
1-1-2002

DNA Patenting and Access to Healthcare: Achieving the Balance among Competing Interests

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Recommended Citation

Note, DNA Patenting and Access to Healthcare: Achieving the Balance among Competing Interests, 50 Clev. St. L. Rev. 253 (2002-2003)

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DNA PATENTING AND ACCESS TO HEALTHCARE:
ACHIEVING THE BALANCE AMONG COMPETING INTERESTS

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I. INTRODUCTION

During the last three decades, scientists have made tremendous advancements in the field of biotechnology.¹ The advent of genetic engineering² and recombinant

¹Generally, biotechnology is the manipulation of biological materials and processes. SUSAN ALDRIDGE, *THE THREAD OF LIFE* 183 (1996). For the purposes of this paper, the term biotechnology refers to the products and processes of isolating, preparing, and replicating fragments of deoxyribonucleic acid (hereinafter DNA) and ribonucleic acid (hereinafter RNA), and using DNA and RNA fragments to produce proteins. John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 113-14 (2001).

²Genetic engineering is just one form of biotechnology. Genetic engineering allows for the transfer of genes from one species into another. A gene is cut out of one organism, placed in a vector, and the vector carries the cut gene into a host organism where the gene will be cloned as the host organism replicates resulting in many copies of the cut gene and its corresponding product. ALDRIDGE, *supra* note 1, at 103-11.

DNA techniques³ in the 1970's was responsible for much of this progress. Biotechnology has opened up the possibility of new treatments for cancer, heart disease, and other genetically based diseases.⁴ Patients' genetic information has become part of their regular healthcare treatment. As genetic information becomes more readily available, it will become a vital resource in the treatment of patients. Doctors can use genetic information to detect patients' risks of developing certain diseases and prescribe preventative measures, identify disease carriers through carrier screening, and treat diseases with pharmacogenomics, gene therapy, and gene-based therapy.⁵ Not only does the biotechnology industry have the potential to dramatically increase doctors' ability to diagnose and cure many of the terrible diseases that afflict millions in this country, it also promises to be very profitable.⁶ In 1999 alone, the biotechnology industry generated \$20 billion in revenue.⁷

Increasing evidence suggests that the biotechnology industry's interest in generating revenue and the public's desire to obtain the best healthcare may be at odds.⁸ The patenting of genetic information is at the core of this debate. Most, if not all, of the products of the biotech industry's research are patentable. Historically, patents have been justified on the grounds that they are needed to create an incentive for researchers and companies to invest time and money in projects that have uncertain outcomes. In the biotechnology arena, patents do not simply encourage innovation and allow innovators to recoup their costs. Patents can also limit the public's access to valuable information that could benefit individuals and society. This Note argues that current patent laws are not socially beneficial when applied to biotechnology products.

The ultimate goal of patent law is to strike a balance between providing rewards for invention, spurring new innovation, and ensuring the availability of the innovations to the public.⁹ This balance is necessary and desirable because there is always more than one stakeholder in a new technology or invention, particularly in

³"The term recombinant DNA literally means the joining or recombining of two pieces of DNA from two different species." *Who Owns Life? Biotech Primer*, THE AMERICAN JOURNAL OF BIOETHICS ONLINE, at <http://www.ajobonline.com> (last visited Feb. 17, 2003) [hereinafter *Biotech Primer*].

⁴*Genetics: The Future of Medicine*, NIH Publication No. 00-4873, at 9, available at <http://www.genome.gov/Pages/EducationKit/brochure.html> (last visited Feb. 17, 2003) [hereinafter *Genetics: The Future of Medicine*]. See Vida Foubister, *Gene Patents Raise Concerns for Researchers, Clinicians*, AMERICAN MEDICAL NEWS, Feb. 21, 2000, available at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm (last visited Feb. 17, 2003).

⁵*Genetics: The Future of Medicine*, *supra* note 4, at 8-11. This publication provides definitions and functions of all these treatment options.

⁶Margaret Graham Tebo, *The Big Gene Profit Machine*, A.B.A. J., Apr. 2001, at 46.

⁷*The Economic Contributions of the Biotechnology Industry to the U.S. Economy*, Ernst & Young Economics Consulting and Quantitative Analysis, May 2000, at 4.

⁸Raphael Lewis & Jamal E. Watson, *Biotech Protest Draws 2,500*, BOSTON GLOBE, Mar. 27, 2000, at B1.

⁹*Brenner v. Manson*, 383 U.S. 519, 533-535 (1966). See Golden, *supra* note 1, at 104-07. See also Clarisa Long, *Patents and Cumulative Information*, 2 WASH. U. J.L. & POL'Y. 229, 229 (2000).

the case of DNA patents.¹⁰ The stakeholders include the private biotechnology and pharmaceutical firms, the scientists and researchers, the federal government, the insurance industry, and the public. Each stakeholder has a unique interest. This Note will focus on the interest of the inventors, who will become the patent holders, and the public. The public's interest lies in having access to the best healthcare at a reasonable cost. This interest often conflicts with that of the inventor patent holder when the patent holder can use the patent to garner excessive profits thus limiting access.

This Note demonstrates that the balance among the various interests of these particular stakeholders is not being met. The next section of this Note provides a background on the patentability of DNA. Part III surveys and explain the recent flood of gene patents into the Patent and Trademark Office (hereinafter PTO). Part IV discusses the public interest in human gene patents. Part V demonstrates that the patenting of human DNA presents unique problems that do not arise in the patenting of other inventions. Finally, Part VI discusses an approach to balance these interests and the need for congressional action to achieve a balance between encouraging innovation and providing the most socially beneficial health outcomes.

II. THE PATENTABILITY OF DNA

It is undisputed that DNA (including genes, gene fragments, and their corresponding products) can be patented.¹¹ This section of the Note briefly reviews the history of DNA-related patents.

Congressional patent power derives from Article 1, section 8, clause 8 of the United States Constitution. This clause reads: “[t]he Congress shall have power...[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹² Based upon this power, Congress enacted the Patent Act.¹³ The Patent Act provides 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 therefore, subject to the conditions and requirements of this title.”¹⁴ The requirements of the title include that the invention

¹⁰In this Note, the terms “human DNA patents,” “human gene patents” or “gene patents” will be used interchangeably. “Gene patent is a broad term that refers to the patenting of either a process that involves the isolation of DNA (where DNA refers to either DNA or associated materials such as RNA) as well as to a chemical substance related to DNA.” *Gene Patenting*, AMERICAN MEDICAL ASSOCIATION, at <http://www.ama-assn.org/ama/pub/category/2314.html> (last visited Feb. 17, 2003) [hereinafter *Gene Patenting*].

¹¹The PTO has issued 6,000 gene-related patents. There are 20,000 applications related to genes currently pending before the PTO. Julie Grisham, *New Rules For Gene Patents*, NATURE BIOTECHNOLOGY, Sept., 2000, Vol. 18, No. 9, at 921. See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991).

¹²U.S. CONST. art. I, § 8, cl. 8.

¹³35 U.S.C. §§ 100-376 (1994 & Supp. V 1999). See Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument For Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1637 (2001).

¹⁴35 U.S.C. § 101 (1994 & Supp. V 1999).

be statutory patentable subject matter,¹⁵ that the patent application include a written description referred to as the enablement requirement,¹⁶ and that the invention be novel,¹⁷ non-obvious,¹⁸ and useful.¹⁹ This patentability analysis is used for all inventions.²⁰

Genes are considered patentable subject matter.²¹ When genes have been isolated and purified²² they are considered a composition of matter that is covered by the Patent Act.²³ However, the Patent Act “does not cover the gene as it occurs in nature.”²⁴ In other words, an isolated and purified gene or segment of DNA is considered a new composition of matter.²⁵ In this way, patent law does not treat DNA differently from other chemical compounds that are compositions of matter because it does not occur naturally in this form.²⁶

Applicants for gene patents can meet the enablement provision by giving a written description of the invention that would enable the invention to be made and used by someone with “ordinary skill in the art.”²⁷ The requirement that the invention be novel simply means that it must not have been done before in exactly the same way.²⁸ In addition, the form of the DNA cannot have been described in a previous patent or patent application.²⁹ The non-obviousness element requires that the invention not be obvious to an ordinary person skilled in the art of the invention’s

¹⁵*Id.*

¹⁶35 U.S.C. § 112 (1994 & Supp. V 1999).

¹⁷35 U.S.C. § 102 (1994 & Supp. V 1999).

¹⁸35 U.S.C. § 103 (1994 & Supp. V 1999).

¹⁹35 U.S.C. § 101 (1994 & Supp. V 1999).

²⁰John J. Doll, *Biotechnology: The Patenting of DNA*, SCIENCE, May 1, 1998, Vol. 280, No. 5364, at 689.

²¹Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (January 5, 2001).

²²Isolation and purification of DNA refers to the process by which a gene is isolated from its natural state and processed through purifying steps that separate the gene from other molecules it is naturally associated with. Utility Examination Guidelines, 66 Fed. Reg. at 1093.

²³Utility Examination Guidelines, 66 Fed. Reg. at 1093.

²⁴*Id.* Explaining that concerns about humans infringing on patents because their body contains the patented gene are unfounded.

²⁵35 U.S.C. § 101. See Utility Examination Guidelines, 66 Fed. Reg. at 1093.

²⁶Utility Examination Guidelines, 66 Fed. Reg. at 1095.

²⁷35 U.S.C. § 112 (1994 & Supp. V 1999). John J. Doll, *Talking Gene Patents*, Scientific American, Aug. 2001, available at <http://www.sciam.com> (last visited Feb. 17, 2003).

²⁸35 U.S.C. § 102 (1994 & Supp. V 1999). Doll, *supra* note 27, at <http://www.sciam.com>.

