the information from the inserted gene. *Id.* Large quantities of a specific gene can, thus, be made available. *Id.* The host cell has acted, in effect, as a manufacturing facility for the production of the required gene. *Id.*

Alternatively, a scientist may desire to produce what is known as a "transgenic" animal. *Id.* Janice Sharp, Comment, Note, *Of Transgenic Mice and Men*, 16 W. ST. U.L.R. 737, 744 n.74 (1989). Such "transgenic" animals are produced by inserting foreign genes into the fertilized egg of the chosen animal. *Id.* Through normal cell division encountered during the development of the animal, the foreign genes are propagated. *Id.* The characteristics of the foreign gene can thus manifest themselves in the adult animal.

14. For example, Amgen, Inc. owns a patent on a gene used to make a drug called erythropoietin ("EPO"). *Mad Scientists*, BUS. MONTH, May 1990, at 54. EPO increases the production of red blood cells in patients afflicted with anemia. *Id.* The drug has potential sales of $1 billion or more per year, and Amgen has already been selling over $1.5 million worth of the drug per month. *Id.* Cambridge BioScience Corp. is co-developer of a recombinant feline leukemia

patent protection.[15]

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vaccine which has a worldwide market that is estimated at over $50 million annually. P.R. NEWSWIRE, Jan. 26, 1990.

15. In order to motivate inventors to engage in scientific research, the United States Constitution authorizes Congress to award inventors limited monopolies on their inventions. U.S. CONST. art. I, § 8, cl. 8 (the Constitution authorizes Congress "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"). In recognition of this grant of authority, Congress passed the first patent statute in 1790. Act of April 10, 1790, ch. 7, Stat. 109. (codified as amended at 35 U.S.C. §§ 1-376 (1990).

The agency which governs the patent system is the Patent and Trademark Office ("PTO"). The PTO is an office "where records, books, drawings, specifications, and other papers and things pertaining to patents and to trademark registrations shall be kept and preserved." § 1.

To obtain a patent, an inventor must file an application with the PTO. § 111. "Application for patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title, in writing to the Commissioner [of patents]." *Id.* The application must include (1) a specification as mandated by section 112 of the Patent Act; (2) a drawing as mandated by section 113 of the Act; (3) an oath by the applicant as mandated by section 115 of the Act; and, (4) the appropriate fees as mandated by section 41 of the Act. The application must also include the "claims." § 112. The claims are the most critical part of a patent application. They sculpt the extent of protection to be afforded the inventor by defining the subject matter which the inventor considers to be his invention. *Id.* An inventor may claim either a tangible object or a process. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor"). A patent claiming a tangible object is easy to conceptualize. For example, an inventor may claim a new type of transistor. In contrast, in a process patent, an inventor claims a process for achieving a given result, for example, a process to heat steel.

After the inventor completes his application, the PTO examines it. § 131. "The Commissioner shall cause an examination to be made of the application and the alleged new invention." *Id.* To be granted a patent, the invention must meet the four requirements of the Patent Act. First, the invention must be within the scope of patentable subject matter. § 101. Patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." *Id.* Second, the invention must be novel. § 102. Section 102 mandates that the invention be "new" in light of the prior art; i.e., previous patents, scholarly articles, trade magazines, etc. *See id. See also* Diamond v. Diehr, 450 U.S. 175, 188-91 (1981) (examination of the novelty of the invention itself is made with reference to section 102, not 101). Third, the invention must be useful. § 101. Absence of the utility of an invention is very rarely contested by the PTO, although the requirement has occasionally been cited as a bar to patentability of "immoral" inventions. *See* R. CHOATE, CASES AND MATERIALS ON PATENT LAW 375 (3d ed. 1987). Fourth, the invention must be nonobvious. § 103. A patent cannot be granted by the PTO "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.*

In addition to the above requirements the invention must meet, the application itself must conform to certain requirements. First, the application must describe the elements of the invention. § 112. The description must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." *Id.* Also, the application must meet the "enablement" requirement by disclosing the best method of making and using the invention. § 112. "The

II. JUDICIAL DECISIONS LEADING TO THE PATENTABILITY OF GENETICALLY ENGINEERED MULTICELLULAR ORGANISMS

A. Patentability of Living Organisms Before Chakrabarty[16]

The Patent and Trademark Office ("PTO") has historically issued *process* patents on inventions that utilized living organisms.[17] These patents claimed a process utilizing a living organism, not the organism itself.[18] For example, there are numerous patents claiming septic tank systems which employ bacteria as part of the process of breaking down waste.[19] Despite the acceptance by the PTO and judicial systems of process patents involving living organisms, inventors have had much difficulty in patenting the living organisms themselves.

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specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention." *Id.*

If the inventor's application is rejected by the examiner, the applicant may appeal the rejection to the Board of Patent Appeals and Interferences. 35 U.S.C. § 134. From the Board of Patent Appeals and Interferences there are two mutually exclusive routes of appeal. The first route is to the Court of Appeals for the Federal Circuit, based entirely on the record developed in the patent office. *Id.* at §§ 141-144. The second route is to the District Court for the District of Columbia, based on a record which may include evidence not presented to the patent office, if good reason is shown why it was not earlier presented. *Id.* at § 145. An applicant may then appeal from the Court of Appeals for the Federal Circuit to the Supreme Court, or in the usual manner from the District Court up to the Supreme Court. *See* CHOATE, *supra*, at 539 (citing Brenner v. Manson, 383 U.S. 519 (1966)).

Once an application is accepted, a patent will issue to the inventor. The term of the patent is 17 years, and begins to run from the date the patent is issued. § 154. During the term of the patent the inventor has the exclusive right to exclude others from making, using or selling his invention. § 271 (a). Section 271(a) states that "whoever without authority makes, uses, or sells any patented invention . . . infringes the patent.". *Id.* If the patent is infringed, then the inventor can bring a civil suit against the infringer. § 281. Section 281 states that "a patentee shall have remedy by civil action for infringement of his patent". *Id.* The patentee may seek injunctive relief to bar further infringement. § 283. The Act empowers a court to "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent." *Id.* Additionally, the patentee may seek damages. § 284. Section 284 states that "the court shall award the claimant [patent holder] damages adequate to compensate for the infringement." *Id.*

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

17. *See, e.g.*, City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577 (7th Cir. 1934) (patent for septic tank using aerobic bacteria held valid and infringed); Guaranty Trust Co. v. Union Solvents Corp., 61 F.2d 1041 (3d Cir. 1932) (patent for a bacterial process used in the synthesis of alcohol and acetone valid and infringed); Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 F. 453, 462 (2d Cir. 1908) (patent claiming a septic tank using anaerobic bacteria valid). *See also* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (the Court acknowledged that the application of a product of nature in a process could be patentable but the bacteria in this case was not novel).

18. *See supra* note 15 for a discussion of process claims.

19. *See supra* note 17 for examples of valid septic tank patents.

In *In re Merat*,[20] an inventor applied for a patent on a dwarf chicken.[21] The chicken was the result of controlled breeding, not genetic engineering.[22] The patent examiner rejected the application[23] because the chicken was something occurring in nature which was produced by controlled propagation, was not a "manufacture" and was, therefore, not patentable under section 101 of the Patent Act.[24] The Board of Patent Appeals ("B.P.A.")[25] agreed.[26] The United States Court of Customs and Patent Appeals ("C.C.P.A")[27] affirmed the B.P.A.'s decision,[28] but on other grounds.[29] Thus, the question of whether the dwarf chicken was patentable subject matter under section 101 remained unanswered.

