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Gene Patents: A Brief Overview of Intellectual Property Issues

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Summary

The courts have upheld gene patents that meet the criteria of patentability defined by the Patent Act. However, the practice of awarding patents on genes has come under intense scrutiny by some scientists, legal scholars, politicians, and other experts. Gene patenting raises ethical, legal, and economic issues. A short discussion of these issues follows. This report will not be updated.

Patents

The Patent Act of 1952, codified in Title 35 of the United States Code, defines current patent law. According to section 101, one who "invents or discovers any new and useful process, machine, manufacture, or any composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." To be patentable, an invention must be useful, novel, and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit. To be judged novel, the invention must not be fully anticipated by a prior patent, publication, or other knowledge within the public domain. A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made. The invention must be fully described. Once the United States Patent and Trademark Office (USPTO) issues a patent, the owner enjoys the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention. Generally, the term of a patent is 20 years from the date the application was filed. In the process of obtaining a patent, the information associated with the patent is published and made available to the public.

Gene Patents

Genes are chemical compounds and, as such, they qualify as compositions of matter with respect to patent criteria. Within the parameters of patentability delineated by the Patent Act, there are several exceptions as interpreted by the courts. Products of nature (a preexisting substance that is found in the wild) may not be patented, *per se*. However, the courts have also determined that such a product of nature may be patentable if

significant artificial changes are made. By purifying, isolating, or otherwise altering a naturally occurring product, an inventor may obtain a patent on the product in its altered form.[1] Thus, "one cannot patent a naturally occurring gene or protein as it exists in the body, but one can patent a gene or protein that has been isolated from the body and is useful in that form as a pharmaceutical drug, screening assay or other application."[2]

The practice of awarding patents on genes, while upheld by the courts, has come under scrutiny and criticism by some scientists, legal scholars, and politicians. The subject of gene patenting involves various ethical, legal, and economic components. While not mutually exclusive, a short discussion of several issues follows.

Ethical Issues

An often held belief is that gene patents permit outsiders ownership of another person's genetic makeup, often without their knowledge or consent.[3] This concern has led to complaints that patients no longer control their own bodies and doctors are being constrained from testing for various diseases.[4] Professor Lori Andrews argues that patents hinder access to testing procedures because "...gene-patent holders can control any use of 'their' gene; they can prevent a doctor from testing a patient's blood for a specific genetic mutation and can stop anyone from doing research to improve a genetic test or to develop a gene therapy based on that gene."[5] This perceived constraint on research and testing options is an issue to opponents of gene patents.[6] According to Dr. Debra Leonard, patents on "...specific genetic information limits the medical use of the information and impedes or prevents widespread research on the disease, the traditional pathway by which medical knowledge is advanced and shared."[7]

However, other experts disagree. As noted by Dr. Jorge Goldstein and Attorney Elina Golod, the courts have consistently "...taken the position that a person does not own any tissues or cells once they are outside the person's body."[8] Attorneys Lee Bendekgey and Dr. Diana Hamlet-Cox found no evidence of patients unable to utilize existing genetic tests because of patents. Instead, they maintain, it is a financial issue associated with the cost of health care and/or an issue of profits for the doctor or clinical geneticist wishing

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[1] Scripps Clinic and Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991).

[2] Biotechnology Industry Organization, *Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine*, available at [http://www.bio.org/ip/primer].

[3] Michael Crowley, "They Own Your Body," *Readers Digest*, August 2006 available at [http://www.rd.com].

[4] Debra G.B. Leonard, "Medical Practice and Gene Patents: A Personal Perspective," *Academic Medicine*, December 2002, 1388.

[5] Lori B. Andrews, "Genes and Patent Policy: Rethinking Intellectual Property Rights," *Nature Reviews*, October 2002, 804

[6] John F. Merz, "Disease Gene Patents: Overcoming Unethical Constraints on Clinical laboratory Medicine," *Clinical Chemistry*, 45:3, 1999, 324.

[7] *Medical Practice and Gene Patents: A Personal Perspective*, 1388.

