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Gene Patents: Promoting Discovery or Hindering Research?

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Granting patent rights for new genetic discoveries is a topic of heated debate in patent law due to the ethical, legal, and economic concerns involved.[1] Since the United States Patent and Trademark Office (USPTO) issued the first gene patent in 1982,[2] the number of gene patents in the United States has skyrocketed.[3] At the start of the biotechnology revolution in the early 1980s, gene patents were widely recognized as the driving motivation behind the willingness of biotechnology companies to invest in extremely expensive and unpredictable development of biotechnology products.[4] Today, it is less clear

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[1] Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091 (2006), *available at* http://www.wulaw.wustl.edu/faculty/documents/kieff/Articles/CaulfieldCookDeeganKieffWalschAnalysisofHumanGenePatents.pdf.

[2] *Gene Patent and Global Competition Issues: Protection of Biotechnology Under Patent Law*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, Jan. 1, 2006, http://www.genengnews.com/articles/chitem_print.aspx?aid=1163&chid=0 (issued to the Regents of the University of California for "work carried out on the construction of a plasmid contained in a bacterium and expression of genes for chorionic somatomammotropin").

[3] Christopher M. Holman, *Recent Legislative Proposals Aimed at the Perceived Problem of Gene Patents*, BIOTECH BRIEFING (ABA Section of Sci. & Tech. Law, Chicago, I.L.), Fall 2008, http://www.abanet.org/scitech/genepatents.html; *see* Caulfield et al., *supra* note 1 at 1091 ("The mid-1990s was also a period of rapid (roughly 50% per annum) growth in DNA-related patents in the United States"); *see also* Mike Stott & Jill Valentine, *Patenting and Medical Research: A View From a Pharmaceutical Company*, 3 NATURE 364, 367 (2004), *available at* http://www.brown.edu/Courses/BI8/2004/group04/PDFSandReviews/BI%208/Ethics%20in%20Biotechnology/Article%202/Gene%20Patenting.pdf ("In 2001 alone, 1500 patents were issue claiming human genetic material.").

[4] Holman, *supra* note 3.

whether the proliferation of gene patents advance biotechnology by providing an incentive for researchers to create new and useful gene sequences or hinder research by making it too costly and cumbersome for researchers to license or design around the patents of others.[5] It is clear that "*both* patents and freedom to undertake research are crucial to the successful delivery of medicines to society."[6]

I. WHAT IS A GENE PATENT?

Traditionally, a "gene patent" is a patent claiming a protein encoding DNA sequence.[7] However, the term is often used loosely to describe patents for gene-fragments, expressed sequence tags (ESTs), or single nucleotide polymorphisms (SNPs).[8] For the purposes of this Article, "gene patent" refers to the traditional definition of a DNA sequence that encodes for a protein. This Article will also address patents claiming "disease genes," gene sequences utilized in diagnostic testing for disease gene markers.[9]

II. PATENTABLE SUBJECT MATTER?

The general rule is that "raw products of nature" are not patentable subject matter.[10] Why then is patent protection extended to DNA when DNA is a product of nature? In *Diamond v. Chakrabarty*, the Supreme Court set forth the broad standard that "anything under the sun made by man" is patentable subject matter.[11] Thus, gene sequences are only patentable when isolated, purified, genetically altered, or genetically engineered by man to produce a unique form

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[5] *See* Caulfield et al., *supra* note 1, at 1091-92.
[6] Stott & Valentine, *supra* note 3, at 364.
[7] *Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing: Hearing Before the H. Judiciary Subcomm. on Courts, the Internet, and Intellectual Property* 2 (Oct. 30, 2007) (statement of Lawrence M. Sung, Partner, Dewey & LeBoeuf LLP), *available at* http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1005&context=cong_test.
[8] *Id.*
[9] JON F. MERZ, PRESENTATION TO THE SECRETARY'S ADVISORY COMMITTEE ON GENETIC TESTING, ON THE EXCLUSIVE LICENSING OF DISEASE GENE PATENTS 4 (June 7, 2000), http://www.bioethics.upenn.edu/prog/ethicsgenes/pdf/SACGT_20000507.pdf.
[10] Genetics and Patenting, Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml (last visited Nov. 6, 2008) [hereinafter Human Genome Project].
[11] *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

not found in nature.[12] Currently, United States patent policy allows for gene patents when an inventor can (1) "identify novel genetic sequences," (2) "specify the sequence's product" and "its use," and (3) "enable one skilled in the field to use the sequence for its stated purpose."[13]