Two years later, the C.C.P.A. expressed an opinion on whether non-naturally occurring microorganisms were patentable subject matter under section 101 of the Patent Act. In *In re Bergy*,[30] an inventor[31] had developed a new method for producing a known antibiotic.[32] In the process of this development, Bergy discovered a previously unknown microorganism.[33] The examiner allowed all of Bergy's process claims for producing the new microorganism.[34] However, the examiner rejected[35] Bergy's claim to the microorganism itself.[36] The examiner rejected the claim on the ground that patentable subject matter under section 101 of the Patent Act did

20. *In re* Merat, 519 F.2d 1390 (C.C.P.A. 1975).

21. *Merat*, 519 F.2d at 1391.

22. *Id.*

23. *Id.*

24. *Id.*

25. The Board of Patent Appeals and the Board of Patent Interferences were combined in 1984 into the Board of Patent Appeals and Interferences. Robert B. Kambic, Note, *Hindering the Progress of Science: The Use of the Patent System to Regulate Research on Genetically Altered Animals*, 16 FORDHAM URBAN L.J. 441, 450 n.95 (1988).

26. *In re* Merat, 519 F.2d 1390, 1393 (C.C.P.A. 1975).

27. In 1982, the Court of Customs and Patent Appeals was combined with the Court of Claims to form the Court of Appeals for the Federal Circuit. *See* Kambic, *supra* note 25, at 450 n.95.

28. *Merat*, 519 F.2d at 1393.

29. *Id.* at 1396. The C.C.P.A. rejected the patent on the ground that it failed to comply with 35 U.S.C. § 112 by failing to distinctly claim the subject matter of the patent. *Id.*

30. *In re* Bergy, 596 F.2d 952 (C.C.P.A. 1977).

31. There were actually three inventors: Bergy, Coats and Malik. *Id.* at 967. The court referred to them collectively as "Bergy"; this comment will follow the same procedure.

32. *Bergy*, 596 F.2d at 967.

33. *Id.*

34. *Id.*

35. *Id.* at 972.

36. *Id.* at 967. The rejected claim was drawn to a biologically pure culture of the microorganism, Stretpmyces vellosus, which produced the antibiotic lincomycin. *Id.*

not include products of nature.[37] On appeal, the C.C.P.A. decided that non-naturally occurring microorganisms were patentable subject matter[38].

B. The Chakrabarty[39] *Decision*

It was against this backdrop that *Chakrabarty* came before the United States Supreme Court.[40] Chakrabarty, a microbiologist, had filed a patent application, claiming a bacterium capable of consuming multiple components of crude oil.[41] Chakrabarty's bacteria were useful for the treatment of oil spills.[42] The examiner rejected Chakrabarty's claims[43] to the genetically engineered bacteria[44] for

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37. *In re* Bergy, 596 F.2d 952, 972 (C.C.P.A. 1977).

38. *Id.* at 975. The court stated that the objectives of the patent system required it to include microorganisms and pure cultures within the terms "manufacture and composition of matter" under section 101. *Id.* The court found no reason to refuse the patent protection for these new and unobvious microorganisms and cultures. *Id.*

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

40. The *Chakrabarty* case and the surrounding events have been extensively critiqued and will only be discussed briefly in this comment. For more in-depth coverage, see John W. Behringer, *Germ Warfare in the Patent Courts?*, 31 HASTINGS L.J. 883 (1980); Allen Bloom, *Designer Genes and Patent Laws: A Good Fit*, 26 N.Y.L. SCH. L. REV. 1041 (1981); Steven A. Bent, Comment, *Living Matter Found to Be Patentable*: In re Chakrabarty, 11 CONN. L. REV. 311 (1978-79); Frank P. Darr, Note, *Expanding Patent Coverage: Policy Implications of* Diamond v. Chakrabarty, 42 OHIO ST. L.J. 1061 (1981); Mark E. James, Note, Diamond v. Chakrabarty: *Living Things as Statutory Subject Matter*, 1 N. ILL. U. L. REV. 119 (1980); Comment, *Man-Made Organisms Receive Patent Protection*: Diamond v. Charabarty, 477 U.S. 303 (1980), 59 WASH. U. L.Q. 261 (1981); Reginald R. Modlin, Note, *Life Forms as Proper Subject Matter Under the Patent Act*: Diamond v. Charabarty, 98 DET. C.L. REV. 939 (1980); Comment, *The Patentability of Living Organisms Under 35 U.S.C. sec. 101*: In re Bergy, 91 HARV. L. REV. 1357 (1978); Donald W. Strickland, Note, *Patenting of Life Forms - Microorganisms More Akin to Inanimate Chemical Compositions and Useful as Industrial Tools Are Not Excluded from Categories of Patentable Subject Matter Merely Because They Are Alive*, 47 GEO. WASH. L. REV. 242 (1978).

41. *Chakrabarty*, 447 U.S. at 305. Before Chakrabarty's invention, biological management of oil spills demanded the utilization of a mixture of naturally existing bacteria, each capable of degrading a single component of the crude oil. *Id.* Through these biological means, the oil is converted into substances which are edible by the indigenous sea life. *Id.* However, when a mixture of bacteria are used in the treatment of oil spills, only a percentage of the bacteria survive to decompose the oil. *Id.* Chakrabarty's single bacterium is, therefore, more efficient in breaking down an oil spill. *Id.* at 305 n.2.

42. *Id.* Commentators have suggested that it was no coincidence that Chakrabarty's "oil eating" bacteria were the first microorganism to be granted a patent. *See* Fishman, *supra* note 3, at 463 n.7. Ecologically concerned groups were among those particularly opposed to the granting of patents for living entities. *Id.* They voiced dismay at the prospect of scientifically transformed life forms being introduced into the ecological chain. *Id.* The Patent and Trademark Office "may have had these groups in mind when it granted the first patent for an organism which would significantly increase our ability to clean up major ocean pollution." *Id.*

43. The patent claims were of three types: (1) process claims for the technique of generating the bacteria; (2) claims for an inoculum including a carrier

two reasons: first, the bacteria were unpatentable "products of nature";[45] second, living entities are not patentable subject matter.[46] Chakrabarty appealed the rejection of the claims to the Patent Office Board of Appeals ("Board").[47] The Board affirmed the decision on the second ground, that the bacteria were not patentable subject matter.[48] The C.C.P.A., however, reversed the Board.[49] In so doing, the C.C.P.A. relied on its prior decision, *In re Bergy*,[50] where the court had held that the validity of a patent claim is not dependent on the fact that the claimed microorganisms are alive.[51] Eventually, the Supreme Court granted certiorari.[52]

The Supreme Court found for Chakrabarty,[53] holding that a live, human-made microorganism is patentable subject matter.[54] The Court studied the legislative history of section 101 and decided that Congress had intended the section to be interpreted broadly.[55] The Court stressed that patentable subject matter was to "include anything under the sun made by man."[56] The granting of Chakrabarty's patent was a crucial event in the evolution of patent law. The PTO's acceptance of the validity of a patent on a multicellular animal was soon to follow.

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substance (i.e., straw) floating on water and the new bacteria; and (3) claims to the bacteria itself. Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980). The P.T.O. granted the claims on the process that produced the bacteria and on the inoculum, but not on the bacteria itself. *Id.*

44. Chakrabarty had found that plasmisds, hereditary units in the cell, influence the oil degradation capabilities of some bacteria. *Id.* He had perfected a process by which numerous plasmids, each capable of degrading different oil components, could be conveyed to and maintained in a single bacterium. *Id.* at 305 n.1.

45. *Id.* at 306.

46. *Id.*

47. *Id.*

48. *Id.* The Board had decided that the claimed bacteria were not "products of nature" because such bacteria containing the essential plasmids were not naturally occurring. *Id.*

49. *Id.*

50. *In re* Bergy, 563 F.2d 1031 (C.C.P.A. 1977).

51. *Id.* at 1038.