²⁹*Id.*

particular field.³⁰ Gene patents meet the non-obvious requirement if they have not been described as a composition of matter prior to the patent application.³¹

The PTO has recently changed the utility requirement for gene patents. In January 2001, the PTO established new patent utility guidelines³² that primarily address utility standards for gene and gene fragment patents.³³ The new guidelines came in response to criticisms that too many gene patents were being issued. Although the new guidelines uphold the general concept that genes can be patented, they raise the utility bar.³⁴ There are two tests under the 2001 guidelines; however, only one test has to be satisfied in order to meet the utility requirement.³⁵

The first test is the Specific, Substantial, and Credible Utility Test. This test states that a utility is “specific” when it is particular to the subject matter claimed.³⁶ “Substantial utility” requires a “real world” use, which means that the immediate benefit must be identified and not need more research.³⁷ Lastly, a “credible” utility is determined by whether a person with ordinary skill in the art would accept that the invention “is currently available for such use.”³⁸ The second test is the Well-Established Utility Test. This test incorporates the Specific, Substantial and Credible Utility test, but allows applicants to meet the requirements by demonstrating that the function of the gene or its protein is connected to a gene or protein that has been identified and is well known.³⁹ This new utility standard significantly eliminates applications where the only claimed utility is that the invention can be used for further study of its own utility.⁴⁰

Historically, the PTO generally rejected patent applications involving living organisms.⁴¹ This trend ended in 1980, when the Supreme Court reversed a PTO rejection of a patent application for a genetically modified bacteria.⁴² In *Diamond v.*

³⁰35 U.S.C. § 103 (1994 & Supp. V 1999). Doll, *supra* note 27, at <http://www.sciam.com>.

³¹Warren Kaplan, *Biotech Patenting 101*, available at <http://www.genewatch.org/genewatch/articles/14-3patenting.html> (last visited Feb. 17, 2003).

³²Utility Examination Guidelines, 66 Fed. Reg. at 1093.

³³*The Fate of Gene Patents Under the New Utility Guidelines*, 2001 DUKE L. & TECH REV. 0008, ¶ 1 (Feb. 28, 2001), available at <http://www.law.duke.edu/journals/dltr/articles/2001dltr0008.htm> (last visited Feb. 18, 2003) [hereinafter *The Fate of Gene Patents*].

³⁴*Id.* at ¶ 3.

³⁵*Id.* at ¶ 10-11.

³⁶*Id.*

³⁷*Id.* “This rule derives from the US Supreme Court’s position in *Brenner* that a chemical or a chemical process is not sufficiently useful if its only use is as an object of scientific research.” *Id.* at ¶ 13 discussing *Brenner*, 353 U.S. at 535.

³⁸*The Fate of Gene Patents*, *supra* note 33 at ¶ 14.

³⁹*Id.* at ¶ 15-17.

⁴⁰*Id.* at ¶ 25.

⁴¹JEREMY RIFKIN, *THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD* 42 (1998).

⁴²*Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

Chakrabarty,⁴³ the Supreme Court found that the bacterium was a “nonnaturally occurring manufacture or composition of matter — a product of human ingenuity”⁴⁴ and was covered by the Patent Act.⁴⁵ In rendering the decision, the Supreme Court did “not distinguish between ‘living and inanimate things...’ but [] distinguish[ed] between ‘products of nature, whether living or not, and human-made inventions.’”⁴⁶ The Court emphasized that Congress intended patents to cover broad subject matters “includ[ing] anything under the sun that is made by man.”⁴⁷ Many believe that the decision in *Chakrabarty*, although it did not address human DNA patents specifically, expanded the scope of patentable biotech subject matter.⁴⁸ The *Chakrabarty* decision then gave rise to *Amgen, Inc. v. Chugai Pharmaceutical Co.*,⁴⁹ where the federal circuit relied on the “human ingenuity” standard from *Chakrabarty* to uphold the patenting of DNA sequences.⁵⁰

When issuing human DNA patents, the PTO has granted three basic types: structure patents, function patents, and process patents.⁵¹ Structure patents cover the isolated and purified molecule as a new composition of matter.⁵² Function patents are issued when the applicant has invented a use for the DNA, such as a diagnostic test.⁵³ Process patents typically are given when an applicant has found a new method of isolating, purifying, analyzing, modifying, or synthesizing the DNA.⁵⁴ Human DNA patents usually fall under a composition of matter (structure) patents or process patents.⁵⁵

The Patent and Trademark Office has stated,

[P]atents do not confer ownership of genes, genetic information, or sequences. The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor’s

⁴³*Chakrabarty*, 447 U.S. at 309.

⁴⁴*Id.*

⁴⁵*Id.*

⁴⁶Kaplan, *supra* note 31, at <http://www.gene-watch.org/genewatch/articles/14-3patenting.html> (quoting *Chakrabarty*, 447 U.S. at 313).

⁴⁷*Chakrabarty*, 447 U.S. at 309.

⁴⁸Kaplan, *supra* note 31, at <http://www.gene-watch.org/genewatch/articles/14-3patenting.html>.

⁴⁹927 F.2d 1200 (Fed. Cir. 1991).

⁵⁰*Id.* at 1218.

⁵¹David B. Resnik, *DNA Patents and Human Dignity*, 29 J. L. MED. & ETHICS 152, 153-54 (2001).

⁵²*Id.*

⁵³*Id.* at 154.

⁵⁴*Id.*

⁵⁵Utility Examination Guidelines, 66 Fed. Reg. at 1095. See Doll, *supra* note 20, at 689.

legal right to exclude other people from making, using, offering for sale, selling, or importing the composition for a limited time.⁵⁶

III. THE PREVALENCE OF HUMAN GENE PATENTS

According to several sources, the PTO has issued approximately 6,000 gene related patents in the United States.⁵⁷ Of these 6,000 patents, more than 1,000 of them are related to human genes and human gene variations.⁵⁸ The PTO also has approximately 20,000 pending gene-related applications.⁵⁹ The sequencing of the human genome,⁶⁰ advances made in genetic engineering, the creation of the Court of Appeals for the Federal Circuit,⁶¹ and the cooperation between the academic world and the biotech industry⁶² have all spurred the development of the biotech industry. This, in turn, has led to a dramatic increase in the number of applications for, and grants of, gene patents.⁶³

The Human Genome Project (hereinafter HGP) began in 1990.⁶⁴ The goal of the HGP was to sequence the entire human genome.⁶⁵ The HGP was an international collaboration spearheaded by the National Institute of Health (hereinafter NIH).⁶⁶ HGP was publicly funded and made the information it obtained available to the public.⁶⁷ At the same time that the HGP was sequencing the human genome, so was a private corporation, Celera Genomics Group (hereinafter Celera). On June 26, 2000, HGP and Celera simultaneously announced that both had completed an entire

⁵⁶Utility Examination Guidelines, 66 Fed. Reg. at 1093-1094.

⁵⁷Grisham, *supra* note 11, at 921. Andrew Pollack, *U.S. Hopes to Stem Rush Toward Patenting Genes*, THE PATRIOT LEDGER (Quincy, Mass.), June 28, 2002, at 18. See Gitter, *supra* note 13, at 1624. This gene patent estimation differs than the one give by John J. Doll, director of biotechnology for the PTO. When asked about the number of genes patented and applications pending, John J. Doll stated, “[t]he only number that I have is a guesstimate: since 1980 we have granted more that 20,000 patents on genes or other gene-related molecules [for humans and other organisms]. And we also know that we have more than 25,000 applications outstanding that actually claim genes or related molecules.” Doll, *supra* note 27, at <http://www.sciam.com>.

⁵⁸Grisham, *supra* note 11, at 921.

⁵⁹*Id.*

⁶⁰J. Craig Venter *et al.*, *The Sequence of the Human Genome*, SCIENCE, Feb. 16, 2001, Volume 291, at 1304.

⁶¹The Federal Courts Improvement Act, Pub. L. No. 97-164 (1982).

⁶²Golden, *supra* note 1, at 101-91 (discussing the interaction between private biotechnology firms, the federal government, and the academic world).

⁶³Grisham, *supra* note 11, at 921. Pollack, *supra* note 57, at 18.

⁶⁴*Genetics: The Future of Medicine*, *supra* note 4, at 1.

⁶⁵*The Human Genome Project: New Tools for Tomorrow's Health Research*, NIH Publication No. 32-3190 (September 1992) at 9-11.

⁶⁶*Id.* at 13.

⁶⁷*Genetics: The Future of Medicine*, *supra* note 4, at 1.

working draft of the human genome.⁶⁸ In February 2001, both groups published the human genome sequence in *Science*.⁶⁹ This was nearly two years ahead of schedule.⁷⁰ This early completion was the result of changes in the way genes were found and DNA was sequenced.⁷¹

The research done by HGP has contributed greatly to the growth of gene patents because it allowed researchers to have use of the HGP sequences. Researchers then matched the HGP sequences to known homologous sequences in other organisms.⁷² The known function of the homologous sequence is then used to obtain a patent on the human gene.⁷³ This research accelerated the process of identifying genes tremendously and led to an increase in patent applications.⁷⁴ Before this type of high-speed gene sequencing and other techniques were developed, scientists would study a protein, discover its function, and work backwards to isolate the gene.⁷⁵ It took years to isolate one gene.⁷⁶ The new methods “are allowing genes or fragments of genes to be discovered *en mass*, without knowing the functions of the proteins produced by the genes.”⁷⁷

The increasing number of patents issued is also due, in part, to the formation of the Court of Appeals for the Federal Circuit.⁷⁸ The Federal Courts Improvement Act of 1982 gave this court exclusive jurisdiction over all appeals of patent cases originally heard in the federal district courts.⁷⁹ This led to uniformity in the law and allowed for easier issuance of patents.⁸⁰

New trends in patents are the privatization of biomedical research and more vigorous patent enforcement.⁸¹ Historically, medical and academic communities shared scientific information related to healthcare believing that this was the best

⁶⁸Nicholas Wade, *Genetic Code of Human Life Is Cracked by Scientists: A Shared Success*, N.Y. TIMES, June 27, 2000 at A1.

