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THE GENE PATENT DILEMMA: BALANCING COMMERCIAL INCENTIVES WITH HEALTH NEEDS

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INTRODUCTION

On January 3, 2000, Donna Rawlinson MacLean filed application GB0000180.0 in the British Patent Office. The patent application entitled "Myself" was MacLean's attempt to patent her own genetic sequence.¹ "It has taken 30 years of hard labor for me to discover and invent myself, and now I wish to protect my invention from unauthorized exploitation, genetic or otherwise," explained MacLean.²

Patent office officials were befuddled as to why she would want to patent her own genes. "It is not really worth patenting something unless you make a lot of money from it," noted Brian Caswell of the British patent office.³ But MacLean, a poet, was interested in making a point, not in making profits. She was protesting the granting of gene patents to companies, which seemingly allowed them to own parts of people.⁴

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¹ *Of Her Own Making*, N.Y. TIMES, March 12, 2000, at A4 REUTERS; see also *Patent*, available at <http://blather.newdream.net/p/patent.html>.

² *Id.*

³ *Woman Tries to Patent Self*, REUTERS, Feb. 29, 2000 [hereinafter Reuters, *Self*], available at <http://more.abcnews.go.com/sections/living/dailynews/selfpatent000229.html>.

⁴ *Id.*

MacLean is not alone in her criticism of gene patents. From French researchers⁵ to the premier of Ontario, Canada,⁶ from Native Americans⁷ to medical professional organizations,⁸ gene patents are under siege. The stakes are high. Thousands of gene-related patent applications have been filed with the U.S. Patent and Trademark Office (USPTO).⁹ Many of them will turn out to be worth several fortunes. The patent on the human erythropoietin gene (which codes for a protein needed by kidney disease patients) is worth more than \$1.5 billion a year because a genetically engineered treatment can be made from it.¹⁰

The challenges to human gene patents come from a variety of interested parties—people from whom the patented genes were isolated, researchers who wish to undertake genetic epidemiology or develop gene therapies, clinicians and health plan operators who cannot afford the crippling licensing fees for genetic tests, and policy-makers who want to assure that the patent system actually meets its goal by encouraging invention. Evidence is mounting that gene patents are inhibiting important biomedical research, interfering with patient care, and causing criticisms from international trad-

⁵ Declan Butler and Sally Goodman, *French Researchers Take A Stand Against the Cancer Gene Patent*, 413 NATURE 95, 95 (2001) (describing the Institut Curie's challenge to the BRCA1 gene patent that is held by Myriad Genetics, a Utah based company).

⁶ Paul Willcocks, *Canadian Premiers Wade Into Gene Patenting Debate*, REUTERS, Aug. 3, 2001.

⁷ Debra Harry, *Letter to Commissioner of Patents and Trademarks, Indigenous Peoples Council on Biocolonialism*, Comment 39, Mar. 21, 2000, available at <http://www.uspto.gov/web/offices/com/sol/comments/utilguide/index.html> (arguing that human genes are nature's products, not inventions, and are thus not patentable).

⁸ ASSOCIATION FOR MOLECULAR PATHOLOGY, CLINICAL PRACTICE COMMITTEE, *AMP Position on Patenting of Genetic Tests*, Dec. 17, 1999, [hereinafter ASSOCIATION FOR MOLECULAR PATHOLOGY] available at <http://www.ampweb.org/patent.htm>. The statement was developed by representatives from the following organizations: the Academy of Clinical Laboratory Physicians and Scientists, College of American Pathologists, American College of Medical Genetics, American Society of Human Genetics, American Association for Clinical Chemistry, National Society of Genetic Counselors, American Medical Association, American College of Obstetricians and Gynecologists, American Society of Clinical Pathologists, Association of American Medical Colleges.

⁹ Ken Garber, *Homestead 2000: The Genome*, SIGNALS MAGAZINE, available at <http://www.signalsmagazine.com/signalsmag.nsf>.

¹⁰ S. M. Thomas et al., *Ownership of the Human Genome*, 380 NATURE 387, 388 (1996); see also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1200, 1203 (Fed. Cir. 1991) (providing more information about erythropoietin and Epogen, the product based on the erythropoietin gene). By the year 2000, Epogen accounted for \$1.9 billion of Amgen's total revenue of \$3.6 billion that year. Amy Tsao, *Amgen: Will Bigger Be Better?* BUSINESS WEEK ONLINE, Jan. 2, 2002, available at http://www.businessweek.com/bwdaily/dnflash/jan2002/nf2002012_2995.htm.

ing partners.¹¹ As a result, various policy alternatives are being considered, including banning gene patents, exempting researchers and diagnosticians from the reach of the patents, encouraging patent pools, compulsory licensing, recognizing the rights of third parties to oppose the granting of a particular gene patent, and allowing the people who are the sources of the patented genes to have a greater say in their use.

Gene patents are undergoing increasing scrutiny because they are pivotal to the future of health care, and patent decisions around the globe have been most challenged and changed when health is at issue. And, while patents on certain products related to health care are appropriate—such as patents on drugs—the rationales for granting such patents do not apply to patents on genes.

I. THE FOUNDATION OF PATENT LAW

Around the world, industrialized nations share a belief in the importance of a strong patent system.¹² The framers of the U.S. Constitution realized two centuries ago that it was important to create incentives for technological innovation. Article I of the United States Constitution gives Congress the 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.”¹³

Under the federal patent law, the patent applicant must show that his or her invention is novel, non-obvious, and useful.¹⁴ When a patent is granted, the inventor has the right to exclude others from making, using or selling his or her invention for twenty years from the date the patent application was filed. The patent laws are designed to assure that the public benefits from a new invention in exchange for the monopoly.¹⁵ The laws do not allow patents on

¹¹ See section IV, *infra*.

¹² This belief is the basis of the Agreement on Trade-Related Aspects of Intellectual Property Rights. See, e.g., Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, *Marrakesh Agreement Establishing the World Trade Organization, Annex 1C Legal Instruments—Results of the Uruguay Round* vol. 31; 33 I.L.M. 84 (1994) (TRIPS Agreement) [hereinafter *TRIPS*].

¹³ U.S. CONST. art. I, § 8, cl. 8.

¹⁴ 35 U.S.C. §§ 101-103 (2002).

¹⁵ Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1022 (1989) (explaining that “[I]n order to obtain a patent, the applicant must first contribute ‘a measure of worthwhile knowledge to the public storehouse.’”).

products of nature because the public would not gain anything new if an individual were allowed to, for example, patent air and charge us each a license fee whenever we breathed. Nor are patents allowed on scientific formulas. The U.S. Supreme Court has pointed out, "The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'"¹⁶

The patent application must also be adequately "enabling;" that is, it must describe the invention fully, in a way that would allow another person skilled in that field to make the invention.¹⁷ This requirement is particularly important because one of the purposes of the patent law is to assure that the public receives information in exchange for the monopoly granted to the patent holder.¹⁸ When a patent is granted, the information in it becomes public. Other inventors can then use that information to further their own research. Other inventors, however, cannot make or use the patented invention itself without the permission of the patent holder.¹⁹

In the United States—unlike in Europe²⁰—the inventor has no duty to actually "work" (use or develop) the invention.²¹ He or she can just put it on the shelf. The public is nevertheless thought to be benefited by the fact that the information about how to make the invention is publicly disclosed in the patent application for others to build on.

Genes straddle the boundary between patentable and unpatentable substances. They seem akin to products of nature or formulas. Moreover, as Rebecca Eisenberg notes, "DNA sequences are not simply molecules, they are also information. . . . Patent claims to information—even useful information—represent a fundamental

¹⁶ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

¹⁷ 35 U.S.C. § 112 (2002).

¹⁸ Eisenberg, *supra* note 15, at 1017.

¹⁹ See *id.* at 1021-22 (relating that this restriction extends even to one who may have innocently and independently developed the same invention).

²⁰ Yee Wah Chin, *Unilateral Technology Suppression: Appropriate Antitrust and Patent Law Remedies*, 66 ANTITRUST L.J. 441, 450 (1998) (revealing that in jurisdictions which require the patentee to use the invention, the failure to do so can result in revocation of the license or even a relicensing to others).

²¹ See Eisenberg, *supra* note 15, at 1021-22.

departure from the traditional patent bargain.”²² That bargain envisioned allowing a patent on an invention in exchange for the disclosure of useful information in the application to spur on other inventors.²³

The fact that genes come from people adds to the concerns about how they are used. In France, for example, there is a variation of the products-of-nature doctrine singling out human materials. Under a French statute, the “human body and its elements and products, as well as knowledge of the total or partial structure of a human gene may not, as such, be the subject of a patent.”²⁴ In a letter to the U.S. Commissioner of Patents, in response to a proposal to revise patent law, the Indigenous Peoples Council on Biocolonialism pointed out, “One of the most basic tenets of modern western biology is that the genetic material of an individual is inherited from previous generations. Our genes are derived from our parents, grandparents, and their progenitors through the germline. It is clear that human genes are the products of nature.”²⁵ Various groups describe genes as the common heritage of mankind which should not be owned by individual companies.²⁶

Some critics of gene patents are concerned that people are “commodified” by turning genes into property. The human origin of patented genes has not only a moral significance, but also a practical one. Genetic tests and treatment technologies are central to the future of health care.²⁷ Genetic testing can lead to true preventive medicine; patients whose genes indicate a propensity to develop emphysema, for example, can avoid jobs that would trigger the disease. Gene therapies could also be used to treat previously fatal and untreatable diseases. Yet the holder of a patent on a disease gene will be able to control any use of that gene for diagnosis or treat-

²² Rebecca S. Eisenberg, *Re-examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 786, 794 (2000) [hereinafter Eisenberg, *DNA Sequences*].

²³ *Id.* at 794.

²⁴ Law No. 94-653 of 29 July 1994, detailed in 45 INT. DIG. HEALTH LEG. 498-99 (1994).

²⁵ See Harry, *supra* note 7.

²⁶ Melissa L. Sturges, Note, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT'L. L. REV. 219, 245-48 (1997); see also Bartha Maria Knoppers, *Status, Sale and Patenting of Human Genetic Material: An International Survey*, 22 NATURE GENETICS 23, 23-26 (1999). The World Medical Association also considers genes to be part of “mankind’s common heritage” and urges medical organizations around the globe to lobby against gene patenting. Matt Borsellino, *World Med. Association Tackling Health Database Issue*, MED. POST, May 23, 2000, at 40.

²⁷ Francis S. Collins and Victor A. McKusick, *Implications of the Human Genome Project for Medical Science*, 285 JAMA 540, 540 (2001).

ment, setting the prices as high as he or she wants, or denying access to certain diagnostic or treatment technologies. Unlike a patent on a drug, where alternative drugs can be developed and patented, the holder of a gene patent has control over any gene therapies that use the patented gene and can deny potential competitors the chance to make alternative products utilizing the gene sequence. Gene patents raise serious concerns for human health. Granting patent monopolies in this field has a much higher social cost than, for example, patenting a marginally better mousetrap or some other invention where consumers can readily choose a substitute or do without.

II. THE LEGAL BASIS FOR GENE PATENTS

There has yet to be a court decision squarely addressing whether human genes are the appropriate subject matter for a patent.²⁸ In the famous case of *Diamond v. Chakrabarty*, the U.S. Supreme Court, in a five to four decision, determined that a genetically-engineered living bacterium was patentable.²⁹ But the inventor in that case had created something new that had not previously existed—a bacterium that could be useful in cleaning up oil spills.³⁰ Human genes already exist. Proponents of gene patents point to language in the *Chakrabarty* decision that “anything under the sun that is made by man” may be patented.³¹ That sweeping statement was limited by the Court itself, which reiterated the statutory requirements for a gene patent and pointed out that manifestations of nature were not patentable.³² The Court also did not address whether the sequence of an existing gene would be considered to be “made by man.”