52. Diamond v. Chakrabarty, 447 U.S. 303 (1980). The Supreme Court granted certiorari to determine whether section 101 includes live, human-made microorganisms within its scope of patentable subject matter. *Id.* at 305.

53. *Id.* at 318.

54. *Id.*

55. *Id.* at 308. Chief Justice Burger wrote "the relevant legislative history ... supports a broad construction ... The Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.' " *Id.*

56. *Id* at 309 (quoting S. REP. NO. 1979, 82d Cong., 2d Sess. 5, *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399).

C. Post-Chakrabarty Animal Patents

Despite the *Chakrabarty*[57] decision, however, the PTO continued to reject patents on multicellular animals.[58] The PTO's position was that it required explicit judicial authorization before the Office would issue such patents.[59] The case of *Ex parte Allen*[60] provided the PTO with this judicial authorization.

In 1984, Allen sought a patent on both the process[61] to induce polyploidy[62] in oysters and on the polyploid oyster itself.[63] The patent examiner had approved the claim for the process of inducing the polyploidy[64] but had rejected the claims for the polyploid oyster itself.[65] The examiner rejected the claims for two reasons: (1) that as living organisms, the oysters were outside the scope of section 101 and thus not patentable,[66] and (2) that the process of creating the oyster would have been obvious to an ordinary person skilled in the art.[67] On appeal, the Board reversed the examiner's section 101 rejection of the claims.[68] The Board relied upon the *Chakrabarty* holding that section 101 included within its bounds all non-natural human-made living entities.[69] The Board reasoned that if a human-

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

58. Jerry E. Bishop, *U.S. To Allow Patents for Genetically Altered Animals*, WALL ST. J., Apr. 20, 1987, § 1, at 6, col. 1.

59. Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, JURIMETRICS J., Summer 1988, at 399, 403 (citing *Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 160 (1980)).

60. *Ex parte* Allen, 2 U.S.P.Q.2d 1425 (B.P.A.I. 1987).

61. The inventor employed a procedure which created an alteration in the number of chromosomes in oyster eggs, by exposing fertilized eggs to pressure for a given length of time. *See id.* at 1426.

62. Polyploid refers to an organism with more than two sets of chromosomes. *See* Kambic, *supra* note 25, at 453 n.115. Humans have two sets of chromosomes and are referred to as diploid. *Id. See generally* W. KEETON, ELEMENTS OF BIOLOGICAL SCIENCE 528 (1982) for a discussion of polyploid and diploid organisms.

63. *Allen*, 2 U.S.P.Q.2d at 1425-26. Polyploidy in oysters causes sterility which not only increases the oysters's size but also makes them edible all year long. *See* Kambic, *supra* note 25, at 453 n.116.

64. *Allen*, 2 U.S.P.Q.2d at 1426. Claims 1 and 9 were valid, as they were drawn to the method of producing polyploid oysters. *Id.*

65. *Id.* Claims 8, 12, 13 and 15 were rejected because they were drawn to the polyploid oyster itself. *Id.*

66. *Id.* The examiner stressed that the oyster was "controlled by the laws of nature and not a manufacture by man that is patentable." *Id.*

67. *Id.*

68. *Id.* at 1426-27. The Board did, however, hold that the claims were appropriately rejected on the alternate ground of obviousness under 35 U.S.C. § 103 in view of the prior art. The Board stated that "[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *Id.* at 1427. Therefore, a patent was not issued on Allen's oyster. *Id.*

69. *Ex parte* Allen, 2 U.S.P.Q.2d 1425, 1426 (B.P.A.I. 1987).

made invention cannot be found in nature, then the invention is patentable subject matter.[70] For the first time, the Board had upheld the patentability of a multicellular animal.[71]

Based on the Board's ruling in *Allen*, the PTO formally announced on April 7, 1987, that it would henceforth regard multicellular living organisms as patentable.[72] The following week, the PTO issued a patent on a genetically altered mouse, the first multicellular animal to be patented in the United States.[73] After this patent was issued, applications for patents covering all kinds of genetically altered multicellular animals arrived at the PTO faster than they could be processed.[74]

III. LEGAL ISSUES RAISED BY THE PATENTING OF GENETICALLY ENGINEERED LIFE-FORMS

A. Ownership of the Offspring of Patented Animals

Once an inventor receives a patent for an invention he will, of course, desire to sell or license the invention to reap the rewards of his research.[75] However, the sale of living organisms presents novel issues in the field of patent law. One unanswered question is

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70. *Id.* at 1427 (citing Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980)).

71. The patent was not issued on the oyster, however, because of other deficiencies in the application. *See supra* notes 65 and 68 and accompanying text for a discussion of the deficiencies in the application.

72. *See U.S. to Grant Patents on Animals*, WASH. POST, Apr. 18, 1987, at A24, col. 1 (quoting memorandum by Patent and Trademark Office Commissioner Donald Quigg). The PTO Commissioner announced that 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. [section] 101." *Id.*

73. The "Harvard Mouse" patent covered a mouse which had been genetically altered so that it would be born with cancer in its cells. *Patent and Trademark Office Issues First Animal Patent*, DAILY REP. FOR EXECUTIVES (Apr. 13, 1988). As a result, the mice are exceptionally susceptible to the development of tumors when exposed to cancer causing agents. *Id.* The mice can be used by scientists as a means of testing various chemicals to determine their propensity to cause cancer. *Id.*

74. By April 8, 1990, over 7800 patent applications involving genetically engineered life forms were on file. *Technology Lets Gene Out of Bottle*, CHI. TRIB., Apr. 8, 1990, at 1. In 1988, the backlog on patents claiming genetically engineered organism was about 39 months. *Speed Bumps*, NAT'L. J., May 20, 1988, at 1268.

75. The very purpose of the patent laws are to promote the progress of science by providing inventors with exclusive rights as an incentive for their research efforts. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974) (the 17-year monopoly offered by a patent is to encourage disclosure of inventions); Universal Oil Co. v. Globe Co., 322 U.S. 471, 484 (1944) (objective of the Constitution in granting Congress the power to legislate in the area of intellectual property is to foster scientific research). *See supra* note 14 and accompanying text for examples of estimates of the value of various drugs made possible by genetically engineered organisms.

whether a patent holder maintains any rights in the progeny[76] of a patented organism.[77]

Obviously, this is a crucial question to the genetic engineering companies which produce and patent such organisms,[78] and farmers, who use and breed such organisms. The farmers fear that the genetic engineering companies, able to infuse enormous sums of money into research and development, will synthesize new strains of animals superior to existing farm animals.[79] If a patent holder is deemed to maintain rights in the offspring of such superior animals, the farmers could be prevented from buying one of the superior animals and breeding it for themselves.[80] The farmers are troubled by the fact that they will not be able to compete under such conditions and will be driven out of business.[81]

Any rights which a patent holder has against a third party are defined in section 271 of the Patent Act.[82] This section defines in-

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76. Progeny is defined as "children, descendants, or offspring collectively." NEW WORLD DICTIONARY 1135 (2d Col. ed. 1978).

77. Representative Robert W. Kastenmeier (D-Wis), in discussing the present patent law, stated: "a farmer who obtains a patented animal would likely also obtain the right to use the animal for the intended use such as milking or slaughter. It is uncertain, however, whether the farmer would be liable for an act of patent infringement if the farmer reproduced the patented animal." 134 CONG. REC. H7436 (1988) (statement of Rep. Kastenmeier).

