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COMMENTS

PATENTING DR. VENTER'S GENETIC FINDINGS: IS THE NATIONAL INSTITUTES OF HEALTH CREATING HURDLES OR CLEARING THE PATH FOR BIOTECHNOLOGY'S VOYAGE INTO THE TWENTY-FIRST CENTURY?

We have a 200-year-old patent system established by Thomas Jefferson for the express purpose of making sure that "both individuals and society reap the benefits of human industry and creativity." Surely, Thomas Jefferson could never have predicted what a quandary his highly successful patent system would face over Mother Nature's secrets.¹

Since the issuance of the first United States patent to Samuel Hopkins in 1790,² patent law has evolved under the guidance of federal legislation and decisions handed down by the Patent and Trademark Office (PTO) and the federal courts. The growth of patent law has not been unproblematic, however, due in large part to the inability and sometimes unwillingness of the courts and Congress to keep up with scientific progress.³ This has especially been the case in the latter half of the twentieth century in the field of biomedical science.⁴ Giant strides in biotechnology

1. Robin Herman, *The Great Gene Gold Rush: U.S. Rankles Other Countries with Preemptive Strike in the Race to Patent Human Genes*, WASH. POST, June 16, 1992, (Health), at 11, 16 (quoting Bernadine Healy, M.D., former Director, National Institutes of Health, Public Health Service, Dept. of Health and Human Services).

2. Alex Barnum, *Biotech Labs Enraged by Bid to Patent Human Genes*, S.F. CHRON., Dec. 2, 1991, at B1. The patent was granted for making potash, which is used to produce fertilizer, soap and other products. *Id.*

3. *On Gene Patenting: Hearings Before the Subcomm. on Patents, Copyrights and Trademarks of the Senate Comm. on the Judiciary*, 102d Cong., 2d Sess. 5 (1992) [hereinafter *On Gene Patenting*] (testimony of Bernadine Healy, M.D., Director, National Institutes of Health).

4. See Jessica Mathews, *The Race to Claim the Gene*, WASH. POST, Nov. 17, 1991, at C7 (suggesting that the decision to patent the gene sequences should be made by elected

have left society behind to deal with the consequences.⁵

Current biotechnology, as well as its attendant patent disputes, had its auspicious beginnings in 1973 with the invention of genetic engineering.⁶ This new technology enabled scientists to recombine human genes and create "tiny factories" from cells.⁷ As discoveries in molecular genetics and recombinant DNA technology proliferated, many policy debates ensued regarding how to protect the inventor's interests while transferring the discovery to the public in a way that they could benefit.⁸ In 1980, the Supreme Court addressed this dispute in the landmark case *Diamond v. Chakrabarty*. The Court concluded that genetically engineered microorganisms are patentable.⁹ Since the *Chakrabarty* decision, "it has been a fast slide down a legal slippery slope."¹⁰ Patent law, by recognizing that plants, animals, genes, cDNA's, hybridomas and monoclonal antibodies are patentable, did its best to keep up with the rapid growth of the biotechnology industry it had encouraged.¹¹

The courts and the PTO were not alone in encouraging the creation of

officials, rather than by patent lawyers, in order to circumvent the pitfalls that accompany unregulated scientific advancements).

5. See *id.* This has particularly been the case in the areas of molecular genetics and recombinant DNA technology, where scientists and policymakers have received no guidance regarding how to "best transfer this powerful information into practical public benefit." *On Gene Patenting*, *supra* note 3, at 5.

6. *Biotechnology Development and Patent Law: Oversight Hearing Before the Subcomm. on Intellectual Property and Judicial Administration of the House Comm. on the Judiciary*, 101st Cong., 2d Sess. 5 (1991) [hereinafter *Biotechnology Development and Patent Law*] (statement of Bernadine Healy, M.D., Director, National Institutes of Health). Genetic engineering, which involves splicing genes from one organism into another, was invented by Stanley Cohen and Herbert Boyer in 1973. They received a patent on this technique in 1980, following the *Chakrabarty* decision. See Barnum, *supra* note 2, at B1.

7. *Biotechnology Development and Patent Law*, *supra* note 6, at 5.

8. See *On Gene Patenting*, *supra* note 3, at 5.

9. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In a 5-4 decision, the Supreme Court held that genetically engineered microorganisms (in this case genetically engineered, oil-eating microbes) merit patent protection. *Id.*

10. Mathews, *supra* note 4, at C7.

11. Reid G. Adler, *Technology Transfer and Genome-Related Research* 9 (Oct. 22, 1991) (transcript available in the NIH Press Office). Reid Adler is the Director of the Office of Technology Transfer at the National Institutes of Health. He has spearheaded the NIH initiative on acquiring patents on the cDNA fragments. The examples noted by Adler fall into the category of products of nature that have been fashioned by humans in some manner. While the line between that which is created in the laboratory and that which is discovered in the "wild" is often difficult to discern, courts are likely to grant patent protection to discoveries that through human intervention take a form that does not naturally occur. *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 161-62 (4th Cir. 1958).

the billion dollar, American biotech industry. Recognizing the rise of biotechnology, Congress passed two acts¹² in 1980 to foster the "transfer of Government laboratory-developed technology to commercial applications."¹³ Six years later, Congress passed the Federal Technology Transfer Act to further stimulate cooperation between industry and government laboratories.¹⁴

The United States was not the only country to realize the benefits associated with advancements in biotechnology. In response to suggestions that the discovery of human genes would likely uncover the mysteries behind certain diseases,¹⁵ the Human Genome Organization, an international collaborative effort, was established in 1988.¹⁶ The United States' national program, the U.S. Human Genome Project,¹⁷ was formed to work with other countries to locate and define the sequences of all human genes in order to create "a framework for molecular medical research directed towards understanding the genetic bases of human health and disease and basic life functions, including development."¹⁸