For any invention to be patented, the patent applicant must demonstrate that his invention is useful, non-obvious, and novel.³³ Yet each of these criteria could raise issues for gene patents. Knowing the sequence of a gene is useful; for example, it allows genetic

²⁸ In the gene patent cases that have been litigated, both sides usually accept the notion that genes are patentable and are battling over who has rights to the patented gene. *See, e.g.,* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1204 (Fed. Cir. 1991).

²⁹ 447 U.S. 303, 304, 317-18 (1980).

³⁰ *Id.* at 305.

³¹ *Id.* at 309 (citing S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

³² *Id.* at 309 (citing Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

³³ 35 U.S.C. §§ 101-103 (2002).

testing of an individual to determine if he or she has a normal sequence or a potentially problematic variation.³⁴ But the useful properties of a gene (such as its ability to bind to another complementary strand of DNA for diagnosis or its ability to code for a particular protein) are not ones that the scientist has invented, but rather are natural, inherent properties of genes themselves. Establishing non-obviousness is also a grey area because computerized homologous sequencing techniques (in which, for example, the function of a human gene is predicted by a computer match to an animal gene whose function is known) seem obvious in light of prior art. The criterion of novelty, too, might also be difficult to meet. How does a disease gene suddenly become “new” enough to be a patentable invention once it is removed from an affected individual by a researcher? Shouldn’t the arrangement of the chemical letters C, A, T and G be viewed as an unpatentable formula or product of nature?³⁵

Although products of nature are not patentable, various courts have upheld patents on isolated and purified natural substances. The 1912 case of *Parke-Davis & Co. v. H.K. Mulford & Co.*³⁶ upheld a patent on adrenaline, a natural hormone that was found in animal glands. The patent applicant identified, isolated, and purified the active ingredient—adrenaline.³⁷ This discovery created a product that did not exist in nature in that precise form and that could be used for medical treatment.³⁸

Individuals who seek gene patents assert that they have isolated and purified genes because genes in the body have both coding and non-coding regions, in contrast to the patented genes which have been manipulated to eliminate the non-coding region, while apparently still performing the same function as a naturally occur-

³⁴ Allen C. Nunnally, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in the New Genetic Age*, 8 B.U. J. SCI. & TECH. L. 306, 307 (2002) (citation omitted) (explaining that the discoveries of disease sequences can be helpful in screening for diseases, providing warnings of potential health problems, and allowing more individualized treatment).

³⁵ Sunny Bains, *Double Helix As Engineer*, 279 SCI. 2043, 2043 (March 27, 1998) (detailing that the letters C, G, A and T stand for the four different bases that make up human DNA: cytosine, thymine, adenine, and guanine).

³⁶ 196 F. 496-97 (2d Cir. 1912).

³⁷ *Id.*

³⁸ *Id.* at 497.

ring gene.³⁹ Scientists and institutions seeking gene patents argue that genes are thus similar to the isolated and purified adrenaline. However, gene patent applicants seek control over all uses of the gene, such as its binding and coding abilities.⁴⁰ Yet those properties are natural properties of the DNA itself, not the invention of the patent holder. Consequently, gene patents might raise the same concerns as the proposed patent at issue in *Cochrane v. Badische Anilin & Soda Fabrik*.⁴¹ In that case, the U.S. Supreme Court invalidated a patent for synthesized alizarine, a dye previously made from an extract of the madder root.⁴² The Court emphasized that the synthetic form was just a copy of the natural one.⁴³

The challenges to gene patents are moving beyond the initial moral concerns about commodifying people and the legal concerns about whether genes are unpatentable products of nature. Now the concerns are being couched in terms of harm to the research enterprise and to public health.⁴⁴ A variety of policy options are being explored to ensure that gene patents do not impede the evolution of science and the practice of medicine.

III. THE UNIQUE CONCERNS ABOUT HEALTH CARE PATENTS

The issue of gene patents arises within the most contested and malleable area of patent law—that of patents related to health. Historically, in the United States, patents on products and processes necessary to treat patients were not even allowed.⁴⁵ Even today, there are exceptions in U.S. patent law⁴⁶ and in the international

³⁹ Lisa A. Karczewski, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnological Industry*, 31 McGEORGE L. REV. 1043, 1056 (2000).

⁴⁰ See Martin Bobrow and Sandy Thomas, *Patents in a Genetic Age: The Present Patent System Risks Becoming a Barrier to Medical Process*, 409 NATURE 763, 763 (2001).

⁴¹ 111 U.S. 293, 294 (1884).

⁴² *Id.* at 297.

⁴³ *Id.* at 311-12.

⁴⁴ See, e.g., Jon F. Merz, Mildred K. Cho, Madeline J. Robertson and Debra G. B. Leonard, *Disease Gene Patenting Is a Bad Innovation*, 2 MOLECULAR DIAGNOSIS 299, 301 (1997) [hereinafter Merz et al., *Bad Innovation*] (asserting that gene patents may limit the best equipped firms from creating new gene therapies for patients, and without an exception for experimental research with gene therapies, gene patents may prevent progress in finding gene mutations that cause disease).

⁴⁵ See p. 73-75 *infra*.

⁴⁶ See, e.g., 35 U.S.C. § 287(c) (2002). Another way in which U.S. laws recognize public health concerns is through march-in rights. Under 35 U.S.C. § 203, if federally-funded research

agreements⁴⁷ to which the U.S. is a signatory that create certain exemptions from traditional patent law for patents related to health care. Even courts faced with patent infringement cases will take action to protect public health.⁴⁸ And government officials, including U.S. Health and Human Services Secretary Tommy Thompson, have threatened to ignore patents that are seen as inimical to public health.⁴⁹ In Canada, in the wake of terrorists' use of anthrax, the government decided to override Bayer's patent for the antibiotic Cipro and ordered a million tablets of a generic version of the drug.⁵⁰ Ultimately, Bayer struck a deal with the Canadians to sell Cipro at a much lower price.⁵¹

A. The History of Health Care Patents

Originally, U.S. patent law forbade patents on health care inventions. Throughout the first 150 years of U.S. history, the USPTO did not issue patents for methods used to diagnose and treat sick patients.⁵² Methods to treat disease were not considered patentable subject matter by the medical profession, the courts, and the USPTO. Patents were granted for tangible discoveries or inventions, and medical or surgical methods did not appear to fall within the scope of the statutory requirements.

In 1862, a New York court was one of the first to address the issue. The court assessed whether a newly discovered use of ether, to eliminate pain experienced by patients undergoing surgical operations, was patentable.⁵³ Although ether was a well-known substance at the time, the alleged invention was that if ether was

contributed to the production of an invention, and that product is not made available to the public in a reasonable amount of time, the federal agency that provided funding has march-in rights allowing it to grant a license to another entity to make the product. See Peter S. Arno and Michael H. Davis, *Why Don't We Enforce Existing Drug Pricing Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part From Federally Funded Research*, 75 TUL. L. REV. 631, 643-44 (2001).

⁴⁷ See, e.g., TRIPS, *supra* note 12.

⁴⁸ See, e.g., *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934).

⁴⁹ *Industry Observers Debate Implications of HHS Secretary's Remarks on Cipro Patent*, 10 BNA HEALTH LAW REPORTER 1709 (Nov. 8, 2001).

⁵⁰ Amy Harmon and Robert Pear, *Canada Overrides Patent for Cipro to Treat Anthrax*, NEW YORK TIMES, Oct. 19, 2001, at A1.

⁵¹ Jill Carroll, Vanessa Fuhrmans, and Joel Baglone, *Questions of Security: Bayer Nears Pact to Sell to Government Anthrax Drug Cipro at Discount Price*, WALL ST. J., Oct. 24, 2001.

⁵² Robert Portman, *Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress*, 4 U. BALT. INTEL. PROP. J. 91, 99 (1996).

⁵³ *Morton v. New York Eye Infirmary*, 17 F. Cas. 879 (S.D.N.Y. 1862) (No. 9,865).

administered in incremental doses, the person would feel no pain.⁵⁴ The court held that the newly discovered use for the ether was not patentable, because "the natural functions of a person or animal was an essential part of the method claimed."⁵⁵ In order to be patentable, the discovery or invention had to fall within the statutory definition of patentable subject matter, including "an art, machine, manufacture, or composition of matter," or, it had to be an improvement on any but the first.⁵⁶ In 1883 in the case of *Ex parte Brinkerhoff*, the patent office rejected a patent application for a method of treating hemorrhoids by surgery, and held that patents could not be granted for methods of treating disease.⁵⁷

In a pivotal case in 1954, the Board of Patent Appeals opened the door to patents on medical methods.⁵⁸ But it was not until the past decade in the United States that an infringement suit was litigated by a physician against another physician for using a patented medical procedure.⁵⁹ In that case, Dr. Samuel Pallin patented a method for performing cataract surgery and, in 1995, sued Dr. Jack Singer for using the technique without paying a royalty.⁶⁰ As a result of Dr. Pallin's action, the American Medical Association amended its Code of Ethics to forbid doctors from patenting medical procedures⁶¹ because it found that these patents compromised patient care.⁶² The implications of such patents are troubling. Say a doctor patents the procedure for appendectomies. Not wanting to pay a high royalty fee to use that procedure, another doctor might use a less safe surgical procedure on a patient rather than risk infringing the patent.

⁵⁴ *Id.* at 883.

⁵⁵ *Id.* at 884.

⁵⁶ *Id.* at 882.

⁵⁷ *Ex parte Brinkerhoff*, 24 Dec. Comm'r Pat. 349 (1883). An additional rationale for denying the patent was that surgical instruments used to perform the surgery had already been patented, and to patent the method would involve granting a second patent on the instruments. *Id.*

⁵⁸ *Ex parte Scherer*, 103 U.S.P.Q. 107, 110 (Bd. Pat. Apps. & Interfs., 1954).

⁵⁹ Portman, *supra* note 52, at 91.

⁶⁰ *Pallin v. Singer*, 36 U.S.P.Q.2d 1050 (D. Vt. 1995). The case was settled with a career judgment barring Dr. Pallin from enforcing the patent.

⁶¹ AMERICAN MEDICAL ASSOCIATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CODE OF MEDICAL ETHICS, *Patenting of Medical Procedures*, § 9.095 (2000-2001).

⁶² Eric M. Lee, 35 U.S.C. § 287(c)—*The Physician Immunity Statute*, 79 J. PAT & TRADEMARK OFF. SOC'Y 701, 703 (1997).

Responding to the concerns raised by patients and by the medical profession, Congress in 1996 created an exception in the patent law so that health care providers are not subject to patent infringement suits when they use a patented medical or surgical technique.⁶³

Courts also take public health seriously when being asked to enforce patents. In *City of Milwaukee v. Activated Sludge, Inc.*, the patentee had patented a process for treating sewage and sought an injunction to close down a municipal sewage treatment facility on the grounds of patent infringement. The Seventh Circuit refused to issue the injunction. The court specifically noted that “where, as here, the health and the lives of more than a half million people are involved, we think no risk should be taken”⁶⁴ The court was concerned that, while both parties had strong equities, “there are many others who are indirectly concerned whose equities are even stronger than those of the parties.”⁶⁵ Such will be the case whenever there is a patent affecting the public health.

B. International Concerns About Health Care Patents

Internationally, patents related to health care are also subject to scrutiny to assure that the public’s welfare is protected. When the U.S. Congress decided to exempt physicians using patented medical procedures from patent infringement suits, at least eighty other countries already had such an exemption.⁶⁶ In fact, internationally, the exemption is much broader than in the United States.⁶⁷

Until recently, many other countries did not even provide intellectual property protection to medicines and other pharmaceutical products.⁶⁸ Some developing countries had short periods of

⁶³ 35 U.S.C. § 287(c) (2002).

⁶⁴ *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934).

⁶⁵ *Id.*

⁶⁶ SETH SHULMAN, *OWNING THE FUTURE* 41 (Boston: Houghton-Mifflin 1999). In addition, the European Patent Convention exempts from patent protection methods for treatment by surgery or therapy and diagnostic methods practiced on the human body. Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, art. 52(4), 13 I.L.M. 268, 285-86 (1974) [hereinafter European Patent Convention].