78. Genetic engineering research requires the investment of enormous sums of money. In April 1990, Monsanto opened a spacious $200 million Life Sciences Research Center in St. Louis. *Technology Lets Gene Out of Bottle*, CHI. TRIB., Apr. 8, 1990, at 1. The new facility is devoted exclusively to the development of genetically engineered crops and farm animals. *Id.*

The genetic engineering companies are willing to invest large amounts of money because the potential markets are immense. For example, this country alone has a beef industry of $30 billion annually and a dairy industry of $18 billion annually. *Cattle-Cloning Labs Transform the Barnyard*, CHI. TRIB., Apr. 10, 1990, at 1. The genetic engineering companies would understandably wish to monopolize the market on pigs that produce lean pork, cows that give skim milk, chickens that lay low cholesterol eggs, etc.

79. *See* Fishman, *supra* note 3, at 470.

80. *Generations of Profits: Firms Seek Royalties for Patented Animals*, NEWSDAY, Oct. 29, 1989, at 62. Farmers would have to "pay suppliers royalties on a cow's calves . . . generation after generation." *Id.* (quoting Michael Cannell, dairy farmer and political activist).

81. Czarnetzky, *supra* note 10, at 1328 n.5. *See also* Kambic, *supra* note 25, at 455; *Generations Of Profits: Firms Seek Royalties for Patented Animals*, NEWSDAY, Oct. 29, 1989, at 62 (improvements in biotechnology will hurt the small farmer); *House Panel Hears Testimony Addressing Animal Patenting Issues*, DAILY REP. FOR EXECUTIVES, Sept. 25, 1989, at A-6. ("without a patent infringement exemption, the future of the family farmer will be no better than that of a sharecropper"). *But cf. Patents: A Crucial Legislator is Leaving*, N.Y. TIMES, Nov. 17, 1990, at 32, col. 5 (biotechnology companies vehemently oppose an infringement exemption for farmers, claiming it would remove all monetary incentive to develop genetically altered animals).

82. 35 U.S.C. § 271(a) (1990). The infringement section states that "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." *Id.*

fringement of a patent as any unauthorized use of a patented invention, which includes making, using, or selling the patented invention.[83] The critical words of this section are "without authority." There clearly is no infringement of a patent owner's rights if his invention is made, used, or sold with his authority. Therefore, in order to examine a patent holder's rights to the offspring of his patented organisms, a review of what rights and authorizations are acquired by a purchaser of such a patented organism must be made.

Currently, there are no court decisions which decide the issue of ownership of offspring of patented organisms. However, a review of the case law resolving an analogous issue will prove helpful. The courts have decided that the "repair" of a patented article is not infringement, while its "reconstruction" is infringement.[84] By examining the reasoning behind the decisions in this area of patent law, we may be able to determine how the present issue will be resolved.

In *American Cotton-Tie Co. v. Simmons*,[85] a patent holder sold patented metal straps for use in tying cotton bales.[86] The straps were marked "licensed to use once only."[87] In normal use, the straps were cut to unbind the cotton and then discarded.[88] The defendant acquired the discarded straps and riveted the ends together.[89] He then resold them for use, once again, as cotton binding supplies.[90]

The Supreme Court found that the defendant had infringed the patent held by the plaintiff.[91] The Court determined that once the bales of cotton had been transported from the plantation to the mill the ties were voluntarily cut because they had performed their intended function.[92] The Court stressed that the metal bands were intended to be used only one time, such intent being made clear by the patentee's marking of the bands.[93] The defendant's reconstruction was, therefore, an impermissible violation of the patentee's rights.[94]

Subsequently, in *Fromberg, Inc. v. Thornhill*,[95] the plaintiff

83. *Id.*
84. *See* Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 342 (1961).
85. American Cotton-Tie Co. v. Simmons, 106 U.S. 89 (1882).
86. *Simmons*, 106 U.S. at 90.
87. *Id.* at 91.
88. *Id.*
89. *Id.*
90. *Id.*
91. *Id.* at 95.
92. *Id.* at 94.
93. *Id.*
94. *Id.*
95. Fromberg, Inc. v. Thornhill, 315 F.2d 407 (5th Cir. 1963).

had patented a tire repair device.[96] The device consisted of a hollow metal tube and a rubber plug which fit into the tube.[97] In operation, the plug was fitted into the metal tube and then the tube was inserted into a puncture in a tire.[98] The plug was then pushed out of the tube as the tube was removed from the tire. The plug was left in the tire to effect an air-tight seal.[99] The defendant sold a replacement plug to be used with the device manufactured by the plaintiff.[100]

The United States Court of Appeals held that the defendant was guilty of inducing[101] infringement of the plaintiff's patented device.[102] In so holding, the court noted that all expectations were that the metal tube would only be used once, then discarded.[103] The court relied heavily on *Simmons*[104] and stated that the decision in that case was still very much applicable as authority.[105]

In *Aro Mfg. Co. v. Convertible Top Replacement Co.*,[106] the Supreme Court faced the issue of whether a defendant had contributorily[107] infringed the plaintiff's patent by causing impermissible reconstruction of a patented article.[108] The defendant manufactured and sold a substitute material tailored to fit the plaintiff's patented convertible car top.[109] When the original fabric of the top

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96. *Thornhill*, 315 F.2d at 409. The tire repair device was especially useful because it facilitated the repair of a tire without dismounting the tire from the wheel. *Id.*

97. *Id.* at 410.

98. *Id.*

99. *Id.*

100. *Id.*

101. In a patent infringement action, a defendant may be sued for three different types of infringement: 1) direct infringement, 2) inducing infringement, and 3) contributory infringement. *See* 35 U.S.C. § 271 (1990).

The Patent Act defines a direct infringer as someone who, without authority, makes, uses, or sells a patented article. § 271(a).

An inducing infringer is defined by the Patent Act as somebody "who actively induces infringement of a patent." § 271(b).

Finally, a contributory infringer is defined by the Patent Act as someone who sells "a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent." § 271(c).

102. Fromberg, Inc. v. Thornhill, 315 F.2d 407, 413 (5th Cir. 1963).

103. *Thornhill*, 315 F.2d at 413.

104. *See supra* text accompanying notes 85-94 for a discussion of American Cotton-Tie Co. v. Simmons.

105. *Thornhill*, 315 F.2d at 413 n.15.

106. Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961).

107. *Aro*, 365 U.S. at 341. The Court had to decide whether the defendant's sales constituted contributory infringement because it had sold only a component of a patented article and had clearly not directed infringement. *Id.* *See supra* note 101 for a discussion of the three different types of infringements.

108. *Id.* at 342.

109. *Id.* at 337.

wore out, consumers replaced the original fabric with the defendant's fabric.[110] The Court held that this replacement was a permissible repair of the top and not an infringing reconstruction.[111] In so holding, however, the Court stressed that a patent holder cannot restrain a purchaser from restoring articles worn by use *"unless they in fact make a new article."*[112]

From the foregoing discussion of the case law, it is apparent that ownership of the offspring of a patented organism might rest with the patent holder because the offspring of the patented animal is a *new animal.* Clearly, a purchaser of a patented animal has the right to "repair" it and to use it. However, under the *Aro* doctrine,[113] the progeny of the patented animal might be interpreted as a new article, whose use would infringe the rights of the patent holder. In light of the *Simmons*[114] and *Thornhill*[115] cases, the patent holder might also be able to further his claim of rights to the progeny of the patented animal if the animal was sold with the express proviso that it not be bred.

However, a strained interpretation of case law is not an appropriate procedure by which the question of the ownership of the offspring of patented organisms should be resolved. Too much depends upon a just and proper resolution of the question. What is needed is legislative guidance.

Congress should amend the Patent Act so as to make the answer to this vexing question clear. The House of Representatives has recognized the uncertainty of the present patent law.[116] In 1988, the House passed the Animal Patent Bill.[117] However, the Senate has not yet passed the bill; therefore, the law on this issue remains unclear. Among other objectives, section two of this bill addresses the fears of farmers by including an exemption from patent infringement for farmers[118] who breed patented farm ani-

110. *Id.* at 338.