As a direct result of this international collaboration, Dr. Craig Venter, a research scientist leading a fifteen person laboratory within the National Institutes of Health's (NIH) National Institute of Neurological Disorders and Stroke,¹⁹ utilized newly developed instrumentation, powerful computers, and advanced robotics to perform gene sequencing at a rapid pace.²⁰ In 1991, NIH decided to seek a patent on the Venter team's findings.²¹ The filing of this patent application took the biotechnology indus-

12. Bayh-Dole Act, 35 U.S.C. §§ 200-212 (1980); Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. § 3710(a) (1980).

13. *Biotechnology Development and Patent Law*, *supra* note 6, at 7.

14. Federal Technology Transfer Act, 15 U.S.C. § 3701 (1986). The Federal Technology Transfer Act (FTTA) creates incentives for companies and federal laboratories to enter into Cooperative Research and Development Agreements (CRADAs), which "allow[s] each participant to direct personnel, services, and property funds toward collaborative joint research projects." *Biotechnology Development and Patent Law*, *supra* note 6, at 7.

15. Hilary Stout, *U.S. Pursuit of Gene Patents Riles Industry*, WALL ST. J., Feb. 13, 1992, at B1.

16. The Human Genome Organization is an international collaborative effort that locates and defines the chemical sequences of all of the 100,000 human genes. Herman, *supra* note 1, at 16.

17. The United States Human Genome Project is jointly financed by NIH and the Department of Energy. *Id.*

18. *On Gene Patenting*, *supra* note 3, at 2.

19. *Feds Trying to Corner Gene Market, Critics Say*, NEWSDAY, Nov. 1, 1991, at 55.

20. Gina Kolata, *Biologist's Speedy Gene Method Scares Peers But Gains Backer*, N.Y. TIMES, July 28, 1992, at C10.

21. *On Gene Patenting*, *supra* note 3, at 8-11.

try by surprise and launched a heated debate among all parties involved.²²

This Comment evaluates the problems and issues that have arisen as a result of NIH's filing of the patent application. This Comment first outlines the circumstances that prompted NIH to file the application.²³ This Comment then focuses on the patentability of human gene sequences, including the PTO's initial rejection of the application and NIH's counterarguments.²⁴ This Comment concludes with a policy discussion of the arguments presented by NIH, the biotech industry, scientists, and foreign countries.²⁵

I. THE ERUPTION OF THE CONTROVERSY

Scientific discoveries have the ability to take the world by storm and transform society. The ultimate effects of scientific advancements are difficult to predict at the outset, thus creating an air of apprehension.²⁶ The human gene mapping initiative has caused great apprehension in the biotechnology community.²⁷

Scientific understanding of the human genetic makeup dates back to 1953, when Drs. James Watson and Francis Crick propounded the double helical structure of DNA in chromosomes.²⁸ Thereafter, scientists, understanding that research into gene sequences may provide both cures and preventative treatments for diseases, have struggled to determine which genetic instructions are coded by which particular nucleotide sequences.²⁹ Mapping genes is a "tedious and daunting endeavor," requiring great amounts of time and money.³⁰

22. Barnum, *supra* note 2, at B1.

23. *See infra* notes 26-48 and accompanying text.

24. *See infra* notes 49-99 and accompanying text.

25. *See infra* notes 100-146 and accompanying text.

26. *On Gene Patenting*, *supra* note 3, at 2.

27. *Double Helix Battles*, WASH. POST, May 1, 1992, at A26 (discussing the dispute between Dr. James Watson, former head of the U.S. Human Genome Project, and NIH). Dr. Watson quit his position with the Human Genome Project because he believed that patenting unidentified gene sequences was "sheer lunacy" and would ruin international cooperation in the genetics field. Herman, *supra* note 1, at 11.

28. Herman, *supra* note 1, at 12. This is the same Dr. Watson who headed the U.S. Human Genome Project. *Id.* at 11.

29. Lynne Langley, *Genetics Holds Hope, Pitfalls*, POST & COURIER, Mar. 24, 1992, at B1.

30. Herman, *supra* note 1, at 12. Determining where one gene ends and the other begins is difficult, especially given that genes range in length from two thousand to two million nucleotide pairs. *Id.*

When scientists identify a gene sequence and determine its role, this valuable knowledge can bring enormous wealth to the licensed company or companies.³¹ The biotech company Amgen is an excellent example of a company that has realized the monetary value of genetic knowledge. After being awarded a patent for a gene sequence it identified that "instructs kidney cells to make an important blood protein missing in people with renal failure and on dialysis," Amgen reaped \$400 million in annual sales from a welcome market.³² With such high financial returns as an incentive, researchers worldwide³³ are focusing their efforts on "cracking the genetic safe." The strong international interest in this area was evidenced by the commitment of three billion dollars to the fifteen year Human Genome Project to "decipher every gene in the blueprint for human life," with the long-term goal of understanding enigmatic diseases.³⁴

At the Project's inception, U.S. scientists maintained that the entirety of the human gene sequences would be defined; however, their concentration today is on cDNAs.³⁵ Dr. Venter and his team of NIH scientists developed a process that quickly sequences genes using cDNA.³⁶ The procedure requires pulling a cDNA out of the human brain cDNA library,³⁷ amplifying the cDNA, and sequencing a portion of it.³⁸ The partial sequence, called an Expressed Sequence Tag (EST), is decoded into its constituent nucleotides, which enables the scientist to determine whether the EST represents a new gene.³⁹ This shortcut method⁴⁰ saves

31. *Id.*

32. *Id.*

33. *Id.* at 11.

