



ETHICS AND THE LAW: THE CASE OF *MYRIAD GENETICS*, ETHICS IN PATENTING AND ETHICS IN LICENSING AND COMMERCIALIZING INNOVATIONS

BY:
KIRBY DRAKE

KLEMCHUK LP

P 214-367-6000

E info@klemchuk.com

8150 N Central Expressway | 10th Floor

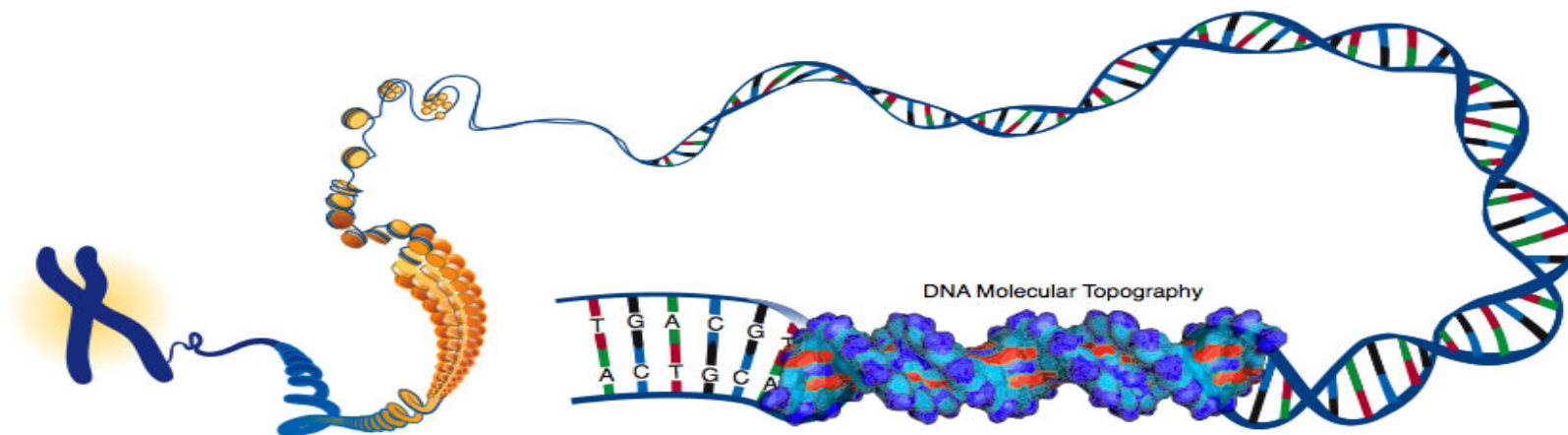
F 214-367-6001

W klemchuk.com

Dallas, Texas 75206

Gene Patents

- Generally defined as a patent on a specific isolated gene sequence, its chemical composition, processes for obtaining or using it, or a combination of such claims



KLEMCHUK LLP

P 214-367-6000

E info@klemchuk.com

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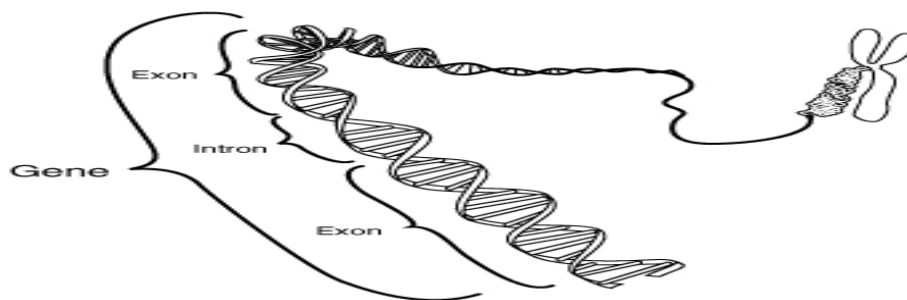
F 214-367-6001

W klemchuk.com

Dallas, Texas 75206

Human and Gene Patents

- Controversial since first grant in 1980s
- Isolated DNA molecules encoding specific genes generally patent-eligible – new and useful chemical compounds isolated or purified from natural substances
- Appropriate to grant commercial rights over components of the human body? Do patents on human genes stifle research?