111. *Id.* at 346.

112. *Id.* at 343 (quoting Judge Learned Hand in United States v. Aluminum Co. of America, 148 F.2d 416, 425 (1945)) (emphasis added). "The patent monopolist cannot prevent those to whom he sells from . . . reconditioning articles worn by use, unless they in fact make a new article". *Id.*

113. *See supra* text accompanying notes 106-112 for a discussion of the *Aro* doctrine.

114. American Cotton-Tie Co. v. Simmons, 106 U.S. 89 (1882). *See supra* notes 85-94 and accompanying text for a discussion of the case.

115. Fromberg, Inc. v. Thornhill, 315 F.2d 407 (5th Cir. 1963). *See supra* notes 95-105 and accompanying text for a discussion of the *Thornhill* case.

116. *See supra* note 77 for a discussion of the uncertainty facing today's farmers regarding this issue.

117. H.R. 4970, 100th Cong., 2d Sess., 134 CONG. REC. H7436 (1988).

118. The Animal Patent Bill proposed to amend 35 U.S.C. § 271 by adding the following subsection: "(g)(1) It shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm

mals.[119] However, the bill would also protect the legitimate interests of the genetic engineering companies by prohibiting the sale of the germ cells, semen, or embryos of a patented farm animal.[120]

Clarification of the patent law on this issue is needed. Legislative action such as the House Animal Patent Bill is suitable because it balances the protection of our nation's farmers against the interests of the emerging genetic engineering companies. The farmers will be able to compete in the farming business, and the genetic engineering companies will be able to prevent wholesale infringement of their patents by people who would buy one patented animal, then use it to enter the genetic engineering business on their own.

B. Compliance with the "Enablement" Requirement

A patent has been referred to as a contract[121] or a franchise[122] between the government and an inventor. The government grants the inventor a "monopoly" in return for disclosure to the public of how to make and use the invention. In addition, the public has the right to use the invention after the patent expires. The government's demand for an enabling disclosure of the invention was found in the first Patent Act of 1790.[123] The enablement requirement is now found in section 112 of the Patent Act.[124] The present

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animal through breeding, use such animal in farming operations, or sell such animal or the offspring of such animal." H.R. 4970, 100th Cong., 2d Sess., 134 CONG. REC. H7436 (1988).

119. The Animal Patent Bill defines a farm animal as any "animal used or intended for use as food or fiber." *Id.* The bill defines a transgenic farm animal as "a farm animal whose germ cells contain genetic material originally derived from another other than the parent of the farm animal." *Id.*

120. The Animal Patent Bill further proposed to amend 35 U.S.C. § 271 by adding the following language: "(g)(2) Notwithstanding the provisions of paragraph (1), [exemption from infringement for farmers] it shall be an act of infringement for a person to sell the germ cells, semen, or embryos of a patented transgenic farm animal." *Id.*

121. Century Electric Co. v. Westinghouse, 191 F. 350 (8th Cir. 1911).

122. Seymore v. Osborne, 78 U.S. 516, 533 (1871).

123. Act of April 10, 1790, ch. 7, Stat. 109 (codified as amended at 35 U.S.C. §§ 1-376 (1990)). The Act provided in part that the specification must "enable a workman or other person skilled in the art of manufacture, whereof it is a branch . . . to make, construct or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term." *Id.*

The purpose of the enabling disclosure was elucidated by the Supreme Court in the case of Grant v. Raymond, 31 U.S. 218 (1832). The Court stated that an enabling disclosure "is necessary in order to give the public, after the privilege [the inventor's monopoly] shall expire, the advantage for which the privilege is allowed and is the foundation of the power to issue the patent". *Raymond*, 31 U.S. at 247.

124. 35 U.S.C. § 112 (1990). This section of the Act stipulates that the specification must include a written description of the invention and "of the manner and process of making and using it, in such full, clear, concise, and exact terms

Patent Act not only requires the inventor to provide an enabling[125] disclosure, but the Act also demands that the inventor specify the "best mode" of making and using the invention.[126] The enablement requirement is normally met by a written specification.[127] However, when living organisms are involved, the written specification has sometimes proved inadequate. To address this inadequacy, the PTO has developed the deposit requirement.

The deposit requirement is a nonstatutory means of compelling inventors to comply with the enablement requirement of section 112. Before patents for genetically engineered organisms were accepted by the PTO, the procedure for determining when a deposit

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as to enable any person skilled in the art to which it pertains . . . to make and use the same." *Id.*

125. The word "enabling" means that one skilled in the art to which the patent pertains can make and use the invention without undue experimentation. *In re* Coleman, 176 U.S.P.Q. 522, 524 (C.C.P.A. 1973).

The limits of undue experimentation had been identified by the court in A.B. Dick Co. v. Barnett, 288 F. 799 (2d Cir. 1923). The court explained that the apparatus disclosed in an application need not necessarily be operative in the exact form in which it is shown and described. It is sufficient if it can be rendered operative by adjustments and corrections which would naturally occur to a skilled worker in the art . . ." *Id.* at 799. *See also* Bennett v. Halahan, 285 F.2d 807 (C.C.P.A. 1961) (an apparatus is deemed disclosed in a patent if it is sufficiently described to allow one skilled in the art to practice the invention by making adjustments); Creed v. Potts, 96 F.2d 317 (C.C.P.A. 1938) (invention disclosure will not be held inoperative if a skilled mechanic could render it operative); Trumbull v. Kirschbraun, 67 F.2d 974 (C.C.P.A. 1933) (if one skilled in the art is able to practice the patented invention then it is sufficiently disclosed).

126. 35 U.S.C. § 112 (1990). The Act states that the specification must "set forth the best mode contemplated by the inventor in carrying out his invention." *Id.*

This best mode requirement is based on the subjective knowledge of the inventor at the time the application was filed. *See* W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (C.A.F.C. 1983). "Section 112 requires that the inventor set forth the best mode of practicing the invention known to him at the time the application was filed." *Garlock*, 721 F.2d at 1540. *See also* Dale Electronics, Inc. v. R.C.L. Electronics, Inc., 488 F.2d 382, 388 (1st Cir. 1973) (failure by inventor to disclose specific materials necessary to practice patent will invalidate patent); Application of Glass, 492 F.2d 1228, 1233 (C.C.P.A. 1974) (the purpose of the best mode requirement is to restrain inventors from concealing preferred embodiments of their inventions, citing Application of Gay, 309 F.2d 769 (C.C.P.A. 1952)); Benger Laboratories, Ltd. v. R.K. Loaros Co., 209 F.Supp. 639, 644 (E.D. Pa. 1962) *aff'd per curiam*, 317 F.2d 455 (3d Cir. 1963) (failure to disclose better method of practicing an invention will not invalidate a patent so long as the better method was not thrown to the inventor).

However, courts have not required the mode disclosed by the inventor to in fact be the optimum mode of carrying out the invention as long as the inventor did not know of the better mode. Application of Gay, 309 F.2d 769, 773 (C.C.P.A. 1952). The court required only a good faith attempt by the inventor to disclose the best mode. *Id.* at 772. *See also Benger Laboratories*, 317 F.2d at 456 (inventor must have made no attempt to conceal what he thought was the best method of using the invention).

127. 35 U.S.C. § 112 (1990). This section requires that "the specification shall contain a written description of the invention." *Id.*

was required on a biotechnological invention[128] was straightforward. If the living organism involved in the patent was known by, and available to,[129] the public,[130] a deposit was not necessary and a patent would be granted.[131] However, if the organism was new and unavailable to the public, a deposit was mandatory.[132]

However, the terms "unknown" and "unavailable" are deceptive because the statute requires *any* patentable invention to be "new"[133] and not "known or used by others."[134] The PTO utilized the terms to identify naturally occurring microorganisms wherein an adequate explanation of how to acquire the microorganism from nature could not be put into words.[135] The PTO's application of the deposit requirement to non-genetically engineered organisms is a

128. Examples of biotechnological inventions that do not involve genetic engineering include process patents employing living organisms and cell lines that have been purified through selective breeding.