34. C. Ezzell, *Speeding the Search for New Human Genes*, SCIENCE NEWS, June 22, 1991, at 389.

35. Leslie Roberts, *Gambling on a Shortcut to Genome Sequencing*, 252 SCIENCE 1618 (1991). DNA is a large molecule in the shape of a double helix, which carries the genetic information necessary for the replication of cells and for the production of proteins. Herman, *supra* note 1, at 12. Complementary DNA (cDNA) is a synthetic chemical analog of DNA from which the non-coding DNA sequences called introns, or "junk DNA," have been removed. *Id.*

36. *On Gene Patenting*, *supra* note 3, at 4.

37. Robert Benson, Address to the Biotechnology Committee of the American Intellectual Property Law Association 3 (May 14, 1992) (transcript available in the NIH Press Office) (discussing the research project performed by Dr. Venter and his group and addressing patentability concerns).

38. *Id.* The sequenced portion ranges from approximately 150 to 500 nucleotides. *Id.*

39. *Id.* "This information is obtained by comparing the nucleotide sequence of the EST or its complement, or the 6 [six] amino acid sequences of the six possible encoded polypeptides, with those contained in databases like GenBank or Protein Information Resource." *Id.*

time and money because it allows the researcher to rapidly understand which genes are active in specific tissues without having to sort through "junk" DNA.⁴¹ Dr. Venter predicts that his technique will enable completion of the Human Genome Project by 1997, far ahead of the original schedule predicting completion early in the twenty-first century.⁴²

Following the development of Dr. Venter's process, the patent controversy arose. Knowledge of partial gene sequences does not tell the researcher the biological function or purpose of a gene in a particular tissue.⁴³ Dr. Venter candidly admits that he does not know what most of his "tagged" DNA does,⁴⁴ and that attaining such information will require additional extensive research and analysis. Nevertheless, NIH feared that the publication of Dr. Venter's findings would be a "tragic mistake" that could seriously undermine the U.S. biotech effort,⁴⁵ and decided to seek patent rights on approximately 2,400 of the DNA fragments (ESTs) without knowledge of their biological function.⁴⁶ NIH's action "set off an international scientific furor,"⁴⁷ involving the entire biotech industry. "The very notion of patenting human genes, the essence of human life, is offensive to some lawyers and scientists. And the idea that someone might be able to use these fragments as a shortcut to claim ownership of genes is sending some experts into near apoplexy."⁴⁸

II. THE PATENTABILITY DEBATE

Patents are defined as, "intensely practical, real-life legal instruments," which serve as a vehicle to protect the scientist's investment in time, resources and money.⁴⁹ The United States Constitution grants Congress the power to enact laws that "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclu-

40. *Fishing for Complements*, *ECONOMIST*, Jan. 18, 1992, at 85 (discussing Dr. Venter's work and NIH's chances of acquiring the cDNA patents).

41. *Id.*

42. Tim Friend, *Gene-Hunting Picks Up Steam*, *USA TODAY*, Feb. 13, 1992, at A1.

43. *On Gene Patenting*, *supra* note 3, at 4-5.

44. Leslie Roberts, *Genome Patent Fight Erupts*, 254 *SCIENCE* 184 (1991).

45. *Id.* at 185.

46. Roberta Friedman, *2-5 Years to Sequence Brain Genes*, *BIOWORLD TODAY*, Feb. 14, 1992, at 3.

47. Edmund L. Andrews, *U.S. Seeks Patent on Genetic Codes, Setting Off Furor*, *N.Y. TIMES*, Oct. 21, 1991, at A1.

48. Gina Kolata, *Ideas and Trends: In Rush to Patent Genes, The Claims Get Smaller*, *N.Y. TIMES*, Sept. 6, 1992, § 4, at 12.

49. Irving Kayton, *PATENT PRACTICE*, Vol. 1, 1-1 (4th ed. 1989).

sive Right to their Writings and Discoveries."⁵⁰ The current American patent system encourages industry to take the risks needed to develop products, enhances public disclosure and limits secrecy, educates the public so that improvements and alternatives can be explored, and fosters invention.⁵¹ A patent is a contract between its owner and the U.S. Government, whereby the owner is given security in exchange for sharing knowledge with the public.⁵² The system is designed to enhance research by guaranteeing inventors seventeen years of protection from "pirates" who would be unjustly enriched in the absence of such restrictions.⁵³

Patent protection has proven very valuable in the field of biotechnology, in which more than \$100 million and ten years of research and testing are routinely invested to develop a single drug.⁵⁴ Biotechnology industry analysts observe that patent protection is a major consideration in a company's decision to pursue a new drug.⁵⁵ Absent protection, the risks of being beaten to the cure outweigh the possibility of a financial windfall.

Understanding biotechnology's competitive climate, NIH decided in June 1991 to pursue patents on the DNA fragments discovered by Dr. Venter.⁵⁶ A continuation-in-part of this application was filed in February 1992.⁵⁷ The most significant basis for the decision to seek patent protection was NIH's fear that the publication of Dr. Venter's data would make the future patenting of his findings impossible, because his gene fragments would become part of the public domain.⁵⁸ Because keeping Dr.

50. U.S. CONST. art. I, § 8, cl. 8. Today, "technological arts" is considered the equivalent of "useful arts." Reid G. Adler, *Biotechnology as an Intellectual Property*, 224 SCIENCE 357, 363 n.12 (1984).