⁶⁷ The U.S. exemption is narrower because the biotech industry was able to get an exception to the exemption. 35 U.S.C. § 287(c)(2)(A) (2002) provides that medical practitioners shall be exempt from patents on medical activities but not on the “practice of a process in violation of a biotechnology patent.”

⁶⁸ Mariana Williams, *The TRIPS and Public Health Debate: An Overview*, International Gender and Trade Network, August 2001, available at <http://www.genderandtrade.net/WTO/TRIPS%20and%20Public%20Health.pdf>.

protection for such products (such as three years of patent protection in Thailand) in order to allow health needs to be met by rapid introduction of generic drugs.⁶⁹

The Trade-Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organization, promulgated in 1995, requires all of its international signatories to agree to provide a twenty year intellectual property protection to inventions (including ones related to health care). But even TRIPS highlights how public health can be given greater weight than the commercial concerns of patentees. Article 27 of TRIPS specifically allows governments to exclude from patentability diagnostic, therapeutic, or surgical methods. It also allows them to deny patentability of a particular invention on grounds of *ordre public* (roughly translated, the "public interest") in order to protect human life or health. Article 8 of TRIPS allows governments to take public health concerns into consideration within their national intellectual property laws. Article 31 allows governments to ignore health care patents under certain situations and grant compulsory licenses to third parties to produce a generic version of a health care product. Under TRIPS, patents can be ignored in a public health emergency. When the South African government passed the Medicines and Related Substances Control Act in December 1997 authorizing compulsory licensing of drugs, forty drug makers initiated a lawsuit to overturn the act.⁷⁰ Subsequently, the drug companies agreed that the law could be enforced, dropped the legal challenge, and negotiated to sell their products at a lower cost.⁷¹

The U.N. Human Rights Commission in April 2001 urged all states to ensure that "the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceutical and mechanical technologies."⁷²

⁶⁹ *Id.*

⁷⁰ Helene Cooper, Rachel Zimmerman and Laurie McGinley, *Patents Pending: AIDS Epidemic Traps Drug Firms in a Vice: Treatment vs. Profits*, WALL ST. J., March 2, 2001, at A1.

⁷¹ Ann M. Simmons, *Suit Against Cheap AIDS Drugs Ends in South Africa*, LOS ANGELES TIMES, April 20, 2001, at A1.

⁷² *Access to Medication in the Context of Pandemics Such as HIV/AIDS*, United Nations Commission on Human Rights Resolution 2001/33, 71st meeting, April 23, 2001.

C. Why Drug Patenting is Not the Appropriate Analogy

Although historically and globally, governments have been cautious about granting patents in the health care arena, patents have been central to the development of new drugs. Proponents of gene patents have tried to justify such patents by claiming that the arguments in favor of patenting drugs apply to patenting genes as well. However, drug development requires a greater economic incentive than does gene discovery and there are fewer social, economic, and public health costs of granting a drug patent than a gene patent.

The pharmaceutical industry argues that patent protection of drugs is necessary to attract the capital necessary to compensate for the creation and testing of new drugs. The cost of bringing a drug to market is estimated to be \$802 million.⁷³ That price includes many expenditures—such as the salaries for research and development scientists, the great expense of animal research and human clinical trials, and the cost of obtaining FDA approval. It also includes the costs associated with failed discoveries—drugs that were initially developed but rejected before, during, or after clinical trials.

The discovery of genes does not require the same incentives as drug development. Molecular biologists were attempting to identify genes long before the U.S. Patent and Trademark Office made clear that genes could be patented. Moreover, there are no expensive clinical trials when a gene is discovered and knowledge about the sequence of the gene is used to identify whether a particular patient has a mutation in that gene. In some cases, a disease gene has been identified one day and testing begun almost immediately. Because the FDA does not regulate the clinical services of genetic tests⁷⁴ (as opposed to the sale of genetic diagnostic kits or gene therapies), there is no costly FDA approval process. Thus, the need to financially compensate a gene-discoverer is not as great as the need to compensate the developer of a drug that must take it through costly clinical trials, with only a small number of drugs actually becoming commercially-viable products.

Gene patents do not seem necessary to encourage technology transfer in the move from gene discovery to the availability of a ge-

⁷³ Tufts Center for the Study of Drug Development *Pegs Cost of a New Prescription Medicine at \$802 million*, TUFTS CENTER NEWS RELEASE, Nov. 30, 2001; see also *R & D Costs Are Staggering*, MED. AD. NEWS, Feb. 1, 2002, at 16.

⁷⁴ LORI ANDREWS, *FUTURE PERFECT: CONFRONTING DECISIONS ABOUT GENETICS* 126 (Columbia University Press 2001).

netic diagnostic test. A group of medical organizations points out, "Most discoveries of pathogen or human disease genes can be effectively translated into genetic tests without recourse to the incentives provided by patents or exclusive license agreements."⁷⁵ As soon as information about the discovery of the hemochromatosis gene was published, laboratories began testing for mutations in the gene. After a patent on the gene was granted seventeen months later, 30% of the 119 U.S. laboratories surveyed reported discontinuing or not developing a genetic test for the disease.⁷⁶ The patent holder was asking for an up-front fee of \$25,000 from academic laboratories and as much as \$250,000 from commercial laboratories, plus a fee of \$20 per test.⁷⁷ The patent interfered with clinical adoption of the test and potentially compromised the quality of testing by limiting the development of higher quality or lower cost alternative testing methods.⁷⁸

As opposed to the development of drugs, which is undertaken primarily with private funds (for which investors expect a commercial return), the discovery of genes has been undertaken with vast quantities of public funds. Over \$1.8 billion of taxpayer money was spent by the U.S. government and non-profit institutions on genomics in the year 2000 alone.⁷⁹ Even the private company that made its own efforts to sequence the human genome, Celera, used sequence data from the publicly-funded project in its sequencing.⁸⁰ "The basic research that yields discoveries of genetic associations with disease have been underwritten by the public," notes bioethicist Jon Merz.⁸¹ The public increasingly feels it is paying twice for research—once to fund the research, and then to the biotech companies mining this taxpayer-funded research for genes to patent.

Moreover, there are fewer downsides to granting a patent on a drug or a medical device than granting a patent on a gene. Other researchers can create alternatives to drugs and devices. There are

⁷⁵ ASSOCIATION FOR MOLECULAR PATHOLOGY, *supra* note 8.

⁷⁶ Jon F. Merz, Antigone G. Kriss, Debra G. B. Leonard, and Mildred K. Cho, *Diagnostic Testing Fails the Test* [hereinafter Merz et al., *Diagnostic Testing*], 415 NATURE 577, 577-79 (2002).

⁷⁷ *Id.* at 578.

⁷⁸ *Id.* at 579.

⁷⁹ See the excellent website created by Stanford in Washington students at <http://www.stanford.edu/class/siw198q/websites/genomics/entry.htm>.

⁸⁰ Ronald Rosenberg, *Biotechnology, Questions Still Linger on Heart Study Access; Private Industry's Right to Use Publicly Funded Data for Profit Remains at Issue*, BOSTON GLOBE, Feb. 21, 2001, at D4.

⁸¹ Merz et al., *Bad Innovation*, *supra* note 44, at 301.

no alternatives to the patented human genes in genetic diagnosis and gene therapy.

IV. THE IMPACT OF GENE PATENTS

The very exclusivity of a patent, the monopoly power of its holder, has created problems in the medical and scientific realms. For twenty years, a gene patent holder controls *any* use of “its” gene.⁸² The patent holder can prevent a doctor from testing a patient’s blood to see if the patient has that gene. The patent holder can prevent anyone else from doing research to improve a genetic test or to develop a gene therapy based on that gene. Policymakers around the world are now questioning whether the incentive of a patent is necessary for gene discovery and whether the benefits of such patents are worth the potential harm to the research enterprise and to public health.

A. Gene Patents as Impediments to Research

When the Human Genome Project proposed to spend \$3 billion of taxpayer money to identify and sequence the entire human genome most biological scientists did not expect to own the genes they studied.⁸³ Because obtaining a gene patent seemed inconceivable at that time, Nobel laureate Walter Gilbert devised a scheme to copyright DNA.⁸⁴ Just as one would copyright a book, his plan was to own the CATTAGTA . . . , etc., sequence and charge a fee each time anyone wanted to find out which sequences corresponded to which genes.⁸⁵ His idea never came to fruition.⁸⁶ Other prominent researchers in genetics, such as C. Thomas Caskey, then at Baylor University and Leroy Hood, then at Cal Tech, cautioned that scientists would be less likely to share material or information if they were allowed to patent intellectual property rights over genes and reap financial rewards.⁸⁷ The predicted problems have indeed come to pass. Research to identify the genes responsible for diseases is

⁸² 35 U.S.C. § 154 (2002).

⁸³ LORI ANDREWS AND DOROTHY NELKIN, *BODY BAZAAR* 49 (Crown Publishers 2001) (citation omitted). In actuality, some scientists were applying for gene patents, but were discreet enough in their actions that few people realized what was happening. *Id.* at n.37.

⁸⁴ Leslie Roberts, *Who Owns the Human Genome?*, 237 *SCI.* 358 (1987).

⁸⁵ *Id.*

⁸⁶ ANDREWS AND NELKIN, *supra* note 83, at 49.

⁸⁷ *Id.* See also Roberts, *supra* note 84.

being impeded by the possibility of gene patents.⁸⁸ Progress in the search for a gene related to autism was impeded because certain researchers were hoarding patients' tissue samples.⁸⁹ They each wanted to be the first one to find the gene and gain commercially.⁹⁰

Researchers may delay publishing their findings about a gene until they attempt to secure patent rights.⁹¹ For example, the scientific report of the discovery of the hemachromatosis gene was submitted for publication over a year after the patent on the gene was filed.⁹² Various studies underscore how commercial incentives to academic genetic scientists can delay the dissemination of scientific information by those scientists. Academic researchers with funds from companies are four times as likely as those without such funds to report that trade secrets had resulted from their research.⁹³ Rates of publication decline as the proportion of the research funded by industry increases. The most productive and entrepreneurial faculty are most likely to withhold data.

One of every five medical scientists in one survey had delayed publication of research results for at least half a year in order to protect financial interests.⁹⁴ Those scientists who were directly engaged in the commercialization of their research were three times more likely to delay publication and twice as likely to refuse to share information than those who were doing basic work.⁹⁵ Among the life scientists, geneticists were the most likely to withhold data.⁹⁶

Collaboration is being stifled as well. A 2002 study found that forty-seven percent of geneticists surveyed had been denied requests from other faculty members for information, data, or materials regarding published research.⁹⁷ When geneticists were asked

⁸⁸ Eliot Marshall, *Whose DNA Is It Anyway?*, 278 Sci. 564, 564 (1997).

⁸⁹ *Id.*

⁹⁰ See generally *id.* (recognizing that the rush to be first to achieve commercial success results in a fear that the quality of the work may suffer).

⁹¹ See generally Merz et al., *Diagnostic Testing*, *supra* note 76 (reporting that in their survey, researchers decreased research efforts because of issues pertaining to patents on medical procedures).

⁹² *Id.* at 578.

⁹³ David Blumenthal et al., *University-Industry Research Relationships in Biotechnology*, 232 Sci. 1361, 1362 (1986).

⁹⁴ David Blumenthal et al., *Withholding Research Results in Academic Life Sciences*, 277 JAMA 1224, 1224 (1997).

⁹⁵ *Id.* at 1226-27.

⁹⁶ *Id.* at 1227-28.