129. *See* Feldman v. Aunstrup, 186 U.S.P.Q. 108, 111 (C.C.P.A. 1975), *cert. denied*, 424 U.S. 912 (1976) (there is no enablement problem when the microorganisms used are known and readily available to the public); *In re* Interference A v. B v. C, 159 U.S.P.Q. 538, 540 (Commr. PTO 1967) (inventor is not required to teach in his specification how to make or procure known materials and ingredients); Merck & Co. v. Chase Chemical Co., 155 U.S.P.Q. 139 (D. N.J. 1967) (inventor's failure to deposit starting materials in a public depository is not fatal to the application so long as the materials are readily available to persons skilled in the art).

130. When analyzing the sufficiency of the enablement disclosure, the term public does not mean the general public, but rather those skilled in the art. *See In re* Storrs, 114 U.S.P.Q. 293, 296 (C.C.P.A. 1957) (patents are written to enable those skilled in the art to practice the invention); A.B. Dick Co. v. Barnett, 288 F. 799, 799 (2d Cir. 1923) ("the specification of a patent is not addressed to people who are ignorant about the subject matter . . .").

131. The patent would be granted, of course, only if the other provisions of the Patent Act were complied with. *See supra* note 15 and accompanying text for the provisions of the Patent Act.

132. *Feldman*, 186 U.S.P.Q. at 108. "No problem exists when the microorganisms used are known and readily available to the public. When the invention depends on the use of a microorganism which is not so readily available, applicants must take additional steps to comply with the requirements of section 112." *Id.* at 111. *See also In re* Argoudelis, 168 U.S.P.Q. 99 (C.C.P.A. 1970) (when microorganisms are used as starting materials, it is impossible to give a sufficient description of how to obtain the microorganism from nature); *Ex parte* Schmidt-Kastner & Hackman, 153 U.S.P.Q. 473, 474 (PTO Bd. App. 1963) (effect of deposit used as a description of a living starting material is similar to a reference to an earlier patent application); *Ex parte* Kropp, 143 U.S.P.Q. 148, 152 (PTO Bd. App. 1959) (an organism used as a starting material unquestionably can not be duplicated from a written description).

133. 35 U.S.C. § 101 (1990).

134. § 102. This section of the Patent Act defines novelty as an unknown or unused invention: "[a] person shall be entitled to a patent - unless (a) the invention was known or used by others in this country" before the date of invention by the applicant. *Id.*

135. *In re* Argoudelis, 168 U.S.P.Q. 99, 102 (C.C.P.A. 1970). The terms "unknown and unavailable" are used to describe naturally occurring microorganisms wherein "[a] sufficient description of how to obtain the microorganism from nature cannot be given." *Id.*

workable solution to the problem of non-enabling disclosures. The deposit is needed because our knowledge is not sufficient to fully describe the anatomic and metabolic properties of complex, naturally occurring organisms.[136]

However, present PTO procedures will not suffice in the genetic engineering age. In contrast to the production of naturally occurring organisms, modification of organisms through genetic engineering can often be performed by using starting materials and techniques which are available to those skilled in the art.[137] Therefore, even though the modified organism is novel and unavailable, the written disclosure can describe the invention sufficiently to comply with the enablement requirement.[138] When such a disclosure is possible, the considerations warranting a deposit no longer endure.

The procedure employed by the PTO to determine whether to require a deposit in a particular case should be modified. The inquiry should no longer center on whether the organism is "unknown and unavailable" because: (1) these terms are misnomers as applied to patentable inventions, and (2) many genetically engineered organisms, unlike naturally occurring organisms, can be described by the written word. Rather than blindly mandate deposit of biological inventions, the PTO should inquire as to whether a disclosure is sufficient, absent a deposit. Such an analysis would avoid unnecessary and wasteful deposits of genetically engineered organisms whose production can adequately be disclosed by a written specification.

C. Constitutional Right of Privacy Issue Raised by the Patenting of Genetically Altered Human Beings

While the initial manipulation of the genes of a human being will likely come about on an embryo with a hereditary disease,[139]

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136. *See* Hampar, *supra* note 13, at 580.

137. *See* Virginia H. Mayer, *Problems and Issues in Depositing Microorganisms for Patent Purposes*, 65 J. PAT. OFF. SOC'Y. 455, 459 (1983) (it is conceivable that sufficient information can be contained in the written disclosure to allow one skilled in the art to reproduce the invention if he has the starting materials); John E. Schneider, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That Is the Question*, 52 FORDHAM L. REV. 592, 600 (1984) (by employing recombinant DNA technology an inventor can develop a new living entity and sufficiently describe how it is done so that others can realize the same result by following the specification).

138. 35 U.S.C. § 112 (1990). *See supra* note 124 for the text of the enablement requirement.

139. Harold M. Schmeck, *Gene Altered Animals Enter New Commercial Era*, N.Y. TIMES, Dec. 27, 1988, at C19, col. 6. Manipulation of an embryo's genes is known as prenatal gene therapy. *See* DeBre, *supra* note 3, at 226 n.32 (citing PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL SCIENCE, SPLICING LIFE: A REPORT ON THE

we have much more to learn before this would become technically feasible.[140] However, technology will advance, and eventually our scientists will be capable of manipulating the genetic make-up of human beings.[141] Inventors will then be in a position to develop human inventions.[142]

Even though an inventor's ownership of patent rights in an original human gene would not infringe the Thirteenth Amendment[143] protection[144] of those bearing the patented genetic mate-

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SOCIAL AND ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS 45-46 (1982)). Prenatal gene therapy is a method of altering or replacing particular genes in every cell of an organism. *Id.* Performance of gene therapy on an embryo would encompass insertion of the selected gene into the mature ovum removed from the woman. *Id.* The egg is then fertilized *in vitro*, and reinserted into the woman's uterus. *Id.* By using this technique, doctors will be able to remedy genetic defects which cause diseases such as cystic fibrosis. *Id.*

In contrast to prenatal gene therapy, post natal gene therapy is implemented on a fully developed child or adult. *Id.* at n.33. This type of treatment consists of a change of genetic material within a single tissue. *Id.* The tissue is removed from the person's body, the "bad" genes are replaced with new genes, and the tissue is reinserted. *Id.* Such surgery is used to correct existing genetic defects. *Id.*

140. Kass, *Babies by Means of in Vitro Fertilization: Unethical Experiments on the Unborn?*, 285 NEW ENG. J. MED. 1174 (1971) (experiments performed on the unborn present possibilities of inadvertent genetic deformations); Schmeck, *supra* note 139, at C10, col. 6. Before corrective surgery would become feasible, however, experimentation would obviously have to be carried out. For a discussion regarding genetic experimentation on human beings see Marilyn J. Clapp, Note, *State Prohibition of Fetal Experimentation and the Fundamental Right to Privacy*, 88 COLUM. L. REV. 1073 (1988) (arguing that laws preventing genetic experimentation unconstitutionally conflict with a couple's right to privacy in reproductive decisions).

141. The entire human genome (collection of genes) is composed of about 100,000 genes. David Fishlock, *Biotechnology: Its All in the Genes*, FIN. TIMES, May 12, 1989, at 19. So far the functions of just a few thousand have been identified. *Id.* It is estimated that the entire mapping process will take 15 years. *Id.* In 1989, the United States government initiated a $3 billion dollar research project to map the entire human genome. *Technology Lets Gene Out of the Bottle*, CHI. TRIB., April 8, 1990, at 1.