51. Adler, *supra* note 11, at 5 n.6.

52. *Id.* at 5-6.

53. Barnum, *supra* note 2, at B9.

54. *Id.*

55. *On Gene Patenting*, *supra* note 3, at 8. A study by the Mansfield group found that "60% of pharmaceutical products would not have been developed without patent protection." *Id.*

56. Mary Knudson, *NIH Criticized for Seeking Patents on Hundreds of Partial Genes*, BALT. SUN, Nov. 3, 1991, at 40.

57. Malcolm Gladwell, *NIH Files Patent Applications on 2,300 More Human Genes*, PHILA. INQ., Feb. 16, 1992, at A3. The application referred to as a continuation-in-part was filed in February. It was added to a much smaller patent filing made by NIH in the summer of 1991. Taken together, these claims constitute a claim by NIH to rights to over five percent of the genes found in the human body. *Id.*

58. Kolata, *supra* note 20, at C1. A patent is barred for lack of novelty if there is enough in the prior art to enable someone skilled in the area to perform the process or produce the product described in the patent application. Therefore, if Dr. Venter pub-

Venter's findings secret until further research could be performed was not an option,⁵⁹ NIH filed the patent application at the PTO.

In August 1992, the PTO rejected NIH's patent application for the gene fragments of unknown function. The patent examiner concluded that NIH failed to satisfy the PTO's four tests for patentability: novelty, non-obviousness, enablement and utility.⁶⁰

A. Novelty

Novelty was the first ground for the PTO's rejection of the application.⁶¹ To satisfy the novelty requirement, the gene fragments must not have been previously known.⁶² The PTO concluded that because the claimed sequences were derived from already existing cDNA libraries, they were already in the public domain.⁶³

Rejection on the basis of novelty should be reversed on appeal. Denying novelty because the sequences were taken from a publicly available clone collection seems irrational when evaluated on a larger scale.⁶⁴ If this policy were followed "virtually all products isolated from expected sources of biomolecules, such as blood, saliva, or tissue" would be unpatentable.⁶⁵ Biotechnology as we know it would cease to exist because any gene traced to a genetic library would be nonpatentable, thus destroying any incentives to industry and scientists.⁶⁶ This is not the policy of the PTO,⁶⁷ and if NIH's cDNA patent claims are rewritten and clarified, the

lishes his findings before pursuing patent rights, there is a distinct possibility that protection will be denied on this basis. *Id.*

59. *On Gene Patenting*, *supra* note 3, at 10.

60. Leslie Roberts, *Rumors Fly Over Rejection of NIH Claim*, 257 *SCIENCE* 1855 (1992). See 35 U.S.C. §§ 101-03, 112 (1988) (codifying the four requirements for patentability).

61. 35 U.S.C. § 102(a) (1988) reads: "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 a patent"

62. Pamela Zurer, *Critics Take Aim at NIH's Gene Patenting Strategy*, *C & EN*, June 8, 1992, at 21.

63. *Patent Office Has Initially Declined NIH's cDNA Patent Application*, *LIFE SCIENCE* (Washington Fax: An Information Service, Wash., D.C.), Sept. 25, 1992, at 1 [hereinafter *Patent Application Initially Declined*].

64. Roberts, *supra* note 60, at 1855. Patent protection is sought for the sequences derived from these libraries. *Id.*

65. *Patent Application Initially Declined*, *supra* note 63, at 1.

66. See *id.* at 1-2.

67. Applied properly, patent law enhances the incentive to develop new technology. An effective patent system ensures the orderly protection of technological innovation to

examiner's novelty rejection is likely to be withdrawn.

B. *Non-Obviousness*

Non-obviousness is the second ground for the PTO's rejection of the NIH application. Under 35 U.S.C. § 103, a patent is denied when the subject matter of the invention would be obvious to one working in the field at the time of the invention.⁶⁸ This section prevents the issuance of a patent when the new art and the prior art are so closely related that the inventor's contribution to prior art does not merit protection.⁶⁹ The PTO reasoned that because some of the sequences presented in the application were derived from smaller fragments that had already been published, creating a larger sequence or an entire gene using this prior art would be obvious to any scientist.⁷⁰ This reasoning is consistent with the views of Dr. James Watson, an outspoken critic of NIH's patenting initiative, who believes that "virtually any monkey" can perform the work of Dr. Venter's laboratory.⁷¹

This rejection is not without merit. Dr. Venter neither invented the concept of sequencing cDNA, nor created the technology to perform the process.⁷² However, the PTO may have been somewhat hasty in arriving at its conclusion of obviousness. If the PTO allows this ruling to stand, no patent can be issued on a gene if any of its sequences have already been published, regardless of how much time and money was spent to determine the full makeup of the gene and its function in the cell.⁷³ Such a policy would destroy incentives for biotech companies to pursue projects

allow creative individuals to expend their time, money and energy in the process of inventing. Kayton, *supra* note 49.

68. Section 103 reads:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such 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.

35 U.S.C. § 103 (1988).

69. Adler, *supra* note 50, at 359.

70. Christopher Anderson, *NIH cDNA Patent Rejected; Backers Want to Amend Law*, 359 NATURE 263 (1992).

71. Roberts, *supra* note 44, at 184.

72. Christopher Anderson, *To Patent a Naked Gene*, 353 NATURE 485 (1991). Scientists before Dr. Venter were aware of this sequencing method, but it was dismissed as impractical on the belief that some genes have so few mRNA copies that they would escape detection. Kolata, *supra* note 20, at C10.