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P 214-367-6000

E info@klemchuk.com

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W klemchuk.com

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Human Gene Patents – Scientific Progress?

- Attract investment capital to develop commercial products
- But inhibit translational research and hinder patients' access to gene-based inventions
 - Stop performing clinical genetic testing services because of human gene patents
- Question of whether there is an effect on price



KLEMCHUK LLP

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W klemchuk.com

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Human Gene Patenting – Popular Culture

- *Next* by Michael Crichton – author’s note of “Stop Patenting Genes”
 - Critical of Myriad Genetics and human gene patents
- “If you invent a new test, you may patent it and sell it for as much as you can, if that’s your goal. Companies can certainly own a test they have invented. But they should not own the disease itself, or the gene that causes the disease, or essential underlying facts about the disease. The distinction is not difficult, even though patent lawyers attempt to blur it.”



Myriad Genetics



- Holds numerous U.S. and international patents on the human breast cancer susceptibility gene BRCA1/2, associated mutations, and associated diagnostic test
- Sole clinical provider of full-sequence BRCA1/2 testing in U.S.
- Aggressive enforcement of patents against providers of commercial diagnostic testing (cease and desist letters; litigation)
- Clash between business model and how public health care administrators make decisions about provision of health care



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E info@klemchuk.com

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W klemchuk.com

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Ass'n for Molecular Pathology v. Myriad

- Declaratory judgment lawsuit
- Patents allegedly invalid for lack of patentable subject matter
- Patents allegedly unconstitutional
 - Article I, section 8, clause 8
 - First Amendment



Ass'n for Molecular Pathology v. Myriad

- Plaintiffs included ACLU, physicians and scientists active in breast cancer research, breast cancer support groups, breast cancer patients and other medical industry groups
- Amicus briefs filed claiming patents directed to unpatentable natural phenomena, unnecessary to promote innovation in genetic research, and violate medical and scientific ethics
- Biotechnology Industry Association filed brief in favor of Myriad saying isolated DNA differs from natural DNA and is patentable



Ass'n for Molecular Pathology v. Myriad

- **COMPOSITION:** An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
- **METHOD:** A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.



Ass'n for Molecular Pathology v. Myriad

- Composition claims - isolated DNA molecules encoding normal or mutant forms of human BRCA1/2 not markedly different from naturally occurring BRCA1/2 DNA
- But claims may be directed to tangible chemical compounds which are compositions of matter.
- Claims may be directed to “manufacture”
- Claims have utility - isolated molecules can be used as diagnostic probes and primers in determining predisposition to breast cancer



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E info@klemchuk.com

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W klemchuk.com

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Ass'n for Molecular Pathology v. Myriad

- Method claims
 - Plaintiffs' argument: not patent-eligible because directed to a law of nature and/or fail *Bilski* machine-or-transformation test
 - Myriad Genetics' argument: initial transformation occurs when primer or probe binds to patient's isolated DNA before analyzing the correlation of patient's DNA sequence encoding human BRCA1/2 and a predisposition to breast cancer
- Court found claims directed to abstract mental process of comparing or analyzing gene sequences (“data-gathering” steps)



Ass'n for Molecular Pathology v. Myriad

- Court declared Myriad patents invalid
 - Composition of matter claims directed to unpatentable products of nature
 - Method claims directed to abstract mental processes that constitute unpatentable subject matter
- “DNA represents the physical embodiment of biological information”