⁶⁹Vetner, *supra* note 60, at 1304.

⁷⁰*Genetics: The Future of Medicine*, *supra* note 4, at 1.

⁷¹*Id.* at 1, 3.

⁷²*Gene Patenting*, *supra* note 10, at <http://www.ama-assn.org/ama/pub/category/2314.html>.

⁷³*Id.*

⁷⁴*Id.*

⁷⁵Pollack, *supra* note 57, at 18.

⁷⁶*Id.*

⁷⁷*Id.*

⁷⁸The Federal Courts Improvement Act, Pub. L. No. 97-164 (1982).

⁷⁹*Id.* Golden, *supra* note 1, at 125.

⁸⁰Golden, *supra* note 1, at 125.

⁸¹Foubister, *supra* note 4, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm.

way to promote progress and benefit public healthcare.⁸² The federal government sponsored basic research that took place primarily in universities and other public institutions such as the NIH.⁸³ This model of publicly funded research enabled scientists to have immediate access to newly developed technologies and the most recent research discoveries in the field of biomedical research.⁸⁴ In essence, biomedical research occurred in the public and stayed in the public domain.

The academic environment that spurred the wealth of public information changed in 1980 when Congress passed the Bayh-Dole Act and the Wydler-Stevenson Act.⁸⁵ Congress passed the acts to promote commercial development of basic biotechnological research.⁸⁶ Bayh-Dole permitted and encouraged universities and other institutions to patent their federally funded research and to transfer their technology to the private sector.⁸⁷ Stevenson-Wydler mandated that federal laboratories actively engage in cooperative research with other laboratories including those in private industry, and requires the federal laboratories to set aside a portion of their budgets for technology transfer activities.⁸⁸ The goal of the Acts is to increase the number of commercialized products that could be derived from the federally funded basic research and keep American inventions under American control.⁸⁹

IV. THE PUBLIC INTEREST IN HUMAN GENE PATENTS

A. *The Source*

One of the fundamental differences between human gene patents and patents on other scientific and medical innovations is that the source of raw material for the gene patents is human tissue.⁹⁰ This is especially significant when researchers are

⁸²*Gene Patents Detrimental to Care, Training, Research*, CAP Advocacy, at <http://www.cap.org/html/advocacy/issues/genetalk.html> (last visited Feb. 17, 2003).

⁸³Kristen Philipkoski, *New Quest: Mapping Gene Patents*, March 6, 2001 at <http://www.wired.com/news/print/0,1294,42214,00.html>. “[] 71.6% of citations to research papers in biotechnology patents are to publicly funded research....” Golden, *supra* note 1, at 117. Twenty-five percent of genomics companies report that their product streams would have been blocked if it were not for academic research.

⁸⁴Foubister, *supra* note 4, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm.

⁸⁵The Bayh-Dole Act of 1980, Pub. L. No. 96-517; The Stevenson-Wydler Technology Innovation Agreement of 1980, Pub. L. No. 96-480.

⁸⁶*Id.*

⁸⁷Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE, 698, 698 (1998).

⁸⁸The Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480. Technology transfer is the formal transferring of scientific research discoveries and innovation that occurred in the universities or federal laboratories to the commercial sector.

⁸⁹Golden, *supra* note 1, at 120.

⁹⁰Sara Dastgheib-Vinarov, *A Higher Non-Obviousness Standard for Gene Patents: Protecting Biomedical Research From the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 143 (2000).

looking at disease-related genes. Oftentimes, patients who are battling a devastating genetic illness are the ones who contribute the genetic material that later becomes patented.⁹¹

Some of these patients consent to provide the samples while others do not.⁹² In either case, the samples help generate enormous profits for those who patent human genes.⁹³ Some ethicists, activists, and advocacy groups contend that patents should not be given at all for human tissue.⁹⁴ These groups are concerned that corporations are selling innovations, that contain individual patient's cellular material, to the public and maybe even to the patients themselves.⁹⁵ Thus, the important public investment in the products, and technological innovations developed using human tissue, are very powerful public interests.

B. Life-Saving Innovation

Gene patents, like other health-related patents, are a matter of heightened public interest because the health of the public is at stake. The controversies surrounding gene patents are not simply debates about legal or scientific policy. Rather, gene patenting is a vital public policy issue that needs to be addressed.⁹⁶

Scientists estimate that over 4,000 diseases stem from mutated genes.⁹⁷ Approximately 1,800 individual genes have been linked to a specific disease as of April 2000.⁹⁸ Genes hold the necessary information for the development of therapies, drugs, and diagnostic tests that can provide life-saving information and innovation.⁹⁹ Human gene patent innovation can be a matter of life or death or, at a minimum, about improving the quality of life for individuals with genetic diseases.¹⁰⁰ Because of this distinction, human gene patents contrast dramatically with typical patents for products like flat-screen TVs.

⁹¹Peter Gorner, *Parents Suing Over Patenting of Genetic Test They Say the Researchers They Assisted are Trying to Profit From a Test for a Rare Disease*, CHI. TRIB., Nov. 19, 2000, at 1, available at 2000 WL 3735425 (describing a suit by parents who provided researchers with tissue samples of their son and daughter while they were alive and pieces of their brains when they died).

⁹²*Moore v. Regents of the Univ. of California*, 793 P.2d 479, cert. denied, 499 U.S. 936 (1991). The plaintiff's blood was used to create a cell line that was patented by a physician and the rights were sold to a biotech company without the plaintiff's knowledge.

⁹³Tebo, *supra* note 6, at 47.

⁹⁴Council For Responsible Genetics, *No Patents on Life!*, at <http://www.genewatch.org/programs/patents.html> (last visited Feb. 17, 2003).

⁹⁵*Id.*

⁹⁶Seth Shulman, *Toward Sharing the Genome*, MIT'S TECH. REV. 6067, (Sept. 1, 2000), available at 2000 WL 11628629.

⁹⁷*Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine*, at 16 (July 2000) at <http://www.bio.org/genomics/primer.html> (last visited Feb. 17, 2003).

⁹⁸*Id.*

⁹⁹*Genetics: The Future of Medicine*, *supra* note 4, at 8-13.

¹⁰⁰*Id.*

C. The Public Investment

The American public has paid for much of the pioneering research and development that has allowed for the enormous progress made in the area of biotechnology.¹⁰¹ Although the HGP made a huge contribution to the biotechnology industry,¹⁰² it cost the public \$3 billion.¹⁰³ In 2001 alone, the government gave the NIH and eight other Health and Human Service agencies \$1.2 billion dollars to support public health, health services, and health policy research.¹⁰⁴ The government also indirectly funds private biotechnology research through tax relief, tax credits and patent protection.¹⁰⁵ While the private biotechnology and pharmaceutical industries are largely responsible for turning basic research into a commercial end product, it is the publicly funded initial research that allows the industry to move forward.¹⁰⁶ This initial investment gives the public a stake in patents on human DNA that is not present with patents on other inventions.

D. Downstream v. Upstream Research

Human gene patents often protect the gene, the protein product of the gene, and the gene fragments that are contained within the gene.¹⁰⁷ This kind of information is considered basic research and provides the data that is necessary for making end products such as drugs, diagnostic tests, and other treatments based on genes and their products.¹⁰⁸

The gene comprises the building blocks of life and, if mutated, can cause devastating diseases.¹⁰⁹ When scientists who study the affect of genes excise DNA from human blood or tissue, their aim is to make an exact replica of what exists in the body. The researcher's goal is to have the gene function (or fail to function as may be the case with a mutation) exactly as it does in the human body. The researchers do not want to modify or enhance the gene at this point. The gene itself is basic to the development of further research (i.e., by understanding how the gene functions in its unaltered state, scientists have the foundation for studying how various interventions alter the expression of the gene.) If predictions are correct and it is possible to cure many diseases by correcting the mutated genes or by using gene products as drug therapies, it is necessary to do as much research as possible into the functioning of genes.¹¹⁰ Under current patent law, inventors can own the rights to

¹⁰¹Abbey S. Meyers, "Intellectual Property at the Public-Private Divide:" A Response, 3 U. CHI. L. SCH. ROUNDTABLE 581, 581-582 (1996).

¹⁰²See *supra* Part III.

¹⁰³Shulman, *supra* note 96, at 6067.

¹⁰⁴Highlights of the President's FY 2002 Preliminary Budget, American Society for Microbiology, at <http://www.asmsa.org/pasrc/budget2002.htm> (last visited Feb. 17, 2003).

¹⁰⁵Golden, *supra* note 1, at 138.

¹⁰⁶Philipkoski, *supra* note 83, at <http://www.lwired.com/news/print/0,1294,42214,00>.

¹⁰⁷Doll, *supra* note 27, at <http://www.sciam.com>.

¹⁰⁸See *supra* Part I.

¹⁰⁹Genetics: The Future of Medicine, *supra* note 4, at 2.

¹¹⁰*Id.* at 8-11.

genes, the proteins they produce, and their gene fragments, thereby preventing or making it costly for other scientists to study the genes and perhaps discover valuable medical or therapeutic uses for the genes.¹¹¹ When this happens, medical progress is inhibited. In this way, genes are being treated as products in and of themselves instead of guides to future product discovery. Some compare gene patenting to “trying to gain ownership of the alphabet, rather than of a novel or play.”¹¹²

When basic research of this kind is patented so far upstream, it covers inventions upon which breakthrough research and end products could be built.¹¹³ As one author put it, “[o]ne firm’s research tool may be another firm’s end product.”¹¹⁴ If the licensing and transaction costs are too high, these valuable downstream innovations will never take place.¹¹⁵ Arguably, patent holders will use their proprietary information to engage in further innovation; however, “[n]ot all patentees who obtain patents on basic research results will have the capacity or interest in conducting further research to turn their patented inventions into commercial end-products.”¹¹⁶ This causes a dual problem. The upstream patent holders are not able to or are not interested in making commercially relevant end products with the gene patents they hold,¹¹⁷ but in an effort to make money, they charge licensing fees or make exclusive licensing arrangements that limit the amount of research that can be done on a particular gene.¹¹⁸ As Clarisa Long has stated:

Patents have been a great source of concern for academic and basic researchers who fear that proprietary rights to basic research results will hamper the progress of science, stifle the free flow of new knowledge and the dissemination of research results, and chill the research efforts of scientists who fear infringement liability.¹¹⁹

Quite simply, patents limit the availability and raise the cost of the therapeutic and diagnostic end products because the patents are owned too far upstream in the research and development process. This is a great concern because human genes have both basic and applied uses.¹²⁰ Unquestionably patents are critical to

¹¹¹Doll, *supra* note 27, at <http://www.sciam.com>.