73. Anderson, *supra* note 70, at 263.

which have the goal of determining the base products on those genes.⁷⁴ Finally, while Dr. Venter's research can fairly be characterized as less than incredible, it is hardly "monkey's work." His team successfully deduced that the human genome could rapidly be mapped by combining large-scale cDNA sequencing with the searching ability of electronic DNA databases.⁷⁵ Their foresight should be given strong consideration, as U.S. patent law explicitly states that it is irrelevant how an invention is made or how little energy is expended.⁷⁶

If the PTO remains steadfast on its views regarding obviousness, Congress should pass legislation to expressly allow a patent to be issued on a full gene, even if a partial gene has already been published.⁷⁷ Without such protection, the dissemination of scientific findings, which is a major purpose of our patent system, will come to a screeching halt.⁷⁸

C. Utility

Utility is the third ground for the PTO's rejection of the NIH patent application.⁷⁹ The PTO concluded that Dr. Venter's discoveries failed to identify the genes of which the sequences were a part, the proteins coded by these sequences, and the function of these partially sequenced genes.⁸⁰ More research was necessary in order to determine the utility of these nucleotide sequences.⁸¹ This rejection is supported by *Brenner v. Manson*, where the Supreme Court concluded that an invention must have a practical use beyond merely being a tool for scientific inquiry.⁸²

74. *Id.*

75. Anderson, *supra* note 72, at 485.

76. Reid Adler states: "Patent law specifically says that you can't consider how the invention was made. It's irrelevant if a trained chimpanzee can do the work. The law doesn't want some judge deciding if someone sweated enough to deserve a patent." *Id.*

77. *Patent Application Initially Declined, supra* note 63, at 2.

78. Reid Adler and Dr. Craig Venter insist that biotech companies "will be leery of touching these inventions without adequate patent and license protection from NIH," and therefore, delay will burden the scientific discovery process. Roberts, *supra* note 44, at 185.

79. See 35 U.S.C. § 101 (1988) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

80. Rebecca S. Eisenberg, *Genes, Patents, and Product Development*, 257 *SCIENCE* 903, 904-05 (1992).

81. Leslie Roberts, *Top HHS Lawyer Seeks to Block NIH*, 258 *SCIENCE* 209, 210 (1992).

82. 383 U.S. 519 (1966). One commentator argues that this opinion suggests that the utility requirement distinguishes between basic research, which should not be patented,

While NIH does not know the exact, future utility of the cDNA sequences, the PTO's rejection on the basis of utility may be premature and unduly restrictive: "Patents have been awarded for discovery of novel biological molecules for which the full range of function—or even most important function—is not known."⁸³ Although the biological function associated with the cDNAs is not presently known, other practical uses, such as chromosome markers, vehicles to differentiate brain tissue from other human tissue, and primers for polymerase chain reactions, are known.⁸⁴ Such possible uses certainly satisfy the PTO's utility requirement, especially in light of the fact that chromosome markers are presently sold throughout industry without any reliance on the gene's biological function.⁸⁵ Furthermore, U.S. patent law does not require that all uses be determined; it only requires some threshold activity.⁸⁶ Finally, the PTO's rejection on the basis of utility appears to directly conflict with several recent lower court decisions that favor granting intellectual property rights to avoid trade secrets and secrecy in the biotechnology industry.⁸⁷ NIH is attempting to patent more than mere research; Dr. Venter's findings are advanced technology with the potential to stimulate advancements in the biotech arena. Requiring an uncharacteristically high threshold for utility will frustrate the dissemination of critical technology into the public domain.

D. Enablement

The final basis for the PTO's rejection of the NIH patent application is the enablement provision in the first paragraph of 35 U.S.C. § 112.⁸⁸ The

and applied technology, which may be patented, thereby "confining the operation of the patent system 'to the world of commerce rather than to the realm of philosophy.'" Eisenberg, *supra* note 80, at 905.

83. Healy *Outlines Likely Patent Debate Issues*, LIFE SCIENCE (Washington Fax: An Information Service, Wash., D.C.), June 2, 1992, at 1 (quoting Bernadine Healy, M.D., former Director, National Institutes of Health).

84. Benson, *supra* note 37, at 6-7.

85. *Patent Application Initially Declined*, *supra* note 63, at 1.

86. Roberts, *supra* note 44, at 185. Adler stated: "[Y]ou don't have to know all the uses for an invention but just some sort of threshold activity." *Id.*

87. Eisenberg, *supra* note 80, at 905.

88. Section 112 reads:

The specification shall contain 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 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 (1988).

provision requires the applicant to provide an adequate written description of the claimed invention and an enabling disclosure.⁸⁹ This enablement provision serves many present and future purposes.⁹⁰ The PTO concluded that the NIH patent application did not provide an adequate definition of Dr. Venter's findings and did not offer enough information to enable an individual skilled in the area to make and use the invention.⁹¹

Once again, the PTO may have been overly critical of NIH's application. The application discusses in great detail numerous examples of how an individual knowledgeable in biotechnology can isolate the cDNA and, if given the sequence, the genomic version of the gene.⁹² The 300 to 500 base fragments sequenced by Dr. Venter encode information that is "more specific than fingerprints at identifying [a person],"⁹³ and therefore should constitute information sufficient to evince entire genes.⁹⁴ While NIH's claims are very broad and general, they are adequate when viewed in light of the advanced level of knowledge present in this field.⁹⁵

Although the PTO initially declined the NIH's cDNA application, the fight is hardly over.⁹⁶ NIH was not surprised by the decision, especially since the PTO rejects ninety percent of all first-time applications.⁹⁷ NIH may respond to the PTO's rejection at the beginning of 1994.⁹⁸ The PTO may reevaluate the application, and if it is rejected again, NIH may appeal the decision in federal court.⁹⁹ Policy promises to be a major consideration if the dispute reaches the courts.