III. GENE PATENT HOLDERS AND LICENSING PRACTICES

The majority of genomic information is either patented or in the public domain.[14] Current holders of gene patents in the United States include academic institutions, the Government, and biotechnology and pharmaceutical companies.[15] Both academic institutions and the Government typically license gene patents non-exclusively to downstream developers who make the genes available to the public.[16] Similarly, many biotechnology and pharmaceutical companies out-license their gene patents on a non-exclusive basis.[17] Some big industry players, however, have stirred up controversy by using important diagnostic disease gene patents exclusively for internal development.[18]

IV. THE OPPOSITION TO GENE PATENTS

Many public institution researchers and medical practitioners strongly oppose gene patents, arguing that patents are not a necessary incentive for biotechnology research[19] and that the costs associated with licensing patented research data impedes the development of diagnostics and therapeutics. [20] For

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[12] Human Genome Project, *supra* note 10.
[13] *Id.*
[14] Lin Sun-Hoffman, How Does Private Sector Handle Licensing of Genetic Discoveries?, Presentation at the National Institute of Health Secretary's Advisory Committee on Genetics, Health, and Society 12th Meeting 8 (March 27, 2007), (slides available at http://www4.od.nih.gov/oba/sacghs/meetings/Mar2007/Tues%20am%20-%20Sun-Hoffman.pdf).
[15] *Id.* at 6.
[16] *Id.* at 9.
[17] *Id.* at 10.
[18] *Id.* (such as the BRCA1 and BRCA2 breast cancer genes).
[19] Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403, 405-06 (2005) (arguing that there are many other incentives for the discovery of genetic sequences other that patents, such as "medical interests and the potential for academic advancement and status").
[20] Human Genome Project, *supra* note 10.

example, a laboratory wishing to run a diagnostic test that involves a plethora of patented gene sequences must pay royalties to patent owners for every gene involved.[21]

An even greater problem arises when a patent owner is unwilling to license disease gene patents necessary for genetic testing to other researchers.[22] Such practices arguably diminish the quality of genetic tests and interfere with access to health care by limiting research and development to the patent owner.[23] If a patented gene sequence needed for research is not being licensed, the only options for researchers are (1) to move offshore to use the gene outside of the United States (this is too costly for smaller startup companies); (2) design around the patented gene (usually difficult in the case of a DNA sequence); or (3) use the patented gene without a license (this is an unstable policy).[24] Therefore, there is currently no satisfactory solution to the problem that arises when patentees engage in exclusive licensing practices.

V. IS THERE REALLY A PROBLEM WITH GENE PATENTS?

A. Gene Patents are Generally Regarded as Positive

Many industry biotechnology and pharmaceutical companies claim that they are unwilling to make a substantial investment in research without the ability to prevent competitors from making or using the invention without a license.[25] Additionally, patents allow private-sector researchers to make new gene sequences public without losing exclusive rights, thus avoiding secrecy and promoting the dissemination of knowledge regarding genetic discoveries.[26]

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[21] *See* Roger D. Klein, *Gene Patents and Personalized Medicine*, 4 PERSONALIZED MED. 237, 239-40 (2007), http://www.futuremedicine.com/doi/pdf/10.2217/17410541.4.3.237?cookieSet=1.
[22] Caulfield et al., *supra* note 1, at 1092.
[23] Andrews & Paradise, *supra* note 19, at 412.
[24] Stott & Valentine, *supra* note 3, at 366; Caulfield et al., *supra* note 1, at 1093.
[25] Human Genome Project, *supra* note 10.
[26] *Id.*