[8] Jorge A. Goldstein and Elina Golod, "Human Gene Patents," *Academic Medicine*, December 2002, Part 2, 1321.

to administer tests patented by other inventors.[9] Similarly, Professor Iain Cockburn found "...there is little quantitative evidence thus far of a negative impact of patents on scientific research activity...."[10] From his perspective, the disclosure obligations of the patent system may better serve the objective of encouraging the diffusion of knowledge and raising social returns than the chief legal alternative, trade secret protection.[11]

Legal Issues

Some commentators argue that genes are products of nature — discoveries, not inventions — that do not meet the criteria necessary to obtain a patent.[12] As stated by Professor Andrews, "The useful properties of a gene's sequence...are not ones that scientists have invented, but instead, are natural, inherent properties of the genes themselves."[13] The fact that the gene has been isolated is considered a "technicality" by experts who subscribe to this position.[14]

The courts have upheld gene patents if they meet the requirements of the Patent Act. According to some experts, the law allows for patents on discoveries:

> ...despite what is repeatedly asserted by the opponents of gene patenting, patent law applies equally to "discoveries" as to "inventions." In fact, Article 1, Section 8 of the U.S. Constitution...explicitly refers to "discoveries," as does the Patent Statute: "Whoever invents or *discovers* any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor...." [Emphasis added.][15]

As Bendekgey and Hamlet-Cox point out, many biotechnology products are built upon compounds existing in nature including such therapies as interferons, interleukins, and insulin.[16] Similarly, a patent on penicillin was awarded to Alexander Flemming who isolated and purified the drug from mold, a "naturally occurring source."[17]

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[9] Lee Bendekgey and Diana Hamlet-Cox, "Gene Patents and Innovation," *Academic Medicine*, December 2002, Part 2, 1378.

[10] Iain M. Cockburn, "Blurred Boundaries: Tensions Between Open Scientific Resources and Commercial Exploitation of Knowledge in Biomedical Research," April 30, 2005, 15, available at [http://people.bu.edu/cockburn/cockburn-blurred-boundaries.pdf].

[11] *Ibid*., 11.

[12] "Owning the Body and the Soul," *The Economist*, March 12, 2005, 77, and *They Own Your Body*.

[13] *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 803.

[14] *They Own Your Body.*

[15] *Gene Patents and Innovation*, 1374.

[16] Lee Bendekgey and Diana Hamlet-Cox, "Rebuttal: Why We Need Gene Patents," *Law.com* [web journal], December 30, 2002.

[17] Q. Todd Dickinson statement in "The Human Genome Project, DNA Science and the Law: The American Legal System's Response to Breakthroughs in Genetic Science," *American University Law Review*, 2001-2002, 380.

The quality of the gene patents awarded by the USPTO is a concern for some experts. A study by Professors Jordan Paradise, Lori Andrews, and Timothy Holbrook found that 38% of the claims contained in 74 patents on human genetic material were "problematic."[18] This research indicated that utility issues were identified as the most prevalent problem, followed by the required written description of the invention.[19] In another paper, Andrews also argues "...gene patents do not meet the criteria of non-obviousness, because, through *in silico* analysis, the function of human genes can now be predicted on the basis of their homology to other genes."[20]

This analysis is not without criticism, as questions have been raised regarding the authors' definition of "problematic" that is based upon the authors' perspectives rather than court decisions. In addition, the data include patents issued in the early 1990s when gene patenting was in its infancy and there was little expertise and experience on which to grant these patents.[21] Such concerns over patent quality, however, are not limited to gene patents. The debate over whether or not the USPTO is too lenient in awarding patents is on-going and is particularly intense as new industries develop and seek patents. The patent process is a "one size fits all" activity leading to claims that certain technologies are not amenable to patenting or that patents granted do not meet the requirements of the Patent Act. However, as patent examiners build up expertise in a new field and develop prior art, the quality of patents typically increase.[22]

Economic Issues

Biotechnology industry leaders perceive patents as critical to protecting innovation. Research by Professor Wesley Cohen and his colleagues found that patents were considered the most effective method to protect inventions in the drug industry, particularly when biotechnology is included.[23] Other commentators note that patents are particularly important in this sector because of the relative ease of replicating the finished product. Costs associated with imitating a product "...are extremely low relative to the innovator's costs for discovering and developing a new compound."[24]

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[18] Jordan Paradise, Lori Andrews, and Timothy Holbrook, "Patents on Human Genes: An Analysis of Scope and Claims," *Science*, 11 March 2006, 1566-1567.

[19] *Patents on Human Genes: An Analysis of Scope and Claims*, 1567.

[20] *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 803.

[21] *Owning the Body and the Soul*, 77.

[22] See CRS Report RL31281, *Patent Quality and Public Policy: Issues for Innovative Companies in Domestic Markets*, by John R. Thomas.

[23] Wesley M. Cohen, Richard R. Nelson, and John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, NBER Working Paper 7552, Cambridge, National Bureau of Economic Research, February 2000, available at [http://www.nber.org/papers/w7552].

[24] Henry Grabowski, "Patents and New Product Development in the Pharmaceutical and Biotechnology Industries," *Duke University Economics Working Paper*, July 2002, available at [http://www.econ.duke.edu/Papers/Other/Grabowski/Patents.pdf], 4.