¹¹²Pollack, *supra* note 57, at 18.

¹¹³Clarisa Long, *Proprietary Rights and Why Initial Allocations Matter*, 49 EMORY L.J. 823, 824 (2000).

¹¹⁴Rebecca S. Eisenberg, *Intellectual Property at the Public-Private Divide: The Case of Large-Scale DNA Sequencing*, 3 U. CHI. L. SCH. ROUNDTABLE 557, 571(1996).

¹¹⁵Long, *supra* note 113, at 827-31.

¹¹⁶*Id.* at 826.

¹¹⁷*Id.*

¹¹⁸Eisenberg, *supra* note 114, at 571. Pollack, *supra* note 57, at 18 (“Most patent holders want people to do research on their genes in hopes of finding a drug, which would bring in really big royalties” *Id.*).

¹¹⁹Long, *supra* note 9, at 229-230.

¹²⁰*Id.* A basic use is one in which the gene would be used strictly for research purpose; applied uses include the development of a marketable product such as a drug, test, or other medical therapy.

innovation, however, the point at which genes and genetic information should be subject to patents is debatable. The stage in which patents are issued can affect the ability to make affordable end products. Strong protection too early in the process has the potential to retard further development, yet at the same time it rewards basic research inventors¹²¹ and gives them an incentive to take on risky and expensive research.¹²² If there are fewer useful products for the public, the balance between rewarding innovation and getting that innovation to the public will not occur.

E. “*The Tragedy of the Anticommons*”

Gene patents can be very broad.¹²³ In *Brenner v. Manson*,¹²⁴ the Supreme Court recognized the danger of issuing patents with broad applications, especially in areas that are “vast, unknown, and perhaps unknowable.”¹²⁵ The area of genes qualifies as vast, unknown, and perhaps unknowable, and there is the danger that gene patents could “confer power to block off whole areas of scientific development, without [a] compensating benefit to the public.”¹²⁶

When a human gene patent holder receives a patent, it covers any commercial use of the gene and the gene product.¹²⁷ The patent holder only has to describe one function of the gene or its protein product, and if any future uses or functions are developed with the gene, the patent still covers those uses.¹²⁸ Gene patents typically do meet utility requirements but their uses may not be optimal. These broad patents cause a problem that Heller and Eisenberg two well known authors in this area, refer to as the “tragedy of the anticommons” for biomedical research.¹²⁹

¹²¹*Id.* at 237-242.

¹²²Heller & Eisenberg, *supra* note 87, at 698.

¹²³Grisham, *supra* note 11, at 921. Quoting Harold Varmus, former of director of the NIH and current president of Memorial Sloan Kettering Cancer Center, who discussed the extensive rights given to gene patent holders. Foubister, *supra* note 4, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm (“The Patent and Trademark Office has issued patents with far too broad a right to patents holders; they essentially end up owning a disease rather than some specific development for a test,” said Michael Watson, PhD, a professor of pediatrics and genetics at Washington University School of Medicine, St. Louis.). Gina Shaw, *Does the Gene Patenting Stampede Threaten Science?*, AAMC Reporter, Feb. 2000, Volume 9, Number 5, available at <http://www.aamc.org/newsroom/reporter/feb2000/gene.htm> (last visited Feb. 17, 2003).

¹²⁴383 U.S. 519 (1966).

¹²⁵*Id.* at 534 (denying a patent application for a chemical whose usefulness had not been shown to the PTO).

¹²⁶*Id.*

¹²⁷Doll, *supra* note 20, at 690. See also David P. Hamilton, *Getting a Patent: Biotech Firms Are Scrambling to Win Exclusive Rights To Newly Discovered Genes*, WALL ST. J., Oct. 15, 2001 at R6.

¹²⁸The new use can be patented but the original patent holder will still be owed a royalty fee for each time the gene or its product is used in any way. Doll, *supra* note 20, at 690.

¹²⁹Heller & Eisenberg, *supra* note 87, at 698.

When people hold a resource in common they tend to overuse it because they lack any incentive to conserve the resource. This overuse is referred to as a “tragedy of the commons.”¹³⁰ Privatization¹³¹ is often used to solve this problem, but when a scarce resource is over-privatized the result can be a “tragedy of the anticommons.”¹³² The “tragedy of the anticommons” results in the underuse of a resource because too many people are excluded from using the resource.¹³³

Underuse is occurring with human gene patents. Once a gene or gene fragment is patented, any further research using the patented materials must go through the patent holder.¹³⁴ These patents are so far upstream and so broad in their scope that they stifle future research.¹³⁵ This problem is especially pervasive as it applies to the patenting of human genes because the information and research needed to produce an end product is cumulative.¹³⁶ Oftentimes, more than one gene, gene fragment, or gene product is needed to make a final product such as a genetic diagnostic test or therapeutic proteins.¹³⁷ Recent genetic research has shown the idea that a single gene being responsible for a disease is the exception, not the rule.¹³⁸ Instead, most diseases are polygenic, meaning that multiple genes are involved in the manifestation of a disease.¹³⁹ If a patent exists for each of the several pieces of genetic material needed to develop a product, the cost and time of developing the end product may be prohibitive.¹⁴⁰

One of the purposes of giving patents is to motivate inventors to design around the current patented invention.¹⁴¹ The “design around” concept leads to competition and progress that betters the public.¹⁴² However, genes cannot be “designed around”

¹³⁰*Id.* The “tragedy of the commons” was used by Garrett Hardin to explain overpopulation, air pollution, and species extinction.

¹³¹Privatization describes the transfer or shift from the public or government sector into the private sector.

¹³²Heller & Eisenberg, *supra* note 87, at 698.

¹³³*Id.*

¹³⁴Doll, *supra* note 20, at 690.

¹³⁵Long, *supra* note 113, at 824.

¹³⁶Long, *supra* note 9, at 237. See John H. Barton, *Reforming the Patent System*, 287 SCIENCE Mar. 17, 2000, at 1933 (describing that new pharmaceutical products are complicated and slowed because of the large number of patent holders that must be negotiated with at the various steps of making the final product).

¹³⁷Heller & Eisenberg, *supra* note 87, at 699.

¹³⁸Matthew Albright, *The Human Genome Projects: Help or Hindrance for Gene Patenting?*, GENEWATCH, Vol. 14 at <http://www.gene-watch.org/genewatch/articles/14-3humangenome.html> (last visited Feb. 17, 2003).

¹³⁹*Id.*

¹⁴⁰Heller & Eisenberg, *supra* note 87, at 698-701.

¹⁴¹DONALD S. CHISUM ET AL, PRINCIPLES OF PATENT LAW 67 (1998).

¹⁴²*Id.*

because no substitute exists for them.¹⁴³ If researchers want to work on a cure for a genetically-based disease, they must use the gene that causes the disease. Patents can prevent these scientists from gaining access to unique and valuable genetic information.

V. THE IMPACTS OF GENE PATENTS ON THE PROVISION OF HEALTHCARE

A. *The Increased Cost*

Gene patents have the potential to make healthcare more expensive and therefore, out of reach for many Americans. Individual testing for predisposition to genetic diseases can be extremely expensive.¹⁴⁴ For example, the *Chicago Tribune* reported that Missouri Medicaid will pay eleven dollars toward a test that screens for Down's Syndrome.¹⁴⁵ The patent holders want to collect nine dollars for each test performed.¹⁴⁶ This leaves the healthcare provider with two dollars to cover the costs of administering the test and interpreting the results. One doctor stated that he will be forced to stop offering the test or have to ask patients to pay the difference between the two dollars he has left and the actual cost of performing the test.¹⁴⁷ Gene patents create a monopoly and under current licensing practices many patients could not afford to have "access to new genetic information about themselves, their children, and their future children."¹⁴⁸ It might not seem like much to ask a patient for ten to twenty-five dollars to cover one test, but when you consider the high number of tests that would be needed for a complete genetic screening, the cost skyrockets.¹⁴⁹

There is concern in the medical field "that genetic testing of patients could become prohibitively expensive if each gene is patented."¹⁵⁰ Currently, researchers are working on "chips" that could screen for 200-300 genetic diseases at a time, but if each gene is patented and each patent holder charges a royalty fee, this screening

¹⁴³Heller & Eisenberg, *supra* note 87, at 700.

¹⁴⁴Gorner, *supra* note 91, at 1.

¹⁴⁵Ronald Kotulak, *Taking License with Your Genes Biotech Firms Say They Need Protection*, CHI. TRIB., Sept. 12, 1999 at 1.

¹⁴⁶Shulman, *supra* note 96, at 6067.

¹⁴⁷*Id.*

¹⁴⁸Foubister, *supra* note 4, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm. A discussion of what parents should be able to know about their children's genetic make-up and the privacy issues surrounding that issue are beyond the scope of this article. For a discussion see DENA S. DAVIS, *GENETIC DILEMMAS: REPRODUCTIVE TECHNOLOGY, PARENTAL CHOICES, AND CHILDREN'S FUTURES* 69-86 (2001).

¹⁴⁹Whether insurance would or should cover the cost of genetic screening is beyond the scope of this article. There has been much debate recently surrounding genetic privacy and how genetic information would be used by insurance companies. See Thomas H. Murray, *Genetics and the Moral Mission of Healthcare*, Hastings Center Report, November-December, 1992. Mark A. Rothstein and Sharona Hoffman, *Genetic Testing, Genetic Medicine and Managed Care*, 34 WAKE FOREST L. REV. 849 (1999).