After the mapping process is complete, scientists will then be able to develop procedures for the manipulation of human genes. Once gene manipulation is possible, scientists will be able to produce human/animal hybrids. Such hybrids might conceivably be developed through the merging of human genetic materials with that of a lower animal. DeBre, *supra* note 3, at 227. Additionally, scientists might manipulate the genetic make-up of a human in order to produce a person with desired impairments, such as lower intelligence, or an obedient personality. *Id.*

142. For the purpose of this comment the term "human invention" means an invention incorporating a human genotype that meets the statutory patent requirements, and which manifests a distinct trait, regardless of whether it is observable.

143. U. S. CONST. amend XIII, § 1. "Neither slavery nor involuntary servitude, except as a punishment for a crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction." *Id.*

144. April 7, 1987, the PTO stated that "[a] claim directed to or including within its scope a human being will not be considered to be patentable . . . [be-

rial, other constitutional issues will arise from the application of the Patent Act to human inventions.

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cause the] grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." *Patents and the Constitution: Transgenic Animals: Hearings before Subcomm. on Courts, Civil Liberties and the Administration of Justice*, 100 Cong., 1st Sess. 22 (1987) (statement of Commissioner Donald Quigg). The PTO did not specify which provision of the Constitution it relied upon, but commentators suggest that the Office's constitutional foundation was the Thirteenth Amendment. LEGAL TIMES, June 15, 1987, at 16, col. 1.

However, the Thirteenth Amendment does not prohibit the patenting of human inventions. The Thirteenth Amendment was enacted solely for the purpose of "establish[ing] the freedom of four million slaves". G. GUNTHER, CONSTITUTIONAL LAW 408 (11th ed. 1985) (quoting Slaughter-House cases, 77 U.S. 273 (1869))). The one purpose of the post-Civil War amendments (13th, 14th, and 15th) was to be the "freedom of the slave race, the security and firm establishment of that freedom, and the protection of the newly-made freeman and citizen from the oppressions of those who had formerly exercised unlimited dominion over him." *Id.*

To carry out the emancipation of the slaves, Congress was given expansive enforcement power. U.S. CONST. amend. XIII, § 2 ("Congress shall have power to enforce this article by appropriate legislation"). *See also* Civil Rights Cases, 109 U.S. 3, 20 (1883) (Congress has authority to "pass all laws necessary and proper for abolishing all badges and incidents of slavery in the United States"). Congress then utilized this power to pass laws to effectuate nationwide emancipation and to prohibit exploitation of one person by another.

The courts have had numerous occasions to apply the protections afforded by the Thirteenth Amendment. For examples of when the Thirteenth Amendment has been liberally utilized to prohibit threats of legal confinement and acts short of forced labor, see United States v. Mussry, 726 F.2d 1448 (9th Cir.), *cert denied*, 469 U.S. 855 (1984) (involuntary servitude includes psychological compulsion to subjugate another's will); United States v. Harris, 701 F.2d 1095, 1100 (4th Cir.), *cert. denied*, 463 U.S. 1214 (1983) ("threat of violence or confinement, backed sufficiently by deeds" qualifies as subjugation of another's will in violation of the Thirteenth Amendment); United States v. Tibbs, 564 F.2d 1165 (5th Cir. 1977), *cert. denied*, 435 U.S. 1007 (1978) (finding of involuntary servitude can result if victim's fear of physical harm prevents him from leaving); Pierce v. United States, 146 F.2d 84 (5th Cir. 1944) (intimidation of women into acts of prostitution prohibited by anti-slavery statute). Nonetheless, even a broad reading of the Thirteenth Amendment only prohibits "conditions that could reasonably be called symptoms of a slave society, inability to raise a family with dignity caused by unemployment, poor schools and housing, and a lack of place in the body politic." Note, Jones v. Mayer: *The Thirteenth Amendment and the Federal Anti-Discrimination Laws*, 69 COLUM. L. REV. 1019, 1026 (1969).

After reviewing the purpose behind the Thirteenth Amendment, it is manifest that the patenting of the genes of a human being exhibiting novel traits does not raise a problem of slavery. An inventor holding a patent on a new human gene would have an exclusive right to practice the patent, that is, he would be the only person who could make, use, or sell the patented gene. 35 U.S.C. § 271 (1990). However, the patent would not grant the inventor a possessory right in the patented article. *See* Fishman, supra note 3, at 474 n.122. An inventor who owns a patent on a particular human gene is not in the position to "enslave" another person, or to subrogate his will. *Id.* Rather, the inventor can simply prohibit others from making an organism with that genetic make-up. *Id.* Therefore, it is not likely that one would have much success in governing the patenting of human beings by resorting to the Thirteenth Amendment. *Id.*

1. Violations of Constitutionally Protected Right of Privacy

The Patent Act specifies that an inventor must provide a written description of his invention.[145] This description, in the case of a patented human gene, would require disclosure of the novel genetic traits possessed by the human being. Such public disclosure of a person's genetic make-up can be interpreted as an infringement of a person's constitutionally protected right of privacy.[146]

The right of privacy includes the prerogative to release or to withhold any and all private facts.[147] The sanctity of an individual's right to privacy is protected by a plethora of federal and state laws which regulate the storage and dissemination of information by governmental agencies.[148] Additionally, the Supreme Court has acknowledged that a person's right of privacy might need to be protected by regulation of the disclosure of private information.[149]

Whether a violation of the right of privacy of a person bearing a patented gene would result from the patent disclosure has yet to be adjudicated. However, in light of the weight the Supreme Court has placed on privacy,[150] it is possible that such a violation will be

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145. 35 U.S.C. § 112 (1990). *See supra* note 125 and accompanying text for a discussion of the written descriptions required.

146. *See* DeBre, *supra* note 3, at 240. While it is true that a patent description would not distinguish an individual by name, the individual would nevertheless be recognizable if the patented trait was distinctive, i.e., blue skin. *Id.*

147. *See* Charles Fried, *Privacy*, 77 YALE L.J. 475 (1968).

148. *See, e.g.*, Privacy Act of 1974, 5 U.S.C. § 552 (authorization required for disclosure of individual records); COLO. REV. STAT. § 24-72-204(3)(a) (1973) (governs disclosure of medical, psychological and scholastic achievement records in public schools); IOWA CODE ANN. § 68A.7(10)-(11) (West 1973) (governs dissemination of information in the records of public employees).

149. *See* Whalen v. Roe, 429 U.S. 589 (1977) (invalidating law that required doctors to disclose the names of patients who receive particular drugs). *But see* Paul v. Davis, 424 U.S. 693 (1976) (suspect's right of privacy was not violated by police disclosure of shoplifting arrest).

150. *See, e.g.*, Roe v. Wade, 410 U.S. 113 (1973) (decision to terminate pregnancy is protected by right of privacy); Griswold v. Connecticut, 381 U.S. 479 (1965) (right of privacy extends to contraceptive use); N.A.A.C.P. v. Alabama *ex rel.* Patterson, 357 U.S. 449 (1958) (First Amendment rights include the freedom to associate and the right to privacy in such associations); Beard v. Alexandria, 341 U.S. 622 (1951) (right of privacy extends to the right to be undisturbed by doorbell ringing of solicitors); West Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624 (1943) (right of privacy regarding religious belief).