Opponents of gene patents argue that they restrain additional research because "...there are no alternatives to a patented gene in diagnosis, treatment, and research,"[25] and owners require licensing fees.[26] However, despite what some experts claim to be a negative result of financial considerations in the biomedical research community,[27] others maintain that, at most, gene patents "...prevent the doctors and clinical geneticists from performing these tests for profit, or in a way that competes with the patent holder, without reimbursement to the inventors of those tests."[28]

Some analysts assert that certain patents, particularly those on research tools[29] in biotechnology, hinder the innovation process. Professors Rebecca Eisenberg and Richard Nelson state that ownership of research tools may "...impose significant transaction costs" that result in delayed innovation and possible future litigation.[30] They argue that patents also can stand in the way of research by others:

> Broad claims on early discoveries that are fundamental to emerging fields of knowledge are particularly worrisome in light of the great value, demonstrated time and again in the history of science and technology, of having many independent minds at work trying to advance a field. Public science has flourished by permitting scientists to challenge and build upon the work of rivals.[31]

Professor Arti Rai argues that "the most important research tools are fundamental research platforms that open up new and uncharted areas of investigation" that need further development by researchers in the field.[32] While acknowledging that patent protection on research tools has stimulated private investment in biotechnology and the development of new products and processes, Eisenberg writes that:

> Patents on research tools threaten to restrict access to discoveries that, according to the firm beliefs of scientists trained in the tradition of open science, are likely to have the greatest social value if they are widely disseminated to researchers who are taking different approaches to different problems.[33]

Other commentators dispute these assertions. Professor F. Scott Kieff maintains that there was no such "norm" regarding open scientific access as opposed to intellectual

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[25] *Patents on Human Genes: An Analysis of Scope and Claims*, 1566.

[26] *They Own Your Body.*

[27] *Medical Practice and Gene Patents: A Personal Perspective*, 1390.

[28] *Gene Patents and Innovation*, 1378.

[29] A biotechnology research tool is a cell line, reagent, or antibody used in research.

[30] Rebecca S. Eisenberg and Richard R. Nelson, "Public vs. Proprietary Science: A Fruitful Tension?," *Daedalus*, Spring 2002.

[31] *Ibid*.

[32] Arti Rai, "Genome Patents: A Case Study in Patenting Research Tools," *Academic Medicine*, December 2002, Part 2, 1369.

[33] Rebecca Eisenberg, "Why the Gene Patenting Controversy Persists," *Academic Medicine*, December 2002, Part 2, 1383.

property protection in the basic biological science community.[34] He notes that "...experience shows that patents on inputs generally do not prevent the production of outputs" and that the availability of intellectual property protection has expanded the resources available in the biotechnology community and led to its success.[35] Bendekgey and Hamlet-Cox agree that there is no evidence that gene patents have caused a decrease in research as a whole in the biomedical arena or in gene therapies.[36]

A study by Professors John Walsh, Ashish Arora, and Wesley Cohen found little evidence that work has been curtailed due to intellectual property issues associated with research tools.[37] Scientists are able to continue research by "...licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges, and simply using the technology without a license (i.e., infringement)." According to the authors, private sector owners of patents permitted such infringement in academia (with the exception of those associated with diagnostic tests in clinical trials) "...partly because it can increase the value of the patented technology."

A later analysis by Professors Walsh, Cohen, and Charlene Cho concluded that patents do not have a "substantial" impact upon basic biomedical research and that "...none of [their] random sample of academics reported stopping a research project due to another's patent on a research input, and only about 1% of the random sample of academics reported experiencing a delay or modification in their research due to patents."[38] However, obtaining "tangible" research inputs (e.g., actual materials) appear to be more difficult because of competition, cost, and time issues.[39]

As genes continue to be patented and research in the field of biotechnology proceeds, the discussion surrounding the ethical, legal, and economic issues of gene patenting remains on-going in the public policy arena.

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[34] F. Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science - - A Response to Rai and Heisenberg," *Northwestern University Law Review*, Winter 2001, 694.

[35] *Ibid.*, 704.

[36] *Gene Patents and Innovation*, 1377, 1378.

[37] John P. Walsh, Ashish Arora, Wesley M. Cohen, "Working Through the Patent Problem," *Science*, February 14, 2003, 1021.

[38] John P. Walsh, Charlene Cho, and Wesley Cohen, "Patents, Material Transfers and Access to Research Inputs in Biomedical Research," September 20, 2005, 37, available at [http://tigger.uic.edu/~jwalsh/WalshChoChoenFinal050922.pdf].

[39] *Ibid.*, 2.