¹⁵⁰Pollack, *supra* note 57, at 18.

device will be very costly. As stated earlier, it is thought that over 4,000 diseases stem from mutated genes, and thus far, 1,792 individual genes have been linked to a disease.¹⁵¹ Tests for individual genetic diseases tend not to be cost prohibitive; however, the cost of multiple tests could become so expensive that most individuals could not afford to be tested.¹⁵²

Gene patents not only raise the price of screening tests for diseases like Downs Syndrome, but also increase the cost of drugs that are made with gene products. 12-14% of the cost of a drug is due to the royalties that have to be paid to patent holders.¹⁵³ As Jeffrey Kahn, the director of the Center for Bioethics at the University of Minnesota, has said, gene patenting “has the potential to create the haves and have-nots in terms of genetic information about health.”¹⁵⁴

Those in favor of broad patents argue that part of the reward and incentive to make their products is the ability to make a profit and recoup the costs of research. However, patents on the human gene are a unique situation. As I discussed previously, the public has funded much of the research.¹⁵⁵ For example, many of the genes and the gene products that are currently being patented are the result of the publicly funded \$3 billion Human Genome Project.¹⁵⁶ In effect, the public pays twice, first by funding the research and then, because of the monopoly the gene patentee holds, by having to pay for the end products.

1. Monopoly Power

The granting of patents creates legalized monopolies designed to encourage innovation. In the case of genes, the creation of such monopolies is having an undesirable and contradictory effect.¹⁵⁷ The broad monopolies are financial disincentives for others to try and improve and expand their genetic research. Patents prevent others from engaging in cutting edge research and impede competition that could drive down healthcare costs.¹⁵⁸ These monopolies appear even more dangerous when one considers that “four private companies could own half of the human genome.”¹⁵⁹ The human genome project revealed the true size of the human genome, which was much smaller than scientists anticipated, therefore,

¹⁵¹Primer: *Genome and Genetic Research, Patent Protection and 21st Century Medicine*, *supra* note 97, at <http://www.bio.org/genomics/primer.html>.

¹⁵²Gorner, *supra* note 91, at 1.

¹⁵³Pollack, *supra* note 57, at 18.

¹⁵⁴Foubister, *supra* note 4, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm.

¹⁵⁵See *supra* Part IV, C. *The Public Investment*.

¹⁵⁶Gorner, *supra* note 91, at 1.

¹⁵⁷See *supra* Part IV, D. *Downstream v. Upstream Research*.

¹⁵⁸See *supra* Part V A.1. *Monopoly Power*.

¹⁵⁹See Albright, *supra* note 138, at <http://www.gene-watch.org/genewatch/articles/14-3humangenome.html>.

corporations own a higher percentage of the human genome than expected.¹⁶⁰ Some examples may serve as a tool to explain the impact of gene patents.

*a. Example: Myriad Genetics Inc. & BRCA1 & BRCA2*¹⁶¹

Myriad Genetics Inc. holds the United States' patents for the hereditary breast cancer genes commonly referred to as BRCA1 and BRCA2.¹⁶² The discovery of BRCA1, the first gene to be identified as predisposing women to hereditary breast cancer, was made through international collaboration and the open exchange of information;¹⁶³ however, Myriad alone holds the patent.¹⁶⁴ As researchers got closer to isolating the gene, Myriad's researchers, using work that had already been done, applied for the patent on the basis that they were the first to complete the sequencing of the gene (BRCA1).¹⁶⁵ In addition, much of the work on BRCA2, for which Myriad also holds the patent, took place in Britain at the Sanger Centre in Cambridge and the Institute of Cancer Research (hereinafter ICR).¹⁶⁶ Myriad filed its patent application for BRCA2 hours before ICR published its discovery in the journal *Nature*.¹⁶⁷

The BRCA1 and BRCA2 patents provide Myriad with exclusive rights to commercialize laboratory testing services, diagnostic test kits, and therapeutic products that use the BRCA1 and BRCA2 DNA sequences.¹⁶⁸ Myriad can decide which labs will do the tests, how many tests will be done, and at what price.¹⁶⁹ In the United States Myriad's monopoly enables it to charge between \$250-500 to screen for the occurrence of the mutation.¹⁷⁰ For the full sequencing of both BRCA genes which would check for any mutation in either gene, Myriad charges about \$2,400.¹⁷¹

¹⁶⁰*Id.*

¹⁶¹BRCA1 is U.S. Patent No. 5,709,999, 5,710,001, and 5,747,282 (issued Jan. 20, 1998) and BRCA2 is U.S. Patent No. 5,837,492 (issued Nov. 17, 1998) and 6,033,857 (issued Mar. 7, 2000).

¹⁶²In May 2001, Myriad announced that it received patents for BRCA1 and BRCA2 in Canada, Australia, New Zealand and from the European Patent Organization. The impact on the cost of hereditary breast cancer screening was not mentioned. *Myriad Genetics Awarded Cancer Gene Patents*, BIOTECH PATENT NEWS, May 1, 2001, Vol. 15, Issue 5, available at 2001 WL 17381672.

¹⁶³*Patenting Genes – Stifling Research and Jeopardising Healthcare*, GeneWatch UK, at 1 (Apr. 2001) available at <http://www.genewatch.org/Publications/Patenting/Patents.pdf> (last visited Feb. 17, 2003) [hereinafter *Patenting Genes – Stifling Research and Jeopardising Healthcare*].

¹⁶⁴*Id.* at 2.

¹⁶⁵*Id.*

¹⁶⁶*Id.*

¹⁶⁷*Id.*

¹⁶⁸*Id.*

¹⁶⁹*Patenting Genes – Stifling Research and Jeopardising Healthcare*, *supra* note 163, at 2.

¹⁷⁰*Id.*

¹⁷¹*Id.*

In the United Kingdom, ICR holds the patent to BRCA2 and does not charge a licensing fee.¹⁷² Scientists at the Central Manchester Healthcare National Health Service Trust (hereinafter NHS) in the United Kingdom calculated that screening for a particular mutation known to occur in a patient's family costs less than \$140 in their own laboratories.¹⁷³ Full sequencing of both BRCA genes would cost about \$1,120.¹⁷⁴ Because Myriad has applied for BRCA1 and BRCA2 patents in Europe, it is pressuring NHS to pay royalties on the patented gene(s) although NHS had developed its own tests for the breast cancer susceptibility genes.¹⁷⁵ In Canada, before Myriad received its Canadian patent,¹⁷⁶ the cost for full sequencing was around \$1,200.¹⁷⁷ In the U.S., where Myriad's patents exist, the cost is nearly double. Myriad will not have any competition in the U.S. for twenty years (the length of the patent) since the hereditary breast cancer gene is needed to do the screening and there is no way to invent around the gene. This is an example of how a human gene patent can inflate the cost of healthcare.

b. Example 2: Canavan Disease

In the fall of 1998, the American College of Obstetricians and Gynecologists announced its recommendation "that all Ashkenazi Jewish women should undergo DNA testing for Canavan carrier status."¹⁷⁸ Canavan disease is a genetic disorder that causes degeneration of the brain.¹⁷⁹ Those doctors who fail to test for the disease face negligence liability if a patient has a child with the disease without being tested.¹⁸⁰

¹⁷²*Id.*

¹⁷³*Id.*

¹⁷⁴*Patenting Genes – Stifling Research and Jeopardising Healthcare*, *supra* note 163, at 3.

¹⁷⁵*Id.*

¹⁷⁶In May, 2001, Myriad announced that it received patents for BRCA1 and BRCA2 in Canada, Australia, New Zealand and from the European Patent Organization the impact on the cost of hereditary breast cancer screening was not mentioned. *Myriad Genetics Awarded Cancer Gene Patents*, *supra* note 162, at 2001 WL 17381672.

¹⁷⁷*Who Owns Life?, Part Two, The Impact of Gene Patents on Health Care and Medical Research: The Case of Breast Cancer Genetic Screening*, Mar. 21, 2000, at http://www.radio.cbc.ca/programs/thismorning/features/life_2.html (last visited Feb. 17, 2003).

¹⁷⁸Gorner, *supra* note 91, at 1.

¹⁷⁹Mary Kugler, *Gene Patent: For Mankind's Good, or For Profit?* Jan. 12, 2001, About.com Guide to Rare/Orphan Diseases, available at <http://www.rarediseases.about.com/library/weekly/aa011201a.htm> (last visited Feb. 17, 2003). Canavan disease results from a lack of the enzyme aspartoacylase (ASPA). ASPA is encoded by the gene of the same name. *Gene Patent Leads to Legal Action*, AMERICAN MEDICAL ASSOCIATION, available at <http://www.ama-assn.org/ama/pub/category/3358.htm> (last visited Feb. 17, 2003). Life expectancy is between the ages 10-15 and there is no cure at this time. Gorner, *supra* note 91, at 1.

¹⁸⁰Gorner, *supra* note 91, at 1.