89. Roberts, *supra* note 81, at 210.

90. "Enablement makes the patent understandable by those in its field to avoid infringement; provides the public with the ability to practice the invention after the patent expires; and secures the continuous disclosure of novel, useful, and unobvious technical advances." Adler, *supra* note 50, at 360.

91. Roberts, *supra* note 81, at 210.

92. Benson, *supra* note 37, at 7.

93. Leslie Roberts, *NIH Gene Patents, Round Two*, 255 *SCIENCE*, 912, 913 (1992) (quoting Dr. Craig Venter).

94. Roberts, *supra* note 81, at 210.

95. Eisenberg, *supra* note 80, at 905.

96. *Patent Application Initially Declined*, *supra* note 63, at 2.

97. Roberts, *supra* note 60, at 1855. The issues of novelty, utility and nonobviousness have proven to be stringent standards that are rarely satisfied in a first-time application. See *Patent Application Initially Declined*, *supra* note 63, at 1.

98. Roberts, *supra* note 60, at 1855.

99. Irving Kayton, *PATENT PRACTICE*, Vol. 4, 18-15 (4th ed. 1989).

III. POLICY ISSUES SURROUNDING THE NIH DNA APPLICATION

Although NIH's application is currently being circulated through the PTO and various NIH offices, some experts believe the dispute will ultimately wind up in federal court.¹⁰⁰ The debate centers not so much on the legal question of whether the cDNAs may be patented, but rather on the societal concerns of the biotech community as to whether the patent should be granted.¹⁰¹ Patent law cannot remain static. The courts and Congress must function as responsive entities that balance the harms and benefits of patenting technological advances and adroitly create policy to reduce risks while enhancing advancements.

NIH directors are frequently asked why patent protection was sought at such an early stage, especially when waiting for further research would make their patent application more readily acceptable.¹⁰² NIH quickly responds that it did not intend to seek patents at the inception of the Human Genome Project,¹⁰³ but that many circumstances, including the celerity of the sequencing, have left it with no other responsible choice except to exercise all available options.¹⁰⁴ Congressional legislation and other federal mandates delegate to NIH the duty to secure inventions emanating from federally-funded laboratories.¹⁰⁵ Licensing intellectual property rights is the primary means to protect taxpayers research investments and scientific ingenuity, and to deliver these discoveries to the public.¹⁰⁶ NIH's policy is to ensure that new therapies and pharmaceuticals

100. Roberts, *supra* note 81, at 210. Henry Wixum, a patent attorney with the Washington, D.C. law firm of Hale & Dorr, stated, "I would not be surprised if the board thinks it is too hot and kicks it upstairs to the next level, to the Court of Appeals for the Federal Circuit." *Id.*

101. Roberts, *supra* note 44, at 185. Much of the argument is cast in terms of the possible effects on industry and international collaboration. *Id.* at 185-86.

102. See generally Adler, *supra* note 11, at 11-14; Healy Explains NIH Position on Patenting cDNA, LIFE SCIENCE (Washington Fax: An Information Service, Wash., D.C.), June 1, 1992, at 1 [hereinafter *NIH Position*]; The Affect of Patent Law on Molecular Biology, Genetics and the Human Genome Is Not Clear, Says Healy, LIFE SCIENCE (Washington Fax: An Information Service, Wash., D.C.), Nov. 20, 1991, at 1 [hereinafter *Affect of Patent Law*].

103. Telephone Interview with Dr. Craig Venter, former NIH Researcher (Mar. 18, 1992) [hereinafter *Telephone Interview*].

104. See Memorandum from Bernadine Healy, Director, NIH, to Colleagues (July 1992) (draft on file in the NIH Press Office) [hereinafter *Memorandum*].

105. See, e.g., Federal Technology Transfer Act of 1986, 15 U.S.C. §§ 3701 et seq. (1986); Exec. Order No. 12,592, 52 Fed. Reg. 13,417 (1987). See also *Affect of Patent Law*, *supra* note 102, at 1.

106. See *NIH Position*, *supra* note 102, at 1-2.

reach the public as quickly as possible.¹⁰⁷

Given the surrounding circumstances, NIH's decision to seek patent protection was logical. If Dr. Venter's research had been published before a patent application was filed, the United States government would have forfeited all international patent rights in the sequences,¹⁰⁸ and possibly all rights in any discoveries resulting from the sequences.¹⁰⁹ Because U.S. patent law is constantly changing,¹¹⁰ NIH felt that "it [is] worth filing the application, if for no other reason than not to miss the boat,"¹¹¹ and possibly lose a valuable technological opportunity.¹¹²

NIH, under the direction of Dr. Bernadine Healy, had been aggressive in seeking patents, not as "fundraising tool[s]"¹¹³ but as vehicles to encourage development and stimulate the commercialization of government funded discoveries by private industry.¹¹⁴ However, NIH policy also requires that advancement be carried out in a socially responsible way.¹¹⁵ Therefore, the concerns of industry and the international scientific community should be evaluated to determine if NIH's policy is acceptable.

A. International Concerns

Controversy erupted among Human Genome Project scientists in Europe and Japan after NIH filed its patent application for Dr. Venter's cDNA fragments.¹¹⁶ NIH's action was viewed as "seriously prejudicial to the whole thrust of the international Human Genome Project,"¹¹⁷ and

107. *Memorandum, supra* note 104, at 1-2.