⁹⁷ David Blumenthal et al., *Data Withholding in Academic Genetics*, 473 JAMA 473, 477 (2002).

why they intentionally withheld data, more than twenty percent listed the need to protect the commercial value of their results.⁹⁸ Even more troubling is the finding that twenty-eight percent of geneticists surveyed reported that they were unable to duplicate published research because other academic scientists refused to share information, data, or materials.⁹⁹

B. The Problem of Verification

Once genes are located and patented, research may be further impeded.¹⁰⁰ The patent examiner has to take what the applicant says as correct, and there is no FDA review when a company offers a genetic test as a service.¹⁰¹ If a patent holder states that one in three people in the population have the gene related to its patent, patent rights allow the holder to prevent others from duplicating the patent holder's research and evaluating it. In one survey, fourteen out of twenty-seven gene patent holders said they would require a license for researchers to study the prevalence of mutations in the gene in the population.¹⁰² Even if the patent holder allows research by other scientists, the licensing costs may prevent other researchers from doing the necessary epidemiological studies to determine, for example, what proportion of people with the mutation in the general population will actually manifest the disease. Some entities offering genetic testing exaggerate the prevalence of the disease, possibly to scare people into being tested.¹⁰³ The researchers discovering and patenting genes have financial incentive to promote the use of those genes for diagnostics as rapidly as possible, and often

⁹⁸ *Id.* at 478.

⁹⁹ *Id.*

¹⁰⁰ See, e.g., Kimberly Blanton, *Corporate Takeover*, BOSTON GLOBE MAGAZINE, Feb. 24, 2002 (describing instances in which genetic researchers were thwarted by a gene patent holder).

¹⁰¹ See generally ANDREWS, *FUTURE PERFECT*, *supra* note 74, at 113, 169 (citation omitted) (discussing how the FDA has the power to regulate genetic testing kits marketed for interstate commerce; however, academic, hospital, government, and commercial organizations create "home brews" that are made of their own genetic research). In a survey from 1995, out of forty-three biotech companies and 215 not-for-profit organizations that marketed their own testing kits, only around fifteen percent contacted the FDA. *Id.* Additionally, the FDA concedes that even though it does have the authority to regulate "home brew" kits, it is still not pursuing them in any manner. *Id.*

¹⁰² Timothy Caulfield et al., *Patenting Human Genetic Material: Refocusing the Debate*, 1 NATURE REVIEWS 227, 230 (2000) (citation omitted).

¹⁰³ ANDREWS, *FUTURE PERFECT*, *supra* note 74, at 125 (stating that when the genetic tests for breast cancer were first offered, one out of the four institutions studied greatly exaggerated the occurrence of the disease).

before sufficient data is available to assess how well the tests predict future disease.

A similar conundrum is occurring with forensic DNA testing. Courts that were first asked to admit forensic DNA testing as evidence sometimes had trouble judging its merits because the testing was developed proprietarily by companies, and all the scientific articles about the tests were written by company employees.¹⁰⁴ An independent evaluation of the merits of DNA identification methods was not available.¹⁰⁵ Chief Judge Judith S. Kaye of the Court of Appeals New York pointed out, "DNA forensic analysis was developed in commercial laboratories under conditions of secrecy, preventing emergence of independent views. No independent academic or governmental laboratories were publishing studies concerning forensic use of DNA profiling."¹⁰⁶ It would be easy for a court to mistakenly think that the technique was uniformly accepted by the scientific community, rather than that it had never been independently assessed.¹⁰⁷

In a 2000 unpublished Vermont district court decision, *State v. Pfenning*,¹⁰⁸ the trial court refused to admit a new type of DNA forensic test that assessed six genetic loci. The test was marketed as a kit, and the manufacturer had refused to publish the primers used in the PCR technique, claiming they were trade secrets.¹⁰⁹ This prevented others from assessing the reliability of the technique and led to a decision not to admit the evidence of a match to defendant's DNA.¹¹⁰ The *Pfenning* court stated:

[T]he failure of the manufacturers of DNA testing systems to disclose the primer sequences they have created to permit amplification of DNA is problematic from the perspective of scientific knowledge and, consequently, validation. It is more than problematic, it is anti-scientific in that it inhibits the ability of scientists in the field (including defense experts) to test the manufacturers' claims. . . . The manufacturer's proprietary concerns . . . cannot trump Defendant's right to a fair trial, which includes the right to have only scientifically validated evidence admitted for the jury to consider in the State's case against him. Especially, with a new test,

¹⁰⁴ *People v. Wesley*, 633 N.E.2d 451, 463 (N.Y. 1994) (Kaye, C.J., concurring).

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 464.

¹⁰⁷ *Id.* at 463-64.

¹⁰⁸ No. 57-4-96 GiCr 1, 49 (Apr. 6, 2000), available at <http://scientific.org/distribution/archive/pfenning.pdf>.

¹⁰⁹ *Id.* at 49.

¹¹⁰ *Id.*

which has not been validated by long use in a variety of settings with a variety of sample types, it is unacceptable to deny independent scientists (including defense experts) access to primer sequences, which could allow the scientists to properly investigate the purported reliability and validity of the new technique.¹¹¹

C. The Problem of Multiple Rightsholders

"The essence of science is cumulative investigation combined with hypothesis testing," notes Berkeley economist Carl Shapiro.¹¹² "As Sir Isaac Newton put it, each scientist 'stands on the shoulders of giants' to reach new heights."¹¹³ But, if a scientist had to pay a fee to every scientist who came before, progress may be blocked rather than enabled.

The patentability of small sections of genes such as Express Sequence Tags (ESTs) leads to a plethora of negotiations before research can be undertaken.¹¹⁴ When the U.S. Patent and Trademark Office first considered a proposal to patent ESTs in 1993, patent officials applied the traditional technical requirements for a patent of novelty, nonobviousness, and usefulness and found the NIH patent application fell short on all three.¹¹⁵

Gene sequencing researchers continued to file patent applications on ESTs, but became more savvy about how they referred to these partial sequences in their applications. They pointed out how the partial gene sequences could be useful as a marker to locate the full gene or as a unit of analysis to understand evolution.¹¹⁶ In 1997, the U.S. Patent and Trademark Office surprised many by announcing that it would grant patents for ESTs where novelty, non-obviousness, and utility were proven.¹¹⁷ By that time, patent applications for over a half million partial gene sequences were pending.¹¹⁸ By

¹¹¹ *Id.* at 49, 52-53.

¹¹² Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard-Setting*, INNOVATION POLICY AND THE ECONOMY, Volume I, 119-50, 119 (Adam Jaffe, Joshua Lerner and Scott Stern eds., MIT Press 2001), available at <http://www.haas.berkeley.edu/~shapiro/thicket.pdf>.

¹¹³ *Id.* at 119-20.

¹¹⁴ Donald L. Zuhn, Jr., *DNA Patentability: Shutting the Door to the Utility Requirement*, 34 J. MARSHALL L. REV. 973, 981 (2001).

¹¹⁵ See *id.* at 981-82 & n.57 (citing Leslie Roberts, *Gene Patents: Rumors Fly Over Rejection of NIH Claim*, 257 SCI. 1855, 1855 (1992)).

¹¹⁶ Tim Friend, *Deciphering the Genetic Code*, USA TODAY, Sept. 28, 1995, at 1D.

¹¹⁷ Lynn Pasahow and Andrew Kumamoto, *Human Genome Project Raises Patenting Issues*, NAT'L L. J., Oct. 20, 1997, at C31.

¹¹⁸ Eliot Marshall, *Companies Rush to Patent DNA*, 275 SCI. 780, 780-81 (1997).

early 2000, a single company, Incyte Pharmaceuticals, Inc., had filed applications on 1.2 million partial gene fragments.¹¹⁹ Another company, Hyseq, had patents pending for 900,000 gene discoveries.¹²⁰ Researchers like those at Incyte and Hyseq are patenting smaller and smaller portions of genes, hoping that one or more of them, like a lottery ticket, will turn out to be valuable. Genetic researcher Leroy Hood responded to the PTO's decision to grant patents on ESTs by saying, "I am not surprised . . . but I am dismayed."¹²¹

The research vice president for the pharmaceutical giant Merck has found that the tangle of multiple ownership claims has threatened the company's ability to create new products.¹²² Similarly, Joseph Stiglitz, then Chairman of the Council of Economic Advisors, stated that

. . . some people jump . . . to the conclusion that the broader the patent rights are, the better it is for innovation, and that isn't always correct [T]he breadth and utilization of patent rights can be used not only to stifle competition, but also have adverse effects in the long run on innovation.¹²³

Michigan law Professors Michael Heller and Rebecca Eisenberg point out how patents can deter innovation in biomedical research: "A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development."¹²⁴ They likened the situation in genetics to that of post-socialist economies in Eastern Europe, where the expectation was that private stores would be loaded with goods once a free market was established. But the stores remained bare while street vendors flourished. The reason was that no individual could set up shop without collecting rights from workers' collectives, privatization agencies, and local, regional or federal governments. Similarly, with genetics, "privatization can go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research."¹²⁵ A researcher who wants to find a cure for breast cancer, for example, would have to negotiate

¹¹⁹ See Garber, *supra* note 9 (noting that the company had only been issued one patent at that time).

¹²⁰ *Id.*

¹²¹ *Gene Fragments Patentable*, Official Says, 275 Sci. 1055 (1997).

¹²² SHULMAN, *supra* note 66, at 147.

¹²³ Shapiro, *supra* note 112, at n.1. His statement was made early in the Federal Trade Commission's hearings on Competition Policy in the New High-Tech Global Marketplace.

¹²⁴ Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Sci. 698, 698-701 (1998).

¹²⁵ *Id.* at 698.

with not only the patent holder for the full BRCA1 and BRCA2 genes, but with all of the other patent holders who had discovered and patented any of the hundreds of other mutations in that gene.

Any one of the patent holders could derail the process. For example, if a particular patent holder wanted to be the entity to find a gene therapy for the disease at issue and did not want any other researcher to have that chance, that patent holder could refuse to negotiate. Even if the holders of genetic samples were willing to allow others to use them, access to databases of genes and gene segments can be costly. Pfizer reportedly paid \$15.75 million to Incyte Pharmaceuticals for access to their DNA database¹²⁶ and SmithKline Beecham has paid \$125 million to Human Genome Sciences for access to its genetic information.¹²⁷

Economist Carl Shapiro elaborates on the problems created by a "patent thicket."¹²⁸ Using traditional economic analysis, he demonstrates how, when there exist multiple monopolists controlling various components of a product, the price of the resulting product is higher than if a single firm controlled all the inputs.¹²⁹ Yet the combined profits of the producers are lower in the presence of complementary monopolies. Thus, if there are a number of patent holders whose permission is needed to create a gene therapy, and any one of them could block the production of the gene therapy, inefficiencies in the market are created which potentially harm both the patent holder and the users of gene therapy.

The United States National Institutes of Health (NIH) raised similar concerns: "Proprietary rights in research tools that do not require further development may function more as a tax on commercial development than as a source of rights to preserve the viability of end products and to motivate further investment."¹³⁰ As a result, the NIH has proposed guidelines to foster sharing—without undue restrictions—of cell lines, proteins, monoclonal antibodies, and other biological research tools created with NIH funds.¹³¹

¹²⁶ *Corporate Agreements*, BIOVENTURE VIEW, Aug./Sept. 1994, at 19.

¹²⁷ Brian O'Reilly, *There's Still Gold In Them Thar Pills*, FORTUNE, July 23, 2001, at 58, 68.

¹²⁸ Shapiro, *supra* note 112.

¹²⁹ *Id.* (relating the historical example of brass producers who had to purchase copper and zinc for their product, both of which were controlled by a monopolist). The required purchasing from monopolists drove up the final cost of brass.

¹³⁰ Principles of Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Resources, 64 Fed. Reg. 28205, 28206 (May 25, 1999).

¹³¹ *Id.* at 28206-07.

The United States does not have an explicit research exception in its patent law that would allow basic research to progress without requiring patent permissions.¹³² In contrast, European patent law allows researchers in both commercial and noncommercial settings to use a patent invention in their research without violating the patent.¹³³ Japan's patent law has a broad exemption to allow researchers to use patented inventions in their research, and this has not diminished Japan's strong biotechnology sector.¹³⁴

D. The Problem of Submarine Patents

It sometimes takes years or even decades for a patent application to work its way through the patent office and be granted.¹³⁵ Meanwhile, another researcher may have independently discovered the same genetic sequence and may have developed a treatment or pharmacogenomic test based on that sequence. When the original patent application is granted, known as a "submarine patent," its owner can prohibit the second researcher from making its test or treatment available; alternatively, the owner can require a hefty licensing fee from the subsequent researcher.¹³⁶

The problem of submarine patents in the gene patent arena is particularly vexing when scientists and companies get patents on gene sequences without knowing fully the functions of the sequences. Other researchers who develop treatments related to that sequence can be blocked from producing that treatment by the patent holder.