For a discussion of the Supreme Court's determination that a constitutionally protected right of privacy derives from a penumbra formed by the various guarantees of the Bill of Rights, *see generally* Robert G. Dixon Jr., *The Griswold Penumbra: Constitutional Charter For an Expanded Law of Privacy?*, 64 MICH. L. REV. 197, 206 (1965) (lists cases recognizing a right to privacy); Thomas I. Emerson, *Nine Justices In Search of a Doctrine*, 64 MICH. L. REV. 219, 228 (1965) (right of privacy formed by protections of the first, third, fourth, fifth and ninth amendments); Paul G. Kauper, *Penumbras, Peripheries, Emanations, Things Fundamental and Things Forgotten: The Griswold Case*, 64 MICH. L. REV. 135 (1965) (same); Robert B. McKay, *The Right of Privacy: Emanations and Imitations*, 64 MICH. L. REV. 259 (1965) (same).

found.[151] Congress should recognize the potential uncertainty and act to clarify the law. An amendment to the Patent Act providing controlled disclosure of human genetic information is appropriate.

An exception to the unlimited disclosure mandated by the Patent Act could be modeled after an exception found in the Freedom of Information Act ("FOIA").[152] The FOIA controls dissemination of government-held information.[153] The exception found in the FOIA provides that the disclosure of medical information may be withheld if such disclosure would result in an unjustifiable invasion of privacy.[154] A Patent Act exception would likewise direct withholding information concerning an individual's patented genetic make-up if the disclosure was unjustified.[155] Of course, at times, disclosure of the information will be justified because the person requesting the information has a legitimate scientific need. For such instances, the proposed amendment would provide for a procedure whereby a request would be made to the Commissioner of Patents, and a decision could be rendered regarding the justification of disclosure versus an individual's interest in maintaining confidentiality.[156] Such a modification to the Patent Act would protect an individual's right of privacy while still meeting the objectives of the patent system, i.e., fostering scientific progress.

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151. *See generally* Tyler Baker, Note, *Roe and Paris: Does Privacy Have a Principle?*, 26 STAN. L. REV. 1160, 1163 (1973) ("right of selective disclosure" is one aspect of privacy). Edward J. Bloustein, *Privacy as an Aspect of Human Dignity: An Answer to Dean Prosser*, 39 N.Y.U. L. REV. 962 (1964) (privacy is an aspect of human dignity rather than merely an interest in property or reputation); Robert G. Dixon, Jr., Comment, *The Griswold Penumbra: Constitutional Charter for an Expanded Law of Privacy?*, 64 MICH. L. REV. 197, 205 (1965) (the right of privacy encompasses not only the right to solitude, but also the right to secrecy); Comment, *Genetic Engineering and the Right of Privacy*, 21 L. TECH. 20, 22 (1988) (right of privacy incorporates right of control over disclosure of personal matters).

152. 5 U.S.C. § 552 (1990).

153. *Id.*

154. *Id.* at § 552(b)(6). This section states that the broad disclosures mandated by the FOIA do not apply to matters which involve "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy". *Id.*

155. An appropriate exception to the disclosure of patent information which would violate a person's right of privacy would be added to the Patent Act after section 154, which defines the contents of an issued patent. *See* 35 U.S.C. § 154. The amendment would read as follows:

> 154A (a) Notwithstanding the provisions of section 154, the descriptive disclosures of patents covering genetically altered human material shall not be made available to any persons unless good cause is shown otherwise. Good cause shall include a legitimate scientific need for disclosure.
>
> (b) Any persons requesting such information shall describe their need for such information to the Commissioner of Patents. The Commissioner, in deciding whether to release the information, shall weigh the interests of privacy against the scientific need for disclosure.

156. *See supra* note 155 for the text of the proposed amendment.

CONCLUSION

The debate over whether genetically altered higher life-forms are patentable subject matter is over. In *Ex parte Allen*,[157] the court answered the question in the affirmative.[158] Shortly thereafter, the PTO responded by granting a patent on a genetically altered mouse.[159] However, the law governing the patenting of genetically altered organisms is far from settled.

One controversy is whether a patent holder who sells a patented animal maintains rights in the animal's offspring. The Patent Act is silent on this issue. Its resolution depends upon the balancing of competing interests. One of these interests is that of our country's farmers. They seek to maintain competitiveness in the marketplace.[160] A competing interest is the interest of the biotechnology companies which invest heavily in research.[161] They invest with the expectation of receiving monopolies on their patented inventions.[162] Congress must address the issue and reach a consensus as to the degree of protection each of these competing interests should receive. A compromise, as drafted by the House of Representatives, is an appropriate measure.[163] Once Congress has reached a consensus, the Patent Act can be amended in order for the law to clearly reflect Congress' intentions.

A second issue involving the patenting of genetically engineered animals is whether the present PTO procedures are adequate to deal with the new technology. The PTO has developed the deposit requirement as a means of compelling enablement of patents claiming living organisms.[164] Present PTO procedures would require a deposit by all inventors who claim genetically engineered organisms. However, deposit by all inventors of genetically engineered organisms is not necessary.

When deciding whether to require a deposit for a particular patent, the PTO should shift its inquiry from: "is the organism 'unknown' and 'unavailable'?" to "is the organism capable of adequate

157. *Ex parte* Allen, 2 U.S.P.Q.2d 1245 (B.P.A.I. 1987). *See supra* notes 60-74 and accompanying text for a discussion of *Allen*.

158. *Allen*, 2 U.S.P.Q.2d at 1426-27.

159. See *supra* note 73 and accompanying text for a discussion of the "Harvard Mouse."

160. *See supra* notes 79-81 and accompanying text for a discussion of a farmers' interests exemption from infringement in order to remain competitive.

161. *See supra* note 78 and accompanying text for a discussion of investments by biotechnology companies.

162. *See supra* note 75 and accompanying text for a discussion of the expectations of investors.

163. *See supra* notes 117-120 and accompanying text for a discussion of the House of Representations proposed amendment to the Patent Act.

164. *See supra* notes 128-135 and accompanying text for a discussion on the PTO deposit requirements.

disclosure absent a deposit?". This new analysis will allow those genetically engineered organisms which have simple starting materials, and which can be disclosed sufficiently without a deposit, to be so disclosed. This approach will ensure adequate disclosure of genetically engineered organisms without being overinclusive by requiring deposits when they are not necessary to comply with the Patent Act.

A third issue raised by the patentability of genetically engineered life-forms involves the consequences of a patent covering a genetically engineered human invention. The Patent Act requires an inventor to disclose what his invention is, and how to make and use it.[165] However, the disclosure of the novel traits of a patented human gene might be an unconstitutional violation of the right of privacy of the person bearing that gene. Congress must address this issue by amending the Patent Act to provide for limited disclosure of human genetic information.

The proposed amendment[166] is modeled after an exception in the FOIA which prohibits disclosure of medical information if the disclosure would result in an unjustified invasion of privacy.[167] The proposed amendment would allow for a case-by-case balancing of priorities between an individual's interest in maintaining confidentiality and a researcher's need for the information. Congress must pass such legislation so that the potential for an unconstitutional invasion of privacy resulting from a patent will not have a chilling effect upon genetic research. Scientists and engineers must be free to wholeheartedly continue their research into human genetics so that humanity may reap the benefits.[168]

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165. 35 U.S.C. § 112 (1990). *See supra* notes 124-26 and accompanying text for a discussion of description and enablement requirements.

166. *See supra* note 155 for the text of the proposed amendment.

167. *See supra* note 154 and accompanying text discussing the FOIA exception for personal information.

168. In September, 1990, a highly experimental trial of a new gene therapy was initiated. Verma, *Gene Therapy*, SCI. AM., Nov. 1990, at 68. The gene was introduced into children impaired with a condition known as severe combined immunodeficiency. *Id.* The results are being watched very closely because the experiment marks the beginning of clinical testing of human gene therapy. *Id.* The benefits of such gene therapy might prove to be immeasurable, because one out every hundred infants is born with a serious genetic defect. *Id.*