B. There is No Empirical Evidence that Gene Patents Hinder Research

Despite the arguments that gene patents hinder research, empirical data shows that this argument is more anecdotal than factual.[27] The data indicates that many researchers do have access to patented technology, suggesting that licensing is non-exclusive.[28] In fact, the "vast majority" of gene patents are available for licensing.[29] Furthermore, only one percent of biomedical researchers in the United States reported having to delay a project, and none reported having to abandon a project, as a result of gene patents, suggesting that licensing costs are not seriously limiting academic research.[30]

C. Real Concern Exists in the Area of Disease Gene Patents

The asserted problems of exclusive licensing may legitimately hinder diagnostic testing in the area of disease gene patents.[31] In this case, there are more instances of researchers and firms abandoning the development of genetic tests as a result of disease gene patents.[32] Furthermore, medical practitioners who diagnose diseases based on genetic information agree that gene patents have limited their medical practice.[33]

VI. RECENT JUDICIAL DECISIONS COUNTERACTING ALLEGED PROBLEMS WITH GENE PATENTS

In light of recent Supreme Court decisions, it is increasingly difficult for applicants to obtain and enforce gene patents.[34] In *KSR Int'l Co. v. Teleflex Inc.*,

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[27] Caulfield et al., *supra* note 1, at 1092.
[28] *Id.*
[29] Stott & Valentine, *supra* note 3, at 366.
[30] Caulfield et al., *supra* note 1, at 1092.
[31] *Id.*
[32] *Id.* ("For example, 30% of clinical labs report not developing or abandoning testing for the HFE gene" and "25% of labs had abandoned one or more genetic tests as a result of patents, with [the BRCA1 and BRCA2 breast cancer gene patents] among the most frequently mentioned").
[33] *See, e.g.*, DEBRA LEONARD, COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS, EFFECTS OF GENE PATENTS ON GENETIC TESTING AND RESEARCH 2 (Oct. 1, 2004), www7.nationalacademies.org/step/Leonard_presentation_October_proteomics.ppt.
[34] *See* Sung, *supra* note 7, at 7.

the Supreme Court held that an invention may be too obvious to be patentable if the invention would "occur in the ordinary course without real innovation," or if "a person of ordinary skill in the art attempting to solve a problem will be led only to those prior art elements designed to solve the same problem."[35] As a result of the human genome project and the availability of genetic sequences in online databases, gene sequences are readily available prior art to biotechnology researchers.[36] Furthermore, the extremely high market demand for genetic testing renders the development of new gene sequences an attractive and potentially obvious investment for researchers.[37] Therefore, *KSR* will most likely reduce the number of gene patents granted due to obvious rejections by the USPTO.

In *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court imposed an injunctive relief restraint based on public interest factors.[38] In this case, the denial of injunctive relief for the patentee, although not compulsory licensing *per se*, amounted to the equivalent because the infringer could continue to use the patented invention in exchange for paying a reasonable royalty.[39] Thus, *eBay* may solve the problem of exclusive licensing by providing a strong incentive for patent holders to grant non-exclusive licenses for reasonable royalties to avoid litigation that might not result in injunctive relief.

Lastly, the Supreme Court Decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*, expanded 35 U.S.C. § 271(e)(1), a statutory research exemption from infringement liability for research related to the preparation and submission of applications for Food and Drug Administration (FDA) approval. [40] *Merck* held that the exemption includes all uses where there is a reasonable basis

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[35] *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 398 (2007).
[36] *See, e.g.*, Gene Gateway – Exploring Disease and Genetic Disorders, http://genomics.energy.gov/genegateway (last visited Nov. 6, 2008) (web site sponsored by the U.S. Department of Energy Biological and Environmental Research containing a "chromosome viewer" and links to comprehensive gene sequence databases such as GenBank).
[37] *See* Research and Markets, U.S. Genetic Testing Markets, http://www.researchandmarkets.com/reports/364798/u_s_genetic_testing_markets.htm (last visited Nov. 6, 2008) (reporting that "genetic testing is the highest growth segment of the diagnostics industry" and "the frontier of tremendous potential for companies").
[38] *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 390-91 (2006).
[39] Sung, *supra* note 7, at 7.
[40] *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005).

to believe that the compound tested could be the subject of an FDA submission, including preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process.[41] Therefore, *Merck* potentially reduces the problem caused by exclusive licensing of disease gene patents if the use of disease genes qualifies for the FDA exemption.