A few weeks after the announcement, Miami Children's Hospital began enforcing its 1997 patent for the Canavan gene. The search for the Canavan gene at Miami Children's Hospital had been done at the insistence of, and with help from, parents who lost two children to Canavan.¹⁸¹ In 1993, hospital researchers discovered the gene and in 1997 they received the patent.¹⁸² The patent obtained by Miami's Children's Hospital was "for the gene and its related applications, including carrier and related testing."¹⁸³

In October 2000, the same parents who helped initiate the research for the disease gene, along with the Canavan Foundation, Dor Yeshorim, and the National Tay-Sachs and Allied Diseases Association, sued the researchers at Miami Children's Hospital as well as the hospital.¹⁸⁴ In their lawsuit, the plaintiffs did "not directly challenge the patent, but instead allege[d] that the researchers secretly obtained it using the genetic information and financial resources that had been donated for the public good and began charging royalties and limiting the availability of testing."¹⁸⁵ The plaintiffs sought to block Miami Children's Hospital commercial use of the Canavan gene and to recover damages derived from the collecting of royalties.¹⁸⁶

The parents claimed that the patent, and its strictly enforced licensing, has inhibited further research and closed down certain testing facilities.¹⁸⁷ According to the complaint, the Canavan Foundation "was forced to stop offering free genetic screening ... after being advised that it would have to pay royalties and comply with other licensing terms."¹⁸⁸ Dor Yeshorim may also stop offering the test because of the royalty fees.¹⁸⁹ Prior to the patent enforcement by Miami Children's Hospital, the cost of the test had been between eight and nine dollars.¹⁹⁰ Miami Children's Hospital's initial fee demand was twenty-five dollars; the hospital later decreased the fee to \$12.50. This increased fee had a huge impact on those who were offering the screening free of charge. The test is given to those who are considering having children and suspect that they are carriers of the disease.¹⁹¹ There are six million

¹⁸¹Kugler, *supra* note 179, at <http://www.rarediseases.about.com/library/weekly/aa011201a.htm>. The parents, the Greenbergs, began the chapter of National Tay-Sachs and Allied Diseases Association in Chicago, they provided blood and tissue samples from their children and convinced others to do the same, they began a registry to keep track of samples, they also enlisted the help and support of the Dor Yeshorim and the Canavan Foundation.

¹⁸²Gorner, *supra* note 91, at 1.

¹⁸³Kugler, *supra* note 179, at <http://www.rarediseases.about.com/library/weekly/aa011201a.htm>.

¹⁸⁴Gorner, *supra* note 91, at 1.

¹⁸⁵*Id.*

¹⁸⁶*Id.*

¹⁸⁷*Id.*

¹⁸⁸*Id.*

¹⁸⁹Kugler, *supra* note 179, at <http://www.rarediseases.about.com/library/weekly/aa011201a.htm>.

¹⁹⁰Shulman, *supra* note 96, at 6067.

¹⁹¹Gorner, *supra* note 91, at 1.

Jews in America.¹⁹² Of those six million, 90% are Ashkenazi and one in forty is a silent carrier.¹⁹³ These numbers indicate that it is very important that everyone be tested.

Not only did Miami Children's Hospital double the cost of the test, it also restricted the number of labs that could perform the test and the number of tests that could be done each year.¹⁹⁴ The hospital defended this move on the grounds that it could get one large company to buy its exclusive license and recoup its costs, and the new owner could engage in widespread testing.¹⁹⁵

Researchers can influence how much profit gene patents generate.¹⁹⁶ The patentees of the cystic fibrosis gene prohibited exclusive licensing and charge only two dollars a test.¹⁹⁷ The same is true with Tay-Sachs disease, another genetic disease that affects Ashkenazi Jews.¹⁹⁸ The reliance on benevolent researchers, however, is not a solution that can be counted on, especially since many patents are held by for-profit companies.

2. Multiplicity of Patents

Science has moved away from thinking that one gene is responsible for each disease. "[B]oth genome projects have affirmed what many scientists have been saying all along: the idea of a single function gene is a myth."¹⁹⁹ Likewise, scientists have abandoned their previously held belief that there is one gene for each protein.²⁰⁰ In the *Financial Times*, Craig Venter, president of Celera Genomics Inc., said, "[t]he notion that one gene equals one disease or that one gene produces one key protein is flying out the window."²⁰¹ Although there are some examples—Tay Sachs, Canavan, Huntington's, Downs Syndrome, and sickle cell anemia—where a single gene is responsible for causing the disease, these are the minority.²⁰² These single gene diseases were probably first discovered because it is easier to establish the link if there is only one gene involved. Now, it is believed that for many diseases

¹⁹²*Id.*

¹⁹³*Id.*

¹⁹⁴*Id.*

¹⁹⁵*Id.*

¹⁹⁶Gorner, *supra* note 91, at 1.

¹⁹⁷*Id.*

¹⁹⁸*Id.*

¹⁹⁹Albright, *supra* note 138, at <http://www.gene-watch.org/genewatch/articles/14-3humangenome.html>.

²⁰⁰*Id.*

²⁰¹*Id.*

²⁰²*Profiting from the Human Genome*, HARVARD MAGAZINE, July-Aug. 200, at 70, available at http://www.harvardmagazine.com/archive/01ja/ja01_jhj_15.html (last visited Feb. 17, 2003) [hereinafter *Profiting from the Human Genome*].

multiple genes work in coordination; therefore, in order to treat or cure a disease, research and experimentation upon many genes and their functions is necessary.²⁰³

The abandonment of the single gene disease theory has triggered a unique problem that could not have been contemplated when gene patents were first issued—a problem of multiplicity. If more than one gene or gene failure is responsible for a single disease, in order to find which genes are linked to which diseases and to develop cures and treatments, researchers will need to be able to experiment with numerous genes. The need to work with numerous genes means finding numerous patentees and paying numerous royalties and/or licensing fees.

At this point in time the number of genes in the human genome is unknown. Scientists at the Human Genome Project and the Celera project have estimated that the number is between 30,000 and 40,000.²⁰⁴ With so few genes to work with and a patent system that does not encourage sharing information, new research is difficult.²⁰⁵ There is a possibility that most of the human genome is, or is about to become patented. Over 1,000 human gene patents already exist and more than 20,000 are pending.²⁰⁶ Researchers who are working on cutting edge medical science may have to go through ten to fifteen patent holders, negotiate licensing, and pay fees, in order to do their work. Even some big drug companies are worried about these obstacles and oppose gene patenting.²⁰⁷ To develop a marketable end product, drug companies often use five to seven genes.²⁰⁸ The need to go through multiple patent holders generates numerous hurdles. Patentees may refuse to deal with the researchers and entire projects could be halted. The transaction costs of having to go through multiple patent holders make it more expensive to do research resulting in more expensive end products or impeding the development of new products altogether. These costs will be passed down until they reach the consumer.²⁰⁹ The multiplicity of patents increases the cost to researchers and consumers beyond what was intended to be reasonable rewards for the patentees' innovations.

²⁰³Albright, *supra* note 138, at <http://www.gene-watch.org/genewatch/articles/14-3humangenome.html>.

²⁰⁴*Id.*

²⁰⁵*Id.*

²⁰⁶Grisham, *supra* note 11, at 921.

²⁰⁷Pollack, *supra* note 57, at 18. Quoting Dr. Bob Levy, senior vice president for science and technology at American Home Products, as saying that the gene patenting situation was a "minefield." There is also a consortium of ten big drug companies who are putting SNPs, single nucleotide polymorphisms, in the public domain. SNPs are the differences between one individual's genome and another.

²⁰⁸*See* Shaw, *supra* note 123, at <http://www.aamc.org/newsroom/reporter/feb2000/gene.htm> ("If a research project or product requires the use of five, six, or seven different patented gene fragments or approaches, even though it might do a great deal of good in society, it becomes impractical from a financial standpoint to develop it." Quoting Robert Kelch, M.D., dean of the University of Iowa College of Medicine and chair of the AAMC's Advisory Panel on Research).

²⁰⁹*See supra* Part IV. C. *The Public Investment.*

Future progress and public health depend on researchers and clinicians having access to genetic information so discoveries can be made as quickly as possible. Multiple patent holders impede this progress.

B. The Inhibition of Research

The PTO contends that gene patents do not stifle research stating that, “[t]he incentive to make discoveries and inventions is generally spurred, not inhibited, by patents.”²¹⁰ Increasingly, scientists and policy-makers are challenging this position arguing that gene patents are not only increasing the cost of research, they are making it harder for researchers to get access to the latest information and, in some cases, stopping the research all together.

[A]s more of the genetic code is mapped and deciphered, it’s frequently becoming more difficult-not easier-to conduct further research and gain more information. With genetic patents staking private claims to huge chunks of the code, researchers and clinicians are finding their genetic research and diagnostic efforts thwarted by various restrictions imposed by commercial, and in some instances, academic, patent holders.²¹¹

The necessity of being the first to apply for the patent in order to obtain the patent has caused some researchers to keep valuable information from one another. Professor Jonathan King of the Massachusetts Institute for Technology has said: “[p]atent attorneys regularly advise researchers to restrict their presentations to colleagues, don’t show your work, don’t show your notebook, don’t give that talk, so as not to jeopardize the planned patent submissions. This has reversed the half century culture of free and open communication in the scientific communities.”²¹² A survey of biotechnology firms done in the mid-1990’s supports Professor King’s statement.²¹³ The survey found that concerns about the effect that patents had on the free flow of knowledge between researchers might be justified: “[a]mong surveyed firms having research relations with academic institutions, 82% sometimes required researchers ‘to keep information confidential until the filing of a patent application’ and 47% ‘occasionally required’ confidentiality beyond the time required to file a patent.”²¹⁴ The information that was withheld included experimental methods, future experimental plans, and gene products, sequences, and locations.²¹⁵ The disincentives to sharing information slows an already painstakingly long process of finding genes and their functions, which in turn retards medical progress.

²¹⁰Utility Examination Guidelines, 66 Fed. Reg. at 1094.

²¹¹Shaw, *supra* note 123, at <http://www.aamc.org/newsroom/reporter/feb2000.gene.htm>.

²¹²*Patenting Genes – Stifling Research and Jeopardising Healthcare*, *supra* note 163, at 1.

²¹³ David Blumenthal et al., *Relationships Between Academic Institutions and Industry in Life Sciences—An Industry Survey*, 334 NEW ENG. J. MED. 368, 371 (1996). See Golden, *supra* note 1, at 135.

²¹⁴Golden, *supra* note 1, at 135. Blumenthal, *supra* note 213, at 371.

²¹⁵Meredith Wadman, *Commercial Interests Delay Publication*, 379 NATURE 574, 574 (1996). See Blumenthal, *supra* note 213, at 372. See Golden, *supra* note 1, at 135.