¹³² Caulfield et al., *supra* note 102, at 229; see also Eisenberg, *supra* note 15, at 1018-19.

¹³³ Eisenberg, *supra* note 15, at 1018-19, n.6.

¹³⁴ See Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 39 (2001) (discussing the fact that Japan's law, in contrast to that of the United States, allows a great deal of leeway for experimental use of patented inventions); see also Yamada Kenji, *Business Trends for an Aging Society*, J. JAPANESE TRADE & INDUS., May 1, 2002 (describing biotechnology as one of fifteen growth areas designated by Japan's government to help create jobs and new markets in the next decade).

¹³⁵ Shapiro, *supra* note 112, at 121.

¹³⁶ See Steven Blount, *The Use of Delaying Tactics to Obtain Submarine Patents and Amend Around a Patent that a Competitor Has Designed Around*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 11, 13 (1999). The submarine patent is filed with broad claims and continuous amendments are then filed to hold the patent in the patent office. When an individual later tries to use the idea contained in the patent, the inventor will demand royalties or threaten to file a lawsuit.

Along those lines, Human Genome Sciences filed for a patent on a genetic sequence related to a receptor.¹³⁷ While the application was making its way through the patent system, AIDS researchers were undertaking detailed research on a receptor known as the CCR5 receptor, which had been found to be critical for HIV infection. In humans, the CCR5 gene normally produces a protein used by the HIV virus to enter cells and infect its victims.¹³⁸ People who lack both copies of the gene for the receptor strongly resist HIV infection, and those who have just one copy or damaged copies become infected much more slowly.¹³⁹

On February 15, 2000, Human Genome Sciences (HGS) of Rockville, Maryland was issued U.S. Patent No. 6,025,154 for "Polynucleotides encoding human G-protein chemokine receptor HDGNR10."¹⁴⁰ The patent covers all possible embodiments associated with the receptor, "including all DNA and amino acid sequences corresponding to the receptor or virtually any portion thereof, and any process for making, using or administering the receptor, including diagnostic assays."¹⁴¹ It turned out that the receptor for which HGS had been granted the gene patent was the CCR5 receptor. Even though the patent applicant was unaware that there was a connection between the claimed gene and AIDS susceptibility,¹⁴² it gained exclusive rights to the gene.¹⁴³ Despite the lack of disclosure as to the protein function, Human Genome Sciences was effectively granted a complete right to require a licensing fee for any diagnostic technique or therapy utilizing the CCR5 gene created by anyone else.

The biggest outcry came from researchers at the NIH who had been examining the CCR5 receptor since early 1996 as having a

¹³⁷ Pat Carson and Melissa Mandrgoc, *Gene-Based Drugs Challenge Patent Process*, 226 N.Y. L.J. 73 Oct. 15, 2001; see also Arthur Allen, *Who Owns My Disease?*, 26 MOTHER JONES 52, Nov. 1, 2001.

¹³⁸ See Nathan Seppa, *Anti-HIV Mutation Poses Hepatitis Risk*, SCI. NEWS, Feb. 24, 2001 (discussing how a mutated CCR5 creates a defective receptor protein so that HIV is unable to enter and attack the cell).

¹³⁹ *Biotech Firm Patents Key HIV Gene*, REUTERS, Feb. 16, 2002, available at <http://www.wired.com/news/print/0,1294,34386,00.html>.

¹⁴⁰ U.S. Patent No. 6,025,154.

¹⁴¹ Carson and Mandrgoc, *supra* note 137.

¹⁴² 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, 1625 (2001).

¹⁴³ Carson and Mandrgoc, *supra* note 137 at 73; see also Allen, *supra* note 137, at 6.

function as a co-receptor in binding the HIV virus.¹⁴⁴ Because HGS had been granted the patent that covered practically all possible applications of the CCR5 gene, NIH could be excluded from research on CCR5 function and use in HIV treatments.¹⁴⁵

The saga of the CCR5 receptor emphasizes that patents are awarded too early in the scientific process, creating a disincentive for the further research necessary to actually provide a health benefit. In some instances, the patent not only confers rights over the gene mutations the patent applicant discovered, but also gives the patent holder rights over any other mutations later discovered by other researchers.¹⁴⁶ In other instances, patents have been granted on all methods of comparing a high risk individual's sequence to a known normal sequence, even though the patent has only described one method.¹⁴⁷ Such patents seem to contravene the holding of the U.S. Supreme Court in *Brenner v. Manson*, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."¹⁴⁸ The *Brenner* court underscored the need to show a specific utility for the patented invention because otherwise "a patent may confer power to block off whole areas of scientific development, without compensating benefits to the public."¹⁴⁹

A British geneticist, Peter Goodfellow, then Professor of Genetics at Cambridge University, argued,

[T]his should not be an ethical debate, but a debate over trade . . . If you allow the Americans to gain patents that cover vast stretches of the entire human genome, the economic consequences could be disastrous. I work on sex determination. There is a group in the U.S. that has applied for a patent on the whole Y chromosome, so if I were to try to claim anything I would be subject to their ownership.¹⁵⁰

¹⁴⁴ Carson and Mandrgoc, *supra* note 137.

¹⁴⁵ *Id.*

¹⁴⁶ See, e.g., U.S. Patent 5,679,635 (issued Oct. 21, 1997), *Aspartoacylase Gene Protein, Methods of Screening for Mutations Associated with Canavan Disease*.

¹⁴⁷ See European Patent 699754 (issued Mar. 6, 1996), *Method for Diagnosing a Predisposition for Breast and Ovarian Cancer* (stating that Claim 1 is for a method of diagnosing a predisposition to breast and ovarian cancer by comparing an individual's BRCA1 gene sequence to that covered by the patent).

¹⁴⁸ *Brenner v. Manson*, 383 U.S. 519, 536 (1966) (holding that the question of patentability of a product must be cleared before any interference can be declared).

¹⁴⁹ *Id.* at 534 (citation omitted).

¹⁵⁰ Susan Watts, *The Genetic Goldrush*, THE INDEPENDENT, Apr. 27, 1994, at 21.

E. Health Care Concerns About Gene Patents

Gene patents can impede the delivery of health care services in several ways. Because a patent holder has the power to prevent any other entity from testing for a particular disease gene, concerns are raised about the quality of the testing and the potential for access.

Like many gene patent holders, the company holding the exclusive license on a gene associated with Alzheimer's disease will not let any laboratory except its own perform the test.¹⁵¹ Doctors and labs across the country face a lawsuit if they try to determine whether one of their patients has the genetic form of Alzheimer's, even though testing can easily be done by anyone who knows the gene sequence without using any product or device made by the patent holder.

Various mutations in the same gene can cause a particular disease.¹⁵² But companies that do not let anyone else test for "their" gene make it more difficult to find mutations than if many laboratories were testing. In countries where the Alzheimer's gene and hemochromatosis gene were *not* patented, researchers found previously unknown mutations.¹⁵³ These mutations can be used to diagnose people who would not otherwise be diagnosed.

The U.S. company Myriad Genetics was granted a European patent related to the BRCA1 breast cancer gene.¹⁵⁴ The patent, EP 699754, covers all methods for diagnosing breast cancer by comparing a patient's gene to the gene sequence that Myriad describes in its patent.¹⁵⁵ Myriad is now asserting that no French doctor or scientist should be allowed to test for BRCA1 breast cancer gene mutations; instead, the company requires that all samples be sent to Myriad's lab.¹⁵⁶ French physicians, though, are concerned that such a mandate compromises patient care. They allege that Myriad's test

¹⁵¹ Julian Borger, *Rush to Patent Genes Stalls Cures for Disease*, THE GUARDIAN (London), Dec. 5, 1999, at 1; see also Andrea Knox, *The Great Gene Grab: Firms Toss Researchers for a Loop*, PHILADELPHIA INQUIRER, Feb. 13, 2000, at A1 (describing how Athena Diagnostics of Worcester, Massachusetts, charges twice as much as a hospital would for Alzheimer's gene testing).

¹⁵² Francis S. Collins, *BRCA1—Lots of Mutations, Lots of Dilemmas*, 334 N. ENGL. J. MED. 186-88 (1996).

¹⁵³ Knox, *supra* note 151, at A8.

¹⁵⁴ Butler and Goodman, *supra* note 5 (reporting that the Utah-based Myriad Genetics obtained its European patent in 2001 after obtaining its U.S. patent in 1999).

¹⁵⁵ *Id.*

¹⁵⁶ Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT'L. CANCER INST. 80, 80 (2002).

only assesses 10% to 20% of the potential mutations in the gene.¹⁵⁷ In fact, a French physician was able to find a mutation in an American family that the Myriad test missed.¹⁵⁸ Critics assert that the patent on the BRCA1 breast cancer gene is just too broad. It is as if a company patented the generic invention "car" and then required all drivers to buy the car that company manufactured—perhaps an unsafe Pinto.

The French Institut Curie also points out that,

The 'compulsory' sending to Myriad of DNA samples obtained from high risk individuals will help the U.S. corporation build up *the only genetic data bank in the world*. This in turn will grant it unchallenged control over the main research materials concerning genes coding for breast and ovarian cancer predisposition, thereby allowing it to make further discoveries and ultimately filing further patent applications as a result of such discoveries.¹⁵⁹

Companies now sequence disease-causing bacteria and virus genes, but this may lead to wasteful duplication because some researchers may attempt to uncover the same sequence not knowing that someone else is quietly patenting it. This occurrence may prevent other companies from undertaking the research necessary for development of a cure. "Why should anyone own the genetic sequence of a natural microorganism?" asks Tufts University Professor Sheldon Krimsky.¹⁶⁰ "Pharmaceutical companies can now exercise property ownership over both the drug to treat a disease and the microorganism that causes it."¹⁶¹ If a company wants to introduce inexpensive, quick public health testing for a common infectious disease, the company holding the patent on the infectious disease can forbid it. The holder of the patent on the infectious disease can require that everyone use its more expensive test.

¹⁵⁷ Butler and Goodman, *supra* note 5.

¹⁵⁸ Sophie Gad et al., *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. MED. GENETICS 388 (2001) (stating that no "BRCA1 or BRCA2 gene mutation was identified by direct DNA sequencing" on an individual who had a high probability of carrying the genetic mutation).

¹⁵⁹ THE CURIE INSTITUTE, PRESS RELEASE, *Against Myriad Genetics's Monopoly on Tests for Predisposition to Breast and Ovarian Cancer, the Institut Curie is Initiating an Opposition Procedure with the European Patent Office*, Sept. 12, 2001, available at <http://www.curie.net/actualites.cfm>.

¹⁶⁰ Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15, 36 (1999) (discussing the harmful effects on research and development if one owned or patented a genetic sequence).

¹⁶¹ *Id.* (predicting that the phenomenon of "owning" a natural sequence can threaten the future of public health medicine).

Gene patents also hamper pharmacogenomics.¹⁶² Most drugs only work on a percentage of patients who use them.¹⁶³ Genetic testing can help distinguish those patients for whom a drug will work from those for whom it will not, but such tests will also limit the market for drugs. For example, a pharmaceutical company has filed for a patent on a genetic test to determine the effectiveness of one of its drugs.¹⁶⁴ But the company says it will not develop the test, or let anyone else develop it.¹⁶⁵ Such a test would cause the company to lose customers.