108. Elizabeth Sullivan, *Pandora's Box Opens*, THE PLAIN DEALER (Cleveland), Mar. 1, 1992, at C1.

109. Adler, *supra* note 11, at 12. Forfeiture of patent rights occurred when the U.S. scientists published their genetic engineering discovery. Today, American scientists have to pay licensing fees on basic gene splicing techniques, while overseas scientists are not charged. Sullivan, *supra* note 108, at 1-C.

110. See Adler, *supra* note 50, at 357-63.

111. Anderson, *supra* note 72, at 485 (quoting Reid Adler). Adler stated: "This is not the strongest case for utility I've ever seen, but it's not the weakest either." *Id.*

112. *Memorandum, supra* note 104, at 2.

113. Larry Thompson, *NIH's Rush to Patent Human Genes*, WASH. POST, Oct. 28, 1991, at A3 (quoting Reid Adler).

114. Edmund L. Andrews, *Dr. Healy's Big Push on Patents*, N.Y. TIMES, Feb. 16, 1992, at F12.

115. *Memorandum, supra* note 104, at 2.

116. David Swinbanks, *Japanese Researchers Rule Out Gene Patents*, 356 NATURE 181 (1992). Scientists worldwide are debating the advantages and disadvantages of issuing such patents and are expressing concern over the future of the Human Genome Project. Roberts, *supra* note 44, at 184.

117. Peter Aldhous, *Tit for Tat on Patents*, 353 NATURE 785 (1991).

fears that international collaboration on genetic mapping and sequencing would deteriorate into unhealthy competition were expressed.¹¹⁸ European scientists and government officials characterized the patent initiative as "a Wild West-style land grab over common human territory,"¹¹⁹ and suggested that the patenting effort would promote secrecy, create an international race to patent genes, and stifle discoveries.¹²⁰ Each country responded differently. In March 1992, Britain's Medical Research Council (MRC) filed an application with the British Patent Office to patent its gene fragments.¹²¹ Although the MRC characterized its action as a defensive measure to protect itself should NIH's application be granted,¹²² the MRC already kept sequences secret and was preparing to sell them to industry.¹²³ Japan, also a vocal critic of the NIH initiative, jumped into the "gene-patent fray" in February 1993, when the Sagami Chemical Research Center (a private foundation in Kanagawa Prefecture) filed applications for sixty gene sequences with the Japanese Patent Office.¹²⁴ Other countries with large biotech industries, such as France, did not follow suit,¹²⁵ but they did express fear that the industry would crumble if they were forced to pay licensing fees for the gene sequences.¹²⁶

At the First South-North International Human Genome Conference in May 1992, international disapproval of NIH's patent initiative was expressed in a declaration, which called for NIH to abandon patenting natu-

118. Rachel Nowak, *Gene Researchers Challenge the Patent Frontier*, JOURNAL OF NIH RESEARCH, Dec. 1991, at 25-26.

119. Richard L. Hudson, *British Move to Patent Gene Fragments Escalates a Battle With Washington*, WALL ST. J., July 16, 1992, at B2. Opinions condemning U.S. efforts to acquire these intellectual property rights have been voiced by the British Medical Research Council. *Id.*

120. Catherine Arnst, *European Scientists Fight U.S. Effort to Patent Genetic Parts*, ST. LOUIS COUNTIAN, Feb. 25, 1992, at 1, 9.

121. Hudson, *supra* note 119, at B2.

122. Christopher Anderson & Peter Aldhous, *Secrecy and the Bottom Line*, 354 NATURE 96 (1991).

123. The U.K.'s desire to sell their data was characterized as "a stye in the eye of international progress on the genome." *Id.* (quoting Charles Cantor, Chief Scientist for the U.S. Department of Energy's Human Genome Project).

124. Aya Furuta, *Japan Jumps Into Gene-Patent Fray*, NIKKEI WEEKLY, Mar. 1, 1993, at 13. There is no precedent for granting a patent on genes without a known specific application in the Japanese Patent Office. However, the applications submitted by Sagami are for genes that have been completely sequenced, which suggests that the functions and structures of the encoded proteins can be inferred. *Id.*

125. Declan Butler, *Who Owns the Building Blocks of Life?*, INDEPENDENT, Nov. 2, 1992, at 14.

126. Nowak, *supra* note 118, at 26.

rally occurring DNA sequences.¹²⁷ Five months later, Charles Auffray, a leading French human genome researcher, released France's genome data to the scientific community as a "symbolic protest" against countries seeking patents on the gene sequences.¹²⁸ In conjunction with this protest, 200 genome scientists worldwide demonstrated their support for a policy of free accessibility by signing a declaration to UNESCO calling for all results of the genome project to "remain part of man's scientific heritage."¹²⁹ This patent dispute, however, embodies more than demanded good will; it also involves monetary considerations, which, if ignored, could cost the nonastute country huge profits and possibly result in the collapse of the country's biotech industry.