Gene patents have also been responsible for shutting down laboratories working at the forefront of genetics. In 1999, survey results indicated that one in four laboratories stopped performing certain genetic tests because they received notifications of patent restrictions or because of high licensing fees.²¹⁶ Debra Leonard, director of the Molecular Pathology program at the University of Pennsylvania Health System, is accustomed to cease-and-desist orders against her laboratory.²¹⁷ The cease-and-desist orders prevent Leonard from conducting tests she's developed for a neurodegenerative condition of the cerebellum, hereditary hemochromatosis, cystic fibrosis delta f508, and for Canavan's disease.²¹⁸ Another lab at Penn that tests for BRCA1 has also been ordered to stop.²¹⁹ This is "[b]ecause other entities have patented the genes that carry these diseases, and they've adopted restrictive licensure agreements permitting one, or at most a few laboratories to do all testing involving these genes."²²⁰ Jon F. Merz, an assistant professor of bioethics at the University of Pennsylvania, has preliminary survey results showing that of about 100 laboratories researching hemochromatosis, 20% did not develop a test in part because the gene is patented.²²¹ The labs closed because they did not want to spend the valuable research time and money knowing that there was a chance they would be shut down by patent holders.²²²

Exclusive licensing of patents can inhibit the progress of science because only a limited number of researchers are using and testing the new information.²²³ Licensing, while not as prohibitive as exclusive licensing, can still retard new information and technologies when it is cost prohibitive.²²⁴ Patent holders can refuse to grant researchers licenses altogether, and when researchers are given the opportunity to purchase licenses, the patent holders set the terms usually charging "both an upfront usage fee and a per test fee, often at rates that small diagnostic laboratories cannot afford."²²⁵ Therefore, even if licensing is available, unreasonably high fees can lead researchers to shut down their labs.²²⁶ Lab shut downs, like the inability to gain access to the latest information, can result in a discovery taking longer or not being made at all.

²¹⁶Gorner, *supra* note 91, at 1.

²¹⁷Shaw, *supra* note 123, at <http://www.aamc.org/newsroom/reporter/feb2000/gene.htm>.

²¹⁸*Id.*

²¹⁹*Id.*

²²⁰*Id.*

²²¹Foubister, *supra* note 4, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm.

²²²*Id.*

²²³Eisenberg, *supra* note 114, at 566-567.

²²⁴*Id.* at 568-569.

²²⁵Foubister, *supra* note 4, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm.

²²⁶*Id.*

One pharmaceutical firm, Merck & Co., has made the Merck Gene index free to the public.²²⁷ The Merck Gene index is a gene library.²²⁸ Keith Elliston, associate director of Merck's department of bioinformatics, is quoted as saying that this kind of gene sequence data should be openly accessed because "it increases the probability of breakthrough discoveries."²²⁹ There is a question whether Merck's release of the information to the public will counteract the problems that are seen with gene patents. It may be that if researchers use Merck's sequences and those sequences are covered by previously filed patent applications, the scientists might be prevented from using the Merck sequences for research without paying fees to the patent holders.²³⁰ The availability of some public databases like Merck's does not necessarily reduce the inhibition of research. The private databases are still more valuable because they use both information that was gathered privately and whatever information the public databases hold.²³¹

C. Decreased Quality of Healthcare

Oftentimes when a gene is associated with a particular disease, scientists work to develop a test that allows them to determine if an individual has the affected gene. Labs spend years developing and validating tests for disease genes.²³² They train physicians, who will implement the tests in their practices, on how to administer the tests, and how to evaluate the results.²³³ Ultimately, the tests become "the standard of medical practice."²³⁴ With the availability of gene patents, some companies, hospitals, and universities are patenting genes and the tests they have developed. The patent holders then authorize a limited number of labs to perform the tests. Labs that have been testing all along without licenses must cease testing and they are also prohibited from answering questions that physicians may have about the tests because they are not permitted to use the gene, even if they have their own tests.²³⁵ This was the case in the Canavan example.²³⁶

Exclusive licensing raises questions about the quality of testing and research.²³⁷ If only one or two labs are licensed to perform certain tests, there is never a chance to do an objective quality control comparison with other researchers at different

²²⁷Dastgheib-Vinarov, *supra* note 90, at 163.

²²⁸*Id.*

²²⁹*Id.*

²³⁰Eisenberg, *supra* note 114, at 569-570.

²³¹*Id.* at 564.

²³²Shaw, *supra* note 123, at <http://www.aamc.org/newsroom/reporter/feb2000.gene.htm>.

²³³*Id.*

²³⁴*Id.*

²³⁵*Id.*

²³⁶See *supra* Part V. A. 1. *Monopoly Power*.

²³⁷Foubister, *supra* note 4, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/prsb0221.htm.

labs.²³⁸ Also, second opinions can be difficult to obtain when only a few labs test for certain traits.²³⁹

Another impact of the exclusive licensing is the effect on physicians. Physicians are the ones who will be interpreting the results of these tests. “The way physicians learn how to use tests is to actually see tests and do tests and interpret them and study them,” said Jonathan F. Tait, MD, PhD, associate professor and director of the Molecular Diagnosis Laboratory at the University of Washington, Seattle.²⁴⁰ If all the tests go to one lab, the ability to participate and learn from the tests is nearly impossible, and in the end the patient suffers because the care is sub-optimal. Disease gene patents prevent clinicians from practicing the best medicine.²⁴¹

D. *The Impact of the PTO’s Current Utility Standards*

In February 2000, the PTO issued a patent to Human Genome Sciences (hereinafter HGS)²⁴² for the gene CCR5.²⁴³ HGS was issued a patent on the CCR5 gene, its protein, and fragments of DNA for locating the gene.²⁴⁴ The utility that HGS described for CCR5 was that CCR5 was a receptor gene that binds protein molecules termed “chemokines.”²⁴⁵ HGS’s patent application claimed that the chemokines would be useful for treatments involving inflammation, immune reactions, allergies, and arthritis.²⁴⁶ The patent application did not disclose the function of CCR5’s particular protein product, although the patent on it was given to HGS.²⁴⁷ The function of the CCR5 protein was later discovered by independent researchers at the NIH.²⁴⁸ The NIH research showed that the CCR5 protein works as a co-receptor in binding HIV.²⁴⁹ It is likely that this protein is necessary for the HIV virus to be transmitted from one person to another.²⁵⁰ Independent researchers also

²³⁸*Id.*

²³⁹*Id.*

²⁴⁰Foubister, *supra* note 4, at http://www.ama-assn.org/scipubs/amnews/pick_001prsb0221.html.

²⁴¹Shaw, *supra* note 123, at <http://www.aamc.org/newsroom/reporter/feb2000/gene.htm>.

²⁴²Human Genome Sciences Incorporated is a publicly traded biotechnology company based in Rockville, MD.

²⁴³U. S. Patent No. 6,025,154 (issued Feb. 2000).

²⁴⁴*The Fate of Gene Patents Under the New Utility Guidelines*, *supra* note 33, at ¶ 6.

²⁴⁵*Id.*

²⁴⁶*Id.*

²⁴⁷*Id.* at ¶ 7.

²⁴⁸*Id.*

²⁴⁹*The Fate of Gene Patents Under the New Utility Guidelines*, *supra* note 33, at ¶ 7.

²⁵⁰Associated Press, *Genetics Face-Off, Scientists, Corporation Feud Over Gene Patent*, abcNews.com, (Feb. 28, 2000) at <http://abcnews.go.com/sections/living/DailyNews/genepatent000228.html> (last visited Feb. 17, 2003) [hereinafter *Genetics Face-Off*].

discovered that the defective versions of CCR5 suppress HIV infection by preventing the virus from attaching to cells.²⁵¹

Despite the fact that HGS was not the one to discover the medically valuable information about the CCR5 gene, and did no research to demonstrate its role in HIV infection, they were still awarded the patent.²⁵² HGS acknowledges that when they applied for the patent they had no knowledge of the gene's role in HIV infection.²⁵³ The patent allows HGS to determine who can use the gene to develop new AIDS drugs.²⁵⁴ This could nullify any research done by the teams that actually found the gene's real use.²⁵⁵ The overall effect is that HGS can now exclude anyone, including the NIH group, from using the gene in HIV treatment.²⁵⁶ Although HGS is making the gene available to academic researchers at no cost, the developer of any commercial product will owe them royalties.²⁵⁷

The PTO issued new utility guidelines in 2001 "with the intent of tightening the standard and restricting the issuance of gene patents."²⁵⁸ However, the NIH contends that the new utility standards issued by the PTO do not do enough to prevent a reoccurrence of the CCR5 situation.²⁵⁹ The HGS patent on the CCR5 gene illustrates two of the main problems that can still occur under the Patent and Trademark Office's current utility criteria.

First, under the new guidelines only one utility has to be described. That utility does not have to be the most medically relevant utility, and that one utility does not even have to be for the gene and its corresponding products. The PTO openly acknowledges that one function, and not necessarily the best or most useful function, will meet the criteria for patentability.²⁶⁰ The requirement that only one utility needs to be described in order to gain a patent on all of a gene's functions makes the patents extremely broad.²⁶¹ The PTO is not opposed to broad genetic patents and has stated that,

A patent on a composition gives *exclusive* rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition. Thus, a patent granted on an isolated and purified DNA

²⁵¹*Id.*

²⁵²*The Fate of Gene Patents*, *supra* note 33, at ¶ 7.

²⁵³*Genetics Face Off*, *supra* note 250, at <http://abcnews.go.com/sections/living/DailyNews/genepatent000228.html>.

²⁵⁴*Id.*

²⁵⁵*Id.*

²⁵⁶*The Fate of Gene Patents*, *supra* note 33, at ¶ 6-7.

²⁵⁷*Genetics Face-Off*, *supra* note 250, at <http://abcnews.go.com/sections/living/DailyNews/genepatent000228.html>.