F. Accessibility of Genetic Tests

The cost of patented tests raises health care concerns as well. The province of British Columbia discontinued paying for genetic breast cancer testing because the health care system there could not afford what Myriad was charging.¹⁶⁶ Geneticists in Canada and in France can offer genetic tests for breast cancer at a lower cost than the \$3,850 (in Canadian dollars) charged by Myriad (which, under its gene patent, requires that samples be sent to its laboratories for testing).¹⁶⁷ In some situations, the very people whose genes were patented may not be able to afford the test that was created using their bodily material, or may find that a company has decided to quash entirely a test related to their condition. This is not a mere fiscal issue, but translates into potential harm to patients. This is true in the case of the patented Canavan gene. Canavan disease is a rare genetic disease that occurs most frequently in Ashkenazi Jewish families and leads to a degeneration of the brain, causing the children to lose their vision, experience seizures, and eventually require

¹⁶² Geeta Anand, *Big Drug Makers Try to Postpone Custom Regimens*, WALL ST. J., June 18, 2001, at B1 (defining pharmacogenomics as "'personalized' medicine, in which doctors would prescribe drugs based on each person's genetic makeup").

¹⁶³ *Id.* The genetic differences in individuals influence the efficacy of the drugs that are used to treat them.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ David Hodges, *U.S. Firm Flexes Its Muscle Over CA Testing*, MED. POST, Sept. 11, 2001 (noting that hospitals in Canadian province British Columbia only had a hereditary cancer program budget of \$500,000, whereas performing the Myriad test alone would cost up to \$1.5 million).

¹⁶⁷ *Id.* (highlighting that Canadian physicians would be able to perform their own genetic breast cancer testing for one-third of the cost that Myriad charges were it not for the patent).

tube feeding.¹⁶⁸ They generally do not reach their teen years. Rabbi Josef Ekstein founded a large genetic testing program in New York that tested for Canavan disease.¹⁶⁹ When the holder of the patent on the gene began demanding a higher-than-usual royalty and attempted to prohibit all but a few labs from conducting the test, Rabbi Ekstein said: "If Canavan testing won't be available—which is how it looks if they enforce the patent—there's no question Canavan children will be born."¹⁷⁰

G. Impact of Gene Patents on the Doctor/Patient Relationship

Because of the ability of physician/researchers to patent genes, patients have become potential treasure troves to researchers seeking lucrative genes. When John Moore, a Seattle businessman, fell ill with hairy-cell leukemia, he went to a top specialist at the UCLA Medical Center.¹⁷¹ He followed his doctor's orders and underwent surgery to remove his spleen, in addition to other treatments.¹⁷² After surgery was completed, Moore returned to Seattle, yet continued to fly back to Los Angeles for tests over the next seven years.¹⁷³ Moore thought these visits were necessary to monitor his condition, and complied out of fear that the leukemia might reappear.¹⁷⁴ In reality, his physician was patenting certain unique chemicals in Moore's blood, as well as a gene isolated from Moore, and setting up contracts for cell line development with a Boston company.¹⁷⁵ Sandoz, the Swiss pharmaceutical company, paid a reported \$15 million for the right to develop the cell line taken from Moore — which the doctors had named the Mo-cell line.¹⁷⁶

¹⁶⁸ Reuben Matalon and Kimberlee Michals-Matalon, *Spongy Degeneration of the Brain, Canavan Disease: Biochemical and Molecular Findings*, FRONTIERS IN BIOSCIENCE 5, d. 307-311, March 1, 2000, available at <http://www.bioscience.org/2000/v5/d/matalon/fulltext.htm>.

¹⁶⁹ See Judy Peres, *Genetic Tests Reduce Neighborhood's Grief: Screening Stops Unwise Matches*, CHI. TRIB., Sept. 12, 1999, at 16.

¹⁷⁰ *Id.*

¹⁷¹ *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 480-81 (Cal. 1990).

¹⁷² *Id.* at 481.

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 481-82. Moore's lymphocytes were valuable because they "overproduced certain lymphokines, thus making corresponding genetic material easier to identify." *Id.* at 482 n.2.

¹⁷⁶ *Moore*, 793 P.2d. at 482. A cell line is important because primary cells, which are taken directly from the body, "reproduce a few times before dying, making them poor contend-

Moore began to suspect that his tissue was being used for purposes beyond his personal care when his UCLA doctor continued to take samples not only of blood, but of bone marrow, skin and sperm.¹⁷⁷ When Moore discovered that he had become patent number 4,438,032, he sued the doctors for lack of informed consent, breach of fiduciary duty and conversion (property theft).¹⁷⁸ Moore felt that his integrity was violated, his body exploited, and his tissue turned into a product: He said, "What the doctors had done, was to claim that my humanity, my genetic essence, was their invention and their property. They view me as a mine from which to extract biological material. I was harvested."¹⁷⁹

The case was so unusual that the trial court judge quickly threw it out of court, but Moore persevered and the California Court of Appeals ruled that he had been wronged.¹⁸⁰ The appellate court underscored the growth of the market: "Until recently, the physical human body, as distinguished from the mental and spiritual, was believed to have little value, other than as a source of labor. In recent history, we have seen the human body assume astonishing aspects of value."¹⁸¹ The appellate court reviewed cases involving celebrities like Bela Lugosi, who was held to have a property interest in his likeness, preventing other people from marketing photos of him: "If the courts have found a sufficient proprietary interest in one's persona, how could one not have a right in one's own genetic material, something far more profoundly the essence of one's uniqueness than a name or a face?"¹⁸² The court pointed out that because the Uniform Anatomical Gift Act gives patients control over what is done with their bodies after they die, it seems logical they should have control before they die.¹⁸³ "Defendants' argument

ers for research purposes." By creating a cell-line, which is a culture capable of reproducing indefinitely, researchers are better equipped to isolate particular genes. *Id.* at 482 n.2.

¹⁷⁷ *Id.* at 481.

¹⁷⁸ *Id.* at 482.

¹⁷⁹ John Vidal and John Carvel, *Lambs to the Gene Market*, *THE GUARDIAN* (London), Nov. 12, 1994, at 25 (quoting John Moore as saying he was "essence-raped").

¹⁸⁰ *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 502 (Cal. App. 2d Dist. 1988) (holding that the plaintiff, Moore, had adequately stated a cause of action for conversion in his original petition and remanding the case back to the district court for a trial on the merits).

¹⁸¹ *Id.* at 504 (noting that the law must reconsider the nexus between property rights and the ownership of the human body).

¹⁸² *Id.* at 508.

¹⁸³ *Id.* at 506.

that the DNA from plaintiff's cells is not a part of him over which he has the ultimate power of disposition during his life is . . . untenable,"¹⁸⁴ said the Court of Appeals. On a more practical note, the court wrote that "if this science has become science for profit, then we fail to see any justification for excluding the patient from participation in those profits."¹⁸⁵

The appellate decision was not the last word on the matter, though. The doctor and biotechnology company to whom the doctor sold the rights to Moore's cell line appealed to the California Supreme Court where the deeply divided justices each wrote eloquently about his or her view of the body, ranging from a sacred temple to a biomedical factory. An acrimonious dispute surfaced in the four different opinions as to whether or not Moore could claim that his tissue was his property.¹⁸⁶ The court said that the physician/researcher's failure to inform Moore of the potential commercialization of his tissue, if proven at trial, violated Moore's right of informed consent and violated the researcher's fiduciary duty.¹⁸⁷ However, a majority of the justices, for differing reasons, rejected the idea that Moore could claim a property interest in his body. Even though the law in many ways was on his side, the majority seemed swayed by the heady promise of biotechnology.¹⁸⁸ They did not want to slow down research by universities and the nation's biotechnology companies by "threaten[ing] with disabling civil liability innocent parties who are engaged in socially useful activities, such as researchers who have no reason to believe that their use of a particular cell sample is, or may be, against a donor's wishes."¹⁸⁹ They were concerned that giving Moore a property right to his tissue would "destroy the economic incentive to conduct important medical research."¹⁹⁰ However, the impact has been just the opposite. Due to the enticing possibility of vast profits, many researchers are not sharing tissue samples or preliminary findings. These researchers each want to be the first to discover the profitable gene.

¹⁸⁴ *Moore*, 249 Cal. Rptr. at 507-08.

¹⁸⁵ *Id.* at 509.

¹⁸⁶ See generally *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990) (displaying varied legal perspectives on bodily property rights in four differing opinions from California Supreme Court Justices Pancelli, Arabian, Broussard, and Mosk).

¹⁸⁷ *Id.* at 497 (holding that even though Moore's cause of action for conversion was not tenable, he could still recover on informed consent and breach of fiduciary duty actions).

¹⁸⁸ *Id.* at 493-94.

¹⁸⁹ *Id.* at 493.

¹⁹⁰ *Id.* at 495.

H. Resource Concerns

Another way in which medical care might be compromised by gene patents is through their effects on the training of future scientists, physicians, and laboratory personnel. The American College of Medical Genetics points out that when patent holders restrict genetic testing (for example, by requiring that all tests be done by their particular laboratory), training is compromised in the area covered by the patent.¹⁹¹

Moreover, gene patents have led to costly legal battles.¹⁹² The University of California at San Francisco and Genentech fought a lengthy battle over a claim that Genentech's genetically-engineered human growth hormone infringed on the university's patent on the human growth hormone gene.¹⁹³ Ultimately, Genentech agreed to settle for \$200 million.¹⁹⁴

V. POLICY ALTERNATIVES

A variety of medical organizations oppose gene patents as threatening medical advances and patient care.¹⁹⁵ The public is beginning to cry foul as well. The *Chicago Tribune* published a major editorial asking the U.S. Congress to "liberate gene data."¹⁹⁶ The concerns about gene patents are leading to policy initiatives via litigation, legislation, and administrative action.¹⁹⁷ Around the globe, major policy discussions about gene patents are taking place.

¹⁹¹ AMERICAN COLLEGE OF MEDICAL GENETICS, *Position Statement on Gene Patents and Accessibility of Gene Testing*, available at <http://www.faseb.org/genetics/acmg/pol-34.htm> (Aug. 2, 1999) (commenting that restricting gene testing affects patient care, in addition to medical and scientific training).

¹⁹² Nicholas Thompson, *Gene Blues*, WASH. MONTHLY, Apr. 2001 (citing the legal battle between Elan, a pharmaceutical company, and the prestigious Mayo Clinic over the clinic's Alzheimer's research with Elan's patented human genes as well as the University of Rochester's lawsuit against Pharmacia over a gene crucial to a painkiller, Celebrex, and Amgen's victory over Transkaryotic Therapies for attempting to create a competitor to Amgen's anemia-fighting drug Epogen), available at <http://www.washingtonmonthly.com/features/2001/0104.thompson.html>.

¹⁹³ Marcia Barinaga, *Genentech, UC Settle Suit for \$200 Million*, 286 SCI. 1655 (1999).

¹⁹⁴ *Id.*

¹⁹⁵ See, e.g., COLLEGE OF AMERICAN PATHOLOGISTS, *ADVOCACY ON THE ISSUES, Gene Patents Detrimental to Care, Training, Research*, July 5, 2000 (discussing how "information derived from mapping of the human genome represents a naturally occurring, fundamental level of knowledge which is not invented by man and should not be patented"), available at <http://www.cap.org/html/advocacy/issues/genetalk.html>.

¹⁹⁶ *Should Congress Liberate Gene Data?*, CHI. TRIB., Sept. 16, 1999, at A26.

¹⁹⁷ See *infra* pp. 133-43.