Despite these international concerns, NIH should not be faulted for moving ahead with its patent applications. All of the countries involved in the Human Genome Project view the role of Human Genome Organization and their respective obligations to the Project differently.¹³⁰ No guidelines or international agreements were created regarding the patentability of the discoveries resulting from this project. While NIH agrees with other countries that an international agreement concerning the patentability of partial gene sequences whose functions are yet unknown should be discussed,¹³¹ it is unreasonable to expect NIH to wait until such an agreement is reached or require NIH to publish its findings and risk losing any patent rights. NIH was wise in seeking patent protection, not only to "hold [their] place" until the issues are resolved, but also to stimulate action to address the problems resulting from this international venture.¹³²

127. Letter from Sergio D. J. Pena, Chairman of the Organizing Committee of the First South-North International Human Genome Conference, to Bernadine Healy, Director, NIH (June 19, 1992) (on file with NIH) (proposed declaration attached). The Conference was an international gathering of scientists and others involved in the Human Genome Initiative. A declaration requesting that consideration be given to avoiding the patenting of naturally occurring DNA sequences was unanimously approved at the meeting. *Id.*

128. Butler, *supra* note 125, at 14.

129. *Id.* The French hope that the declaration, as well as Auffray's noble gesture of turning over all research results to Unesco for free diffusion, will serve as the building blocks for an international agreement. *Id.*

130. *Telephone Interview*, *supra* note 103. The U.S. supports patenting the sequences. The U.K. condemns the U.S. for their position, but has decided to seek similar patents to remain competitive. France has decided not to seek or support patent protection and will make the data freely available. Swinbanks, *supra* note 116, at 181.

131. Daniel Q. Haney, *NIH Might Accept Ban on Patenting Gene Fragments*, BOST. GLOBE, Aug. 27, 1992, at 5 (reporting that the U.S. is willing to explore other avenues of compromise).

132. *Id.* (discussing American concerns and the reasons behind NIH's patent initiative).

B. Industry's Concerns

The biotech industry has also voiced reservations regarding NIH's patent application for Dr. Venter's gene fragments.¹³³ Some disagree with NIH's argument that it has the industry's best interests in mind, and believe that patents will serve as a disincentive for biotechnology investment.¹³⁴ One concern is that when gene fragments are patented, private companies will rush to the PTO to patent their partial genes and then charge inordinate licensing fees.¹³⁵ Under this scenario it is possible that a single company with only economic profits in mind could hold a monopoly on large sections of the human genome and thereby hamper scientific advancement.¹³⁶ Another industry concern is that biotech companies, especially small ones with limited capital, will invest substantial time and money to find a gene with valuable utility, only to find out that their work was futile because someone else already had patented a sequence of the gene.¹³⁷ The biotech industry, which in the past has regarded the determination of a gene's function as the prize in the Cracker Jack box, is not receptive to the idea of requiring a firm that has discovered the gene's function to pay royalties to the lab that has isolated the gene.¹³⁸ The biotech industry also is concerned about skyrocketing costs for product development and the increase in infringement litigation that naturally accompanies an increased number of patents circulating in the industry.¹³⁹ Finally, the Industrial Biotechnology Association, whose members constitute eighty percent of U.S. investment in biotechnology, submitted a position paper to NIH arguing that it is unfair for the government to seek patents on the gene fragments absent a determination of function, and that such a policy will reduce investment in biotechnology.¹⁴⁰

NIH must be responsive to the concerns of industry because it relies on industry to carry NIH discoveries, patented or unpatented, from its labs

133. Eisenberg, *supra* note 80, at 906-07.

134. *U.S.'s DNA Patent Moves Upset Industry*, WALL ST. J., Oct. 22, 1991, at B5 [hereinafter *Industry Upset*]. Biotechnology companies, most of which are small in size and funded by venture capital, fear an "expensive technology free-for-all" if NIH is awarded the patents. *Id.*

135. Stout, *supra* note 15, at B1.

136. *Id.* at B3.

137. See *Industry Upset*, *supra* note 134, at B5.

138. Stephen Green, *The Race for Gene Patents*, WASH. TIMES, Nov. 2, 1991, at D1.

139. Eisenberg, *supra* note 80, at 907.

140. *Id.*

into the commercial sector.¹⁴¹ NIH maintains that by allowing the gene fragments to enter the public domain without any intellectual property rights, industry will lose incentives to develop products because there is always the fear that a competitor will have the same sequence and win the race.¹⁴² Protecting the rights to gene sequences will also stimulate industry to exploit any commercial aspects of the gene, thus delivering additional benefits to the public.¹⁴³ Although some in the biotech industry disagree with these predictions,¹⁴⁴ the majority see the merits of patent protection, as evidenced from the fact that American Biotechnology Association, which represents a strong percentage of the U.S. biotechnology industry, gave their support for the NIH patent initiative.¹⁴⁵ In addition, filing the application is wise because it tests the waters to see if cDNA is patentable, and also protects NIH's property interests should another company or institute file a similar patent claim.¹⁴⁶

IV. CONCLUSION

The United States' system of patent law, as created by Thomas Jefferson, has stood the test of time as a result of the efforts of all of the branches of the federal government to adapt when new technology dictated change. Presently, our world is enveloped in a biotech revolution which has provided novel challenges in the field of patent law. NIH has properly set the stage for the future of biotechnology by filing an application to patent the gene sequences. Now, it is up to the PTO, the courts, Congress and the Executive branch to guide biotechnology on the course it will follow into the 21st century. The protection of scientific discoveries is necessary to encourage scientists and companies to expend the time and money needed to carry the cures for disease from the minds of researchers to the hands of patients.

Paul J. Riley

141. *Memorandum, supra* note 104, at 3.

142. Christopher Anderson, *NIH Defends Gene Patents As Filing Deadline Approaches*, 357 *NATURE* 270 (1992).

143. Benson, *supra* note 37, at 8.

144. Eisenberg, *supra* note 80, at 906-07.

145. *Memorandum, supra* note 104, at 3.

146. *Biotechnology Development and Patent Law, supra* note 6, at 1.

* In February 1994, after this paper was sent to press, NIH, under new Director, Dr. Harold Varmus, decided to drop its application to the cDNA sequences. The controversy over the patentability of these sequences, however, is far from over. There are still foreign countries, and most likely private companies, who will continue to seek patent protection over this genetic information.