²⁵⁸*The Fate of Gene Patents*, *supra* note 33, at ¶ 8.

²⁵⁹*Id.*

²⁶⁰Utility Examination Guidelines, 66 Fed. Reg. at 1094.

²⁶¹*Id.* For a discussion on the impacts of a broad patent *see* Part IV. D. *Downstream v Upstream Research*.

composition confers the right to exclude others from *any* method of using that DNA composition, for up to twenty years from the filing date. This result flows from the language of the statute.”²⁶²

If a subsequent researcher finds a new use for the patented DNA or gene, a process patent can be issued; however, the holder of the process patent may still owe the original patent holder royalty or licensing fees.²⁶³ The PTO posits that broad patents encourage subsequent discoveries and promote progress and are one of the ways in which the patentee can recoup costs.²⁶⁴ Although it is likely that broad patents enable patent holders to recoup costs, these patents do not encourage discoveries nor do they promote progress. Although HGS is allowing researchers to use the CCR5 gene free of charge, this is not required by patent law. Rather, an original patent holder has the ability to exclusively license and to set royalty fees at any rate.

The second problem that arises from the current utility criteria is that the utility can be speculative in nature. HGS determined that CCR5 would be useful as a chemokine receptor by using homology studies.²⁶⁵ Homology studies determine gene function by comparing the human gene sequence to gene sequences of other species whose functions are already known.²⁶⁶ If there is enough homology between the two gene sequences, then it is assumed that the genes function in the same way. The PTO accepts homology-based assertions of utility, although some scientists believe that homology studies are unpredictable.²⁶⁷ Many groups, such as Celera and HGP, believe that a patent should not be given on a particular DNA sequence until the applicant is able to clearly describe the gene's role.²⁶⁸ Utilities based on homology can be incorrect and can prevent the most medically valuable function of a gene from being discovered. CCR5 is an example where one research team discovered a “function” based on a homology and then another publicly-funded team discovered a true medically valuable function of the gene. DNA sequences that are patented through homology patents could have “multiple unexplored functions.”²⁶⁹ These other functions are likely to remain unexplored because homology utilities can be found very quickly.

The fact that one utility description is enough to get a patent that covers all of a gene's functions is detrimental to finding the best use for a gene which ultimately effects the quality of public healthcare. Homology studies also decrease the quality of healthcare by encouraging the quick patenting of genes without any demonstration

²⁶²Utility Examination Guidelines, 66 Fed. Reg. at 1095.

²⁶³Doll, *supra* note 20, at 690.

²⁶⁴*Id.*

²⁶⁵*The Fate of Gene Patents Under the New Utility Guidelines*, *supra* note 33, at ¶ 6.

²⁶⁶*Gene Patenting*, *supra* note 10, at <http://www.ama-assn.org/ama/pub/category/2314.html>.

²⁶⁷Utility Examination Guidelines, 66 Fed. Reg. at 1096.

²⁶⁸Gitter *supra* note 13, at 1631.

²⁶⁹Albright, *supra* note 138, at <http://www.gene-watch.org/genewatch/articles/14-3human-genome.html>.

of the benefits to the public, and by restricting researchers, who could develop socially beneficial products, from having access to the genes.²⁷⁰

VI. AN APPROACH TO BALANCING THE INTERESTS

Since the Patent Act of 1952, the patent laws of the United States have remained relatively unchanged.²⁷¹ The few revisions that have been made were primarily “to correct minor technical issues and to make the patent laws of the United States consistent with various international treaty obligations.”²⁷² In order for the current problems of gene patenting to be addressed, Congress needs to amend the patent laws.

The PTO is without authority to make the fundamental changes that are needed to address the issues that gene patents raise. The role of the PTO is to interpret and implement the federal statutes and guidelines.²⁷³ Likewise, the courts are not the source of change in this area. First of all, patent suits concern infringement issues not public policy, and the cost of going to court over a patent is extremely expensive.²⁷⁴ Second, in *Diamond v. Chakrabarty*, the Supreme Court recognized that it was not competent to hear arguments on the hazards of genetic research and that the legislative and executive branches of government were the appropriate audiences.²⁷⁵

There is precedent for Congress to change patent law when public health is at stake. In 1996, Congress passed a law protecting physicians and institutions from liability for infringing on patents that covered medical process such as surgical incisions.²⁷⁶ This law was passed in response to the medical community’s concern that the patents on medical procedures would decrease the quality of patient care because the newest techniques could not be used without the threat of a potential patent infringement lawsuit.²⁷⁷ The legislation does not eliminate patent protection.²⁷⁸ Rather, it exempts certain medical practitioners from patent infringement claims.²⁷⁹

Congress should adopt the American Medical Association’s (hereinafter AMA) policy on gene patents. The AMA’s policy reads:

²⁷⁰*Gene Patenting*, *supra* note 10, at <http://www.ama-assn.org/ama/pub/category/2314.html>.

²⁷¹Warren D. Woessner & Michael A. Dryja, *Patent Law Amendment Provides Swift Relief for US Doctors*, IP WORLDWIDE (Apr. 1997) at <http://www.slwk.com/papers/paper12.htm> (last visited Feb. 17, 2003).

²⁷²*Id.*

²⁷³*Patenting Genes and Their Mutations*, available at <http://ama-assn.org/ama/pub/article/2036-3063.html> (last visited Feb. 17, 2003).

²⁷⁴Shaw, *supra* note 123, at <http://www.aamc.org/newsroom/reporter/feb2000/gene.htm>.

²⁷⁵*Chakrabarty*, 447 U.S. at 316-17.

²⁷⁶Pub. Law No. 104-208, H.R. 3610.

²⁷⁷Woessner and Dryja, *supra* note 271, at <http://www.slwk.com/papers/paper12.htm>.

²⁷⁸*Id.*

²⁷⁹*Id.*

AMA policy on gene patents is: (1) Patents on processes—for example, processes used to isolate and purify gene sequences, genes and proteins, or vehicles of gene therapy—do not raise the same ethical problems as patents as the substances themselves and are thus preferable. (2) Substance patents on purified proteins presents fewer ethical problems than patents on genes or DNA sequences and are thus preferable. (3) The AMA: (a) supports the concepts of gene patents only if the inventor has demonstrated a practical, real world, specific and substantial use (credible utility) for the sequence; (b) supports equitable access to licenses and sublicenses of gene patents for diagnostic genetic tests to any Clinical Laboratory Improvement Act (CLIA)-certified laboratory at a reasonable royalty (c) supports the concept of gene patents only if the inventor has demonstrated a practical use beyond merely being a tool for scientific discovery, (d) recommends that the Department of Health and Human Services (DHHS) Secretary's Advisory Committee on Genetic Testing consider the development of special guidelines for the licensing of human gene-related patents as a way of promoting research and other benefits; (e) encourages the DHHS as part of its regulatory oversight of genetic testing to continue to monitor the impact of gene patenting and licensing agreements on access to relevant medical care; and (f) encourages the DHHS Secretary's Advisory Committee on Genetic Testing to further discuss what "credible utility" should refer to within the fields of biotechnology. (4) One of the goals of genetic research is to achieve better medical treatments and technologies. Granting patent protection should not hinder this goal. Individuals or entities holding patents on genetic material should not allow patents to languish and should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.²⁸⁰

The AMA's policy adequately addresses the major problems that result from gene patents. Although the patentee will still hold the patent for twenty years, under the AMA policy the monopoly given will resemble the kind of monopoly that was intended to exist. In section 3(b), the AMA supports access to gene patents by all certified laboratories at a reasonable cost. By requiring that licensing come at a reasonable cost, laboratories will be able to continue their research, which means the public will benefit from the results sooner. The reasonable cost to the lab can be passed on to the consumer. In addition to advocating reasonable costs, Section 3(b) prohibits exclusive licensing of gene patents. This will end the problems of decreased quality and lab shut downs that exist with exclusive licensing.

Section 3(b) also addresses the problems that occur with the multiplicity of patents. Laboratories seeking to use patented genes will still have to locate the patent holders, but this effort will not be in vain because access will be guaranteed for a reasonable royalty. While section 3(a) accepts the PTO's revised utility standards, section 3(f) encourages the Department of Health and Human Services (DHHS) to further examine what "credible utility" should mean in the area of biotechnology. Further examination into defining utility may lead policy-makers to

²⁸⁰AMA Policy H-140.944, *Report 9 of the Council of Scientific Affairs (I-00)*, (2000), at <http://www.ama-assn.org/ama/pub/article/2036-3063.html> (last visited Feb. 17, 2003).

prohibit infringement actions against people who use patented genes to develop more medically useful utilities. Section 3(e) encourages the DHHS to monitor the impact of gene patents on medical care. This is extremely important since there are divergent views on the topic and little empirical evidence. The DHHS is in a better position than the PTO to investigate the impact of patents on healthcare because it can enlist the NIH and other groups to help develop a well conceived study.

VII. CONCLUSION

Gene patents are needed as an incentive for biotech companies to develop products for consumers.²⁸¹ However, under the current patent law, biomedical research is inhibited and the public is paying twice for biotech innovation. In order to protect public health, Congress must amend the patent law. The best existing model for legislative change has been proposed by the American Medical Association. The AMA model addresses all of the public policy concerns, but still allows biotech companies to hold gene patents.

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²⁸¹*Make Human Gene Data Public*, BBC News Online, (Mar. 14, 2000), at http://news.bbc.co.uk/1/hi/english/sci/tech/newsid_677000/677246.stm (last visited Feb. 17, 2003).

²⁸²J.D., Cleveland-Marshall College of Law, 2003; B.A., Taylor University, 1998. I would like to thank Kathleen Engel, without her support, advice, editing, and friendship this Note would not have been possible. I give special thanks to my parents, Gary and Becky Mazza, for encouraging me in everything I do. Lastly, I want to thank my husband, Ryan Horn, for making me believe that I could do this and loving me every step of the way.