A. Litigation

The patent system is a three-way give-and-take among the U.S. Patent and Trademark Office, the courts, and Congress. All three have active roles in assuring that the goals of the patent system are met and that the monopoly granted by the patent is not too broad. Most often, this means that the courts and Congress winnow back patents granted by the Patent Office. When Samuel Morse convinced the U.S. Patent and Trademark Office to grant him a patent on all uses of electromagnetic waves, the Supreme Court stepped in, stating that he could not patent every conceivable use of electromagnetic waves.¹⁹⁸ Morse could only patent his invention—the telegraph.¹⁹⁹

The courts' role in narrowing patents is particularly important, given that there are incentives for the U.S. Patent and Trademark Office to grant patents. "We are the patent office, not the rejection office," said Bruce Lehman, the PTO's commissioner at the time.²⁰⁰ The USPTO's budget comes out of money collected through the fees of applicants. In 1990, the first year of the Human Genome Project, the U.S. Patent and Trademark Office collected \$175 million in patent processing fees.²⁰¹ By 1993, the fees had risen to \$423 million. Moreover, each patent examiner receives a salary bonus based on how many final allowances or rejections of a patent he or she allows. Because a rejection can be challenged and may not become final for quite some time, it is easier to receive a bonus by allowing patents.²⁰²

Suits directly challenging the patentability of genes have not been undertaken, in part, because of the high costs of bringing such litigation; sometimes it is just cheaper for a laboratory to pay licensing fees for use of a gene and pass that cost on to the patients who are tested, rather than initiate a legal challenge. Some geneticists at medical schools have approached their university lawyers asking

¹⁹⁸ *O'Reilly v. Morse*, 56 U.S. 62, 112, 117 (1853) (stating that the inventor Samuel Morse "has not discovered that the electro-magnetic current, used as motive power, in any other method, and with any other combination, will do as well"). This holding left open the possibility for other scientists to invent tools that utilized electro-magnetic power.

¹⁹⁹ *Id.* at 117.

²⁰⁰ *Patently Absurd*, THE ECONOMIST, June 23, 2001.

²⁰¹ Robert P. Merges, *As Many As Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 610 (1999).

²⁰² *Id.* at 607. This has led Professor Merges to advocate an alternative bonus system such as one that pays bonuses based on minimizing error rate (by assessing whether the patents are later found invalid in a lawsuit or re-examination). *Id.*

them to challenge a gene patent, only to be told that such a challenge is untenable given that the university itself has gene patents. The University of California, for example, was ranked third in a study listing institutions granted gene patents in the year 2000.²⁰³

Just recently, however, legal assaults on gene patents have been launched by two constituencies. The first set of challenges have been brought by patients against researchers and their institutions in instances where the defendants did not specifically disclose their intentions to patent a gene isolated from the patients.²⁰⁴ The patients rely on precedents requiring physician/researchers to disclose potential financial conflicts of interest to the patients or research subjects in advance of undertaking the research.²⁰⁵ In a pro bono case in which the author is serving as an attorney, the research subjects from whom the gene was isolated have claimed that the researcher violated the subjects' right of informed consent, breached his fiduciary duty to them, engaged in fraud, and converted their property by not disclosing his intent to patent their disease gene.²⁰⁶

Patenting genes violates several ethical and legal principles. To find the genes, physicians and genetic researchers rely on large numbers of patients and their families to supply the tissue to search for the genes.²⁰⁷ A variety of laws support the concept that physicians have a fiduciary relationship with their patients and should avoid conflicts of interest.²⁰⁸ For example, there are legal prohibitions against self-referrals, fee-splitting and kickbacks.²⁰⁹ Yet genetic researchers searching for a commercially valuable gene and geneticists who get royalties from genetic tests both have a financial conflict of interest with their patients.

²⁰³ GARY ZWEIGER, *TRANSDUCING THE GENOME: INFORMATION, ANARCHY, AND REVOLUTION IN THE BIOMEDICAL SCIENCES* 213 (McGraw-Hill 2001) (listing the University of Texas as tenth on this list, as well).

²⁰⁴ *Greenberg v. Miami Children's Hosp. Research Inst.*, No. 00 C 6770 (N.D. Ill., filed 2000).

²⁰⁵ See, e.g., *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 494 (Cal. 1990) (holding that a doctor's research interests are "material" to a patient's informed consent).

²⁰⁶ See *Greenberg*, No. 00 C 6770; see also Peter Gorner, *Parents Suing Over Patenting of Genetic Test*, CHL. TRIB., Nov. 19, 2000, at 1C.

²⁰⁷ See *Greenberg*, No. 00 C 6770; see also Gorner, *supra* note 206, at 1C.

²⁰⁸ See, e.g., Antikickback Statute, 42 U.S.C. § 1320a-7b (1997 & 2002 Supp.); Stark Law, 42 U.S.C. § 1395nn (2002 Supp.).

²⁰⁹ See, e.g., Antikickback Statute, 42 U.S.C. § 1320a-7b (1997 & 2002 Supp.); Stark Law, 42 U.S.C. § 1395nn (2002 Supp.).

The second type of legal challenge provides a more direct attack against gene patents themselves.²¹⁰ Such attacks could broadly challenge the patent on a gene as being, at its core, an inappropriate patent on a product of nature or they could whittle away at the patents on various grounds.

In October 2001, the Institut Curie in Paris challenged Myriad Genetics' European breast cancer gene patent on the grounds of lack of novelty (because predisposition tests for breast cancer based on indirect methods were available prior to the Myriad patent), lack of inventive step (because the gene sequence patented by Myriad was based, in part, on information from public genome databases), and inadequate description (because there were errors in the original sequence published by Myriad).²¹¹

On February 22, 2002, the Institut Curie initiated a challenge to another Myriad patent, EP 705903 ("Mutations in the 17q-linked breast and ovarian cancer susceptibility gene"). The governments of Belgium and the Netherlands intend to challenge that same patent as well. Geneticists in those countries issued a joint statement saying that if gene patents were not narrowed or eliminated "the monopolies on genes and genetic testing will wreck the reimbursement system and negatively influence health care."²¹² Other challenges to gene patents might try to narrow the patent claims. The breadth of patents claiming future mutations and methods of diagnosis could be challenged on the grounds that the patent has not sufficiently described and enabled all of the mutations or methods that the patent holder has claimed rights to.

Still other legal challenges might try to raise a public health exemption under TRIPS. In 2001, premier Mike Harris, the government leader of the province of Ontario, Canada, decided that it was detrimental to Ontario's health plan to recognize Myriad Genetics' patents on the BRCA1 and BRCA2 breast cancer genes.²¹³ "The frontier of gene patenting has been treated like the Wild West for too long," said Harris. "The benefits of a worldwide effort such as the

²¹⁰ See Butler and Goodman, *supra* note 5, at 95 (discussing the Institut Curie's challenge to a European patent held by Myriad Genetics).

²¹¹ *Id.* (announcing their criticism of Myriad Genetics' BRCA1 gene at a press conference in Paris on September 6, 2001).

²¹² *The Belgium and Dutch Genetic Centres and Ministers Join Forces in the Opposition Against the Breast Cancer Patent*, Press Release, Feb. 22, 2002.

²¹³ Willcocks, *supra* note 6.

Human Genome Project should not be the property of a handful of people or companies.”²¹⁴

B. Legislation

Because the U.S. Constitutional provision about promoting the useful arts is quite general, the actual provisions of patent law are enacted by Congress and can be modified by that body.²¹⁵ For example, gene patents could be banned altogether. It is quite common internationally to have exceptions to patent laws. The European Patent Convention Article 53(a) prohibits patents for “inventions the exploitation of which would be contrary to ‘ordre public’ or ‘morality’ . . .”²¹⁶ The European Union’s Biotechnology Directive considers certain subject matter to be per se unpatentable, including:

- 1) processes for cloning human beings;
- 2) processes for modifying the germ line genetic identity of human beings;
- 3) uses of human embryos for industrial or commercial purposes; and
- 4) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.²¹⁷

The U.S. Congress is considering a proposed law that would amend the medical procedures exemption to exclude from patent liability those health care providers involved in genetic testing so that their ability to diagnose patients will not be compromised by patents on genes.²¹⁸ The bill was introduced by Members of Congress Lynn Rivers (D-Mich.) and Dave Weldon (R-Fla.).²¹⁹ “Abraham Lincoln described the patent system as ‘adding the fuel of

²¹⁴ *Ontario Won’t Halt Gene Test For Cancer*, LONDON FREE PRESS, Sept. 20, 2001, at A10.

²¹⁵ U.S. CONST. art. I, § 8, cl. 8.

²¹⁶ European Patent Convention, *supra* note 66, at art. 53(a), 13 I.L.M. 268, 286; *see also* Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U.J. L. & POL’Y 247, 256-57 (2000).

²¹⁷ *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*, O.J. 1998 L213/13 [hereinafter *Directive 98/44/EC*], available at http://www.europarl.eu.int/comparl/tempcom/genetics/links/directive_44_en.pdf.

²¹⁸ *Genomic Research and Diagnostic Accessibility Act of 2002*, H.R. 3967, 107th Cong. (2d Sess. 2002).

²¹⁹ *Id.*

interest to the fire of genius,'” Rivers said. “I am concerned that the current Federal patent policy as applied to genetic sequences may be smothering the fire of genius.”²²⁰ The proposed “Genome Research and Diagnostic Accessibility Act of 2002” would ensure that researchers and diagnosticians can obtain appropriate access to patented sequence information.²²¹ The bill exempts two groups from patent infringement: 1) medical practitioners and related health care entities providing genetic diagnostic, prognostic, or predictive tests, and 2) scientists undertaking non-commercial genetic research.²²² The bill also requires public disclosure within thirty days of filing a patent application involving a genetic sequence discovered with federal funds.²²³ This provision would help to eliminate “submarine” patents.

A companion bill, also introduced by Rivers and Weldon, the “Genomic Science and Technology Innovation Act of 2002,” directs the federal Office of Science and Technology Policy (OSTP) to initiate a study of the impact of federal policies on the innovation process for genomic technologies.²²⁴ The study bill is based on the presumption that federal intellectual property laws and technology transfer laws can stimulate the development of innovative genetic technologies by attracting commercial investment, but may also inhibit basic research and information sharing, thereby slowing innovation. Rivers was primarily concerned that gene patents were being granted without an adequate understanding of their impact on innovation.²²⁵

The mandated study would assess the impact of federal policies, including intellectual property policies, on the innovation process for genomic technologies. The study would identify and quantify the actual and reasonably expected effects of patenting policy on genomic science and technology innovation and explicitly consider various alternative levels of intellectual property protection of genomic materials and their likely impacts on genomic inno-

²²⁰ CONG. REC. E355 (daily ed. Mar. 14, 2002) (statement of Rep. Rivers).

²²¹ H.R. 3967, 107th Cong. § 4 (proclaiming that the purpose of the legislation was to share genetic information for research and diagnostic testing).

²²² *Id.* at § 2.

²²³ *Id.* at § 4. Congress has already enacted a law requiring that patent applications become public after 18 months (as another way to combat submarine patents). 35 U.S.C.S. § 122(b)(1)(A).

²²⁴ Genomic Science and Technology Innovation Act of 2002, H.R. 3966, 107th Cong. (2d Sess. 2002).

²²⁵ CONG. REC. E353-55 (daily ed. Mar. 14, 2002) (statement of Rep. Rivers).

vation. The study would assess researchers' access to genomic materials; the rate and quality of innovation; the cost and public availability of new genomic technologies including genomic diagnostics; and possible research barriers.²²⁶

C. Patent Pools

Policy options within traditional patent law are also being explored, such as creating patent pools. Attorneys and others at the U.S. Patent and Trademark Office published a paper noting that "no single company or organization . . . has the resources to develop any significant fraction of the genetic information present in an organism. If the proprietary information is not freely available or licensed in an affordable manner, researchers will be precluded from using these protected nucleic acids to develop new therapeutics and diagnostics."²²⁷

A potential solution would be something similar to the pool created by the American Society of Composers, Authors, and Publishers (ASCAP), which handles the licensing of music under the copyright laws. Instead of negotiating with each holder of a copyright for thousands of songs, a radio station or bar can buy a blanket license from ASCAP and play any song from the pool at any time.²²⁸ Likewise, a gene patent pool could potentially extend non-exclusive licenses to all comers for set fees. That way, a researcher who wants to develop a treatment for breast cancer is not prevented from doing so by the holder of a patent on all or a section of the breast cancer gene. Nor does the researcher need to negotiate with each holder of each patent for the hundreds of mutations in the breast cancer gene, thus saving transaction costs and preventing future litigation.

²²⁶ H.R. 3966, 107th Cong. § 3(d).