Constitutionality of Gene Patents

- Constitutional challenge to patentability – alleged human gene patents in general, and Myriad’s patents in particular, impede rather than promote progress of science
- Court did not address constitutional challenge - decided only on statutory grounds
- Article I, section 8, clause 8 delegates Congress the power to promote the progress of science
- Constitution gave Congress power to delegate the Patent Office power to grant patents



Constitutionality of Gene Patents

- First Amendment Issues
 - Alleged human gene patents “directly limit thought and knowledge”
 - However, Patent Act requires complete disclosure of claimed inventions in exchange for right to exclude others in U.S.
 - Patents not granted on human gene sequence information and Myriad Genetics not granted exclusive right on knowledge of human BRCA1/2 genes



Gene Patents – Conflicts over Norms and Practices, Politics and Ideology and Ethics



KLEMCHUK LLP

P 214-367-6000 E info@klemchuk.com 8150 N Central Expressway | 10th Floor
F 214-367-6001 W klemchuk.com Dallas, Texas 75206

Conflict of Norms and Practices

- BRCA test different from other diagnostic tests – most women with breast cancer do not have a known genetic predisposition for disease
- BRCA test more complex than most kits that can be bought in a pharmacy



KLEMCHUK LLP

P 214-367-6000

E info@klemchuk.com

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W klemchuk.com

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Politics and Ideology

- Concern over quality of health care services
- Objection to ownership of human genes
- Belief that gene patents stifle research and development by making it too difficult or expensive for researchers to obtain patented inventions necessary to work in the field



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Ethical Fine Line

- Many see no issue with a company developing and patenting a test for a specific gene mutation that might cause an issue with humans
- Some have an issue with company claiming that because they “discovered” a naturally occurring gene that they then “own” that gene.
- Issue when a company given a patent for gene which may prevent others from researching or developing further tests related to gene
- Who knows what other useful information / tests could have come from this gene if the underlying gene were left un-patented?



Is Issue Validity of Human Gene Patents of Licensing Practices Used with Gene Patents?



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Licensing Issues – Myriad Genetics

- Operated through exclusive licensing of BRCA patents
- Formed tight group of laboratories, health insurers, sales and distribution teams, physicians and communication team to promote tests and only offered testing services through physicians
- Perceived as refusing to recognize “research exemption” – block research to turn a profit
- Acted fast to send cease-and-desist letters shortly after obtaining patents



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Compulsory Licensing of Gene Patents

- Based on “March-In” Rights Under Bayh-Dole Act and mandatory licensing under Clean Air Act
- Apply to patents on inventions that did not result from federal funding
- Require compulsory licensing when (1) patented gene-related inventions not reasonably available; (2) there are no reasonable alternatives; and (3) compulsory licensing is necessary to alleviate public health needs



Exemption from Infringement Remedies

- Extend statutory exemption in 35 U.S.C. 271(e)(1) and 287(c)(1)
- Apply to medical practitioners' performance of human diagnostic testing that would otherwise constitute infringement
- Redefines term “medical activity” in 35 U.S.C. 287(c)(2)(A) to include “performance of a genetic diagnostic, prognostic, or predictive test or a medical or surgical procedure”
- Keeps human gene patents enforceable for therapeutic use and still stimulates investment in biotech industry



Federal Agency Guidelines

- NIH – nonbinding guidelines on human gene patenting and licensing
 - Favor broad research and commercial access to gene patents
 - Nonexclusive licensing
- Health and Human Services –February 2010 report
 - Acknowledge validity of gene patents
 - Encourage exemption of diagnostic gene testing from patent infringement claims



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Other Possibilities

- Lower- or limited-cost gene testing
- Free at-home gene testing
- Personal Genome Project – Wikipedia-style model for interpreting genome
- Elimination of gene patents



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Final Points

- *Myriad Genetics* lawsuit
 - Flaws in Myriad Genetics business model caught up in broader debate related to gene patents
- Upcoming appeal of *Myriad Genetics* decision at Federal Circuit
- Will Congress elect to take action on human gene patenting?



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