VII. SOLUTIONS OUTSIDE OF THE JUDICIARY

Outside of the judiciary, existing and proposed legislation aims to counter the alleged negative impacts of exclusive licensing, unreasonable royalties, and the costs associated with licensing multiple genes for complex genetic tests. First, the Bayh-Dohl Act (P.L. 96-517) already exists to allow a federal agency, such as the National Institutes of Health (NIH), to compel a patent owner to non-exclusively license patented technology when necessary for public health and safety.[42] Although the NIH has never done so, the Bayh-Dohl Act is a potential means for the government to compel non-exclusive licensing of disease gene patents.[43]

Instead of relying on the Bayh-Dole Act or *eBay* to ensure non-exclusive licensing, Congress could alternatively adopt laws to ensure that physicians and non-profit research institutions can access non-exclusive licenses at a reasonable cost.[44] Or, instead of compulsory licensing laws, Congress could create statutory infringement exemptions for these groups.[45] Either proposal accomplishes the

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[41] *Id.*
[42] Holman, *supra* note 3.
[43] *Id.*
[44] MERZ, *supra* note 9, at 20.
[45] *See* Sung, *supra* note 7, at 13 (proposing draft legislation that would preclude claims against public non-profit researchers and institutions on the condition the use is for basic research that becomes dedicated to the public, and that the patent owner is provided with actual notice of "open and notorious" use); Genome.gov, Roundtable Summary on Genetic Patenting, http://www.genome.gov/11007377 (last visited Nov. 6, 2008) (finding that the NIH should explore a "Bayh-Dole – like" research exemption for Federal grant recipients giving royalty free research use licenses to federally funded inventions).

goal of preserving "freedom to undertake research"[46] while maintaining the integrity of the patent system.

One last, particularly valuable proposal is the creation of "patent pools," wherein gene patent owners who collectively wish to pursue a certain research endeavor or genetic test involving multiple patents come together and create a so called "clearing house" of patented gene sequences.[47] Such a system would allow technologies utilizing related patents to collaborate to prevent such patents from "blocking" one another, thus, minimizing transaction costs for all collaborators using the technology.[48] The patent pool proposal gained interest in recent years,[49] and is an excellent addition to non-exclusive licensing or research and/or physician exemption laws.

VIII. CONCLUSION

While gene patents have been hotly opposed, there is little factual evidence to show that gene patents are hindering research, except in the context of disease genes and diagnostic testing.[50] These problems may be alleviated by the new obviousness standard in *KSR*, the broad interpretation of the statutory FDA exemption in *eBay*, and the refusal to grant injunctions for infringement in *Merck*.[51] Furthermore, the Bayh-Dole Act provides the NIH with the opportunity to compel gene patent licensing if it is necessary for public health and safety. Additionally, Congress should consider new laws creating statutory infringement exemptions or compelling non-exclusive licenses at reasonable royalty rates for non-profit research institutions and doctors engaged in genetic testing. Lastly, gene pools are a progressive way for industry and academia to work together in

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[46] Stott & Valentine, *supra* note 3, at 364.
[47] HUGO INTELLECTUAL PROPERTY COMMITTEE, STATEMENT ON THE SCOPE OF GENE PATENTS RESEARCH EXEMPTION, AND LICENSING OF PATENTED GENE SEQUENCES FOR DIAGNOSTICS 3 (Dec. 2003), http://www.hugo-international.org/img/ip_gene_2003.pdf [hereinafter HUGO]; Sung, *supra* note 7, at 8-10.
[48] Sung, *supra* note 7, at 9.
[49] *Id.* at 9-10.
[50] Caulfield et al., *supra* note 1, at 1091-92
[51] *See* Sung, *supra* note 7, at 5-7, 10-11.

furtherance of similar research goals, thus encouraging and enabling research to go forward at a reasonable cost.[52] Notwithstanding promising policy proposals, gene patent holders must adopt responsible licensing policies to ensure that gene patents continue to serve their purpose of advancing the progress of science.

[52] *See* HUGO, *supra* note 47, at 3.