²²⁷ Jeanne Clark et al., PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? U.S. PATENT AND TRADEMARK OFFICE, available at <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>, Dec. 5, 2000 (defining a patent pool as an "agreement between two or more patent owners to license one or more of their patents to one another or third parties."). By implementing patent pools, one can more easily access patented genomic inventions, which would promote research and development while promoting competition.

²²⁸ See AM. SOC'Y OF COMPOSERS, AUTHORS, AND PUBLISHERS, COMMON LICENSING TERMS, available at <http://www.ascap.com/licensing/termsdefined.html>; see also Michael J. Meurer, *Copyright Law and Price Discrimination*, 23 CARDOZO L. REV. 55, 111 & n.231 (2001) (explaining that the "blanket license itself could be a tactic used to achieve price discrimination").

Patent pools are often created voluntarily by those within an industry.²²⁹ For instance, in the DVD industry, Sony, Philips and Pioneer created a patent pool for inventions that needed to be used to comply with particular DVD-Video and DVD-ROM standards.²³⁰ There are economic and antitrust concerns about the terms under which patents are licensed in a pool. The ASCAP model creates non-exclusive licenses for a set fee.²³¹ In contrast, licensing patents in a pool under the ambiguous standard of "reasonable royalties" may lead to legal disputes to define reasonableness. If reasonableness is defined only after a subsequent researcher has developed a lucrative gene therapy, the benefits of the pool are lessened because the patent holder can still gouge the patent user.²³² For that reason, it is more appropriate to have a fee determined in advance.

Gene patent holders may be less likely to participate in voluntary patent pools than are patent holders from other industries. Patents are more important in the biotechnology and pharmaceutical industries than in other industries.²³³ In addition, "the lack of substitutes for certain biomedical discoveries (such as patented genes or receptors) may increase the leverage of some patent holders, thereby aggravating holdout problems."²³⁴

Patent pools are particularly appropriate when patent exclusivity is being used contrary to the public interest, but governmental pressure may be necessary to create a pool. During World War I, the Assistant Secretary of the U.S. Navy, Franklin D. Roosevelt, pressured the aircraft industry to form a patent pool to facilitate the production of airplanes.²³⁵ Previously, the Wright-Martin Aircraft Company and the Curtiss Aeroplane and Motor Company were able to block such production due to their control of key patents.

²²⁹ Steven C. Carlson, *Note, Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359, 373 (1999). ("Over the last one hundred and fifty years, patent pools have played an important role in shaping both the industry and the law in the United States.")

²³⁰ Clark et al., *supra* note 227, at 5-6.

²³¹ See AM. SOC'Y OF COMPOSERS, AUTHORS, AND PUBLISHERS, ASCAP LICENSING, ABOUT ASCAP LICENSING, available at <http://www.ascap.com/licensing/about.html> (stating that ASCAP licenses easily enable businesses to obtain the right to perform songs in one transaction).

²³² Shapiro, *supra* note 112, at 128 (explaining that if firm price standards are not established, companies may be emboldened to seek substantial royalties later).

²³³ Heller and Eisenberg, *supra* note 124, at 698, 700 (noting that firms in these industries may be less willing to participate in pools because of the financial disincentives); see also, Gitter, *supra* note 142, at 1681 (citation omitted).

²³⁴ *Id.*

²³⁵ Shapiro, *supra* note 112, at 127 (demonstrating how patent holders can license their complementary patents together and then divide the proceeds).

D. Compulsory Licensing

If voluntary patent pools cannot be achieved, compulsory licensing might also be explored as a way to counter some of the problems of gene patents. Under compulsory licensing, the government would grant licenses to physicians, researchers, and others to use a patented gene sequence without the patent holder's permission for a reasonable fee paid to the patent holder.²³⁶ Laboratories would be able to undertake genetic diagnostic testing and potentially require diagnostic tests and discover new mutations. Pharmaceutical companies would not be able to prevent pharmacogenomic testing related to their products and research on gene therapies would be stimulated. The French Minister of Research, Roger-Gérard Schwartzenberg, advocated "a system of compulsory and ex officio licensing in the interest of society at large and of public health promotion."²³⁷ The European Union also provides for compulsory licensing of patented inventions under certain circumstances to prevent the abuses that can result from the exclusive rights granted under a patent.²³⁸

E. Creating Roles for Third Party Opposition to Patents

Another potential way to deal with the problems created by gene patents is to create a greater opportunity for third party challenges to the grant of a patent. Some commentators advocate expanding the existing procedure within the patent office whereby any third party can ask for a patent to be re-examined.²³⁹ Measures to ensure greater scrutiny of patents could include greater participation of third parties in the initial U.S. Patent Trademark Office interviews about a patent application, and the chance for third parties to

²³⁶ See Sara M. Ford, *Note, Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills And Patents*, 15 AM. U. INT'L L. REV. 941, 945 (2000).

²³⁷ INSTITUT CURIE, *Against Myriad Genetics's Monopoly on Tests for Predisposition to Breast and Ovarian Cancer, The Institut Curie is Initiating an Opposition Procedure With the European Patent Office*, Sept. 12, 2001 (quoting a speech given by the French Minister of Research after the announcement of the completion of the first large scale analysis of the human genome sequence), available at http://www.curie.net/actualites/myriad/declaration_e.htm.

²³⁸ See WORLD TRADE ORGANIZATION, *Compulsory Licensing and Data Protection*, 3-4 (noting that each World Trade Organization member has the right to provide for compulsory licenses to prevent patent abuses), available at http://europa.eu.int/index_en.htm. Article 8.2 of TRIPS also allows for compulsory licenses in that it states that "appropriate measures . . . may be needed to prevent abuse of intellectual property rights by right holders." *Id.* at 4.

²³⁹ See 35 U.S.C. §§ 302, 303. For more detail, see Manual of Patent Examination Procedure § 2209 and 37 C.F.R. 1.20.

appeal patent office re-examination decisions. This would allow, for example, organized patient groups to have their interests represented in the decisions about the granting of gene patents.

This policy approach is being advocated by commentators because there are social costs to granting patents with claims that are too broad. These include costs associated with patent litigation and also a myriad of indirect costs, including: unnecessary licensing fees; foregone research opportunities, abandoned or avoided by the patentee's competitors who fear infringement liability; and the activities of rent-seekers who may respond to the combination of lax patent standards and robust rewards to patentees by diverting excessive resources out of productive activities and into the 'patent game.'²⁴⁰

These social risks of overbroad and invalid patents are the reason we have a patent office in the first place.²⁴¹ Initially, inventors merely registered their inventions. But so many patents were granted that did not actually meet the intellectual property criteria, that Congress established the patent office.²⁴²

F. Strengthening the Role of Gene Sources

Various movements are under foot to give the sources of genes, such as patients, their family members, and other research subjects, a greater say in whether or not their genes are patented and what uses are made of the patented genes. In the United States, the American Medical Association's Code of Ethics requires that a patient's consent be obtained before doctors commercialize products developed from the patient's genetic material.²⁴³ The European Parliament's Directive on the Legal Protection of Biotechnological Inventions states that if a patent application uses material of human origin, the source must have had the opportunity of expressing a free and informed consent.²⁴⁴ Consequently, Europeans have a right

²⁴⁰ Merges, *supra* note 201, at 592.

²⁴¹ *Id.* at 596.

²⁴² *Id.* at 595.

²⁴³ AMERICAN MEDICAL ASSOCIATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CODE OF Medical Ethics: CURRENT OPINIONS WITH ANNOTATIONS 25-26 (2000) (stating that "physicians contemplating the commercial use of human tissue should abide by the following guidelines: (1) Informed consent must be obtained from patients for the use of organs or tissues in clinical research . . .").

²⁴⁴ Directive 98/44/EC, *supra* note 217. Recital 26 of this Directive relates that:

Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose

to refuse to allow their genes to be patented. Foreign governments have expressed outrage when their citizens' genes have been patented by U.S. researchers.²⁴⁵ Protests against the audacity of U.S. government researchers patenting the genes of a woman in Panama and a man in Papua, New Guinea were sufficiently widespread that the patents were withdrawn.²⁴⁶

When Sharon Terry learned that her two young children had inherited PXE (pseudoxanthoma elasticum), a connective tissue disorder that leads to blindness and potential heart attacks, several groups of researchers called to ask for tissue samples from her children to try to find the gene.²⁴⁷ She inquired as to why they did not get samples from other researchers and was told that scientists would not share the samples.²⁴⁸ Terry started a bank with tissue samples from her children and began a collaborative project with researchers.²⁴⁹ When University of Hawaii pathobiologist Charles Boyd isolated the gene, he listed Sharon Terry as a co-inventor on the patent.²⁵⁰ The PXE patients' group she formed will make the decisions about how to license the rights to the gene. Additionally, the PXE group will give 50% of the resulting royalties to the University.²⁵¹ This way the PXE patients' group can keep the price of diagnostic tests down by licensing providers who charge a lower fee.

But allowing those from whom genes are taken to have a property interest in the patent is not a comprehensive solution to the problems created by gene patents. It will be an extremely rare case where researchers will actually need to negotiate with the people who have a gene mutation associated with a particular disease or their family members. For common complex genetic diseases, such as heart disease, so many people will have a particular mutation

body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.

²⁴⁵ See ANDREWS AND NELKIN, *supra* note 83, at 65-66 (describing how the harvesting of blood and tissue samples from random subject populations across the world for the Human Genome Diversity Project created a similar furor).

²⁴⁶ *Id.* at 71.

²⁴⁷ Matt Fleischer, *Seeking Rights to Crucial Gene*, THE NAT'L LAW J., June 25, 2001, at C1.

²⁴⁸ *Id.*

²⁴⁹ *Id.* (describing how the Terry family began their quest by first setting up a PXE website, starting a blood and tissue bank by mailing blood extraction kits to fellow PXE sufferers, and storing these samples in a neighbor's lab freezer).

²⁵⁰ *Id.* (noting that Dr. Boyd was a pathologist who specialized in the elasticity of human tissue).

²⁵¹ *Id.*

that researchers will likely be able to find research subjects who will not insist on participating in the patent application. Moreover, for most diseases, researchers will not have to collect DNA from people in the first place. Researchers will be able to use DNA samples that already exist in hospital pathology laboratories, public health screening programs, research centers, and DNA banks.²⁵²

Patients are being by-passed entirely as the source of DNA for gene patents. A New York City cancer hospital, Sloan-Kettering, was given \$5 million by a California biotechnology company for access to its pathology samples of cancer tissue biopsies for genetic research.²⁵³ Duke University Medical Center entered into a commercial agreement with Ardaïs, granting the start-up genomics company access to Duke's patients' tissue.²⁵⁴ Harvard Beth Israel Deaconess Medical Center entered into a similar arrangement.²⁵⁵

CONCLUSION

Using the biological resources of the public (and a substantial amount of public funding), genes have been discovered and patented. Although copyright law has a fair use exemption for socially valuable uses, patent law does not.²⁵⁶ Consequently, policymakers are considering a variety of alternatives, inside and outside of traditional patent law, to assure that gene patents will be used in socially valuable ways.

²⁵² See ANDREWS AND NELKIN, *supra* note 83, at 4-5.

²⁵³ MEMORIAL SLOAN-KETTERING CANCER CENTER, *Press Release: Cancer Joint Venture Completed by Memorial Sloan-Kettering and Sequana*, available at <http://www.mskcc.org/mskcc/html/1252.cfm>, Jan. 30, 1997, (announcing that the joint venture is to be named Genos Biosciences, Inc., and will be based in La Jolla, California).

²⁵⁴ Deborah Josefsen, *Human Tissue for Sale: What Are the Costs?*, 173 W.J. MED. 302 (2000) (commenting that these arrangements "are among the latest academic hospitals to form partnerships with biotechnology companies for the purpose of providing human tissue for use in research, treatment, and drug development").

²⁵⁵ *Id.* (noting that both the Harvard and Duke hospital arrangements raise legal and bioethical concerns).

²⁵⁶ 17 U.S.C. § 107 (2002); see Eisenberg, *DNA Sequences*, *supra* note 22, at 796.