

*The Impact of Gene Patents on Patient Liberty Interests*¹

Sapna Kumar, Assistant Professor of Law
The University of Houston Law Center

1. Introduction

Gene patents are among the most controversial categories of intellectual property in the United States and abroad. Some scholars claim that gene patents create an anti-commons effect² and contribute to a “progress gap” in research, while others argue that gene patent rights are needed to ensure that companies continue to fund life-saving research.³ A Department of Health and Human Services (“HHS”) Advisory Committee studied gene patents and patient access, and found that gene patents can harm genetic research, “are not needed to stimulate the disclosure of research discoveries,” and “do not result in faster test development.”⁴

In the patent community, much of the debate regarding gene patents has focused on whether isolated, purified genes are patentable under § 101 of the Patent Act. This issue has been highlighted by the ongoing litigation in *Association for Molecular Pathology v. Myriad Genetics*,

¹ For a more detailed discussion of these issues, please see Sapna Kumar, *Life, Liberty, and the Pursuit of Genetic Information*, available at <http://ssrn.com/abstract=2203436>.

² Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation: The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (May 1998), available at <http://www.sciencemag.org/content/280/5364/698.full> (“A proliferation of patents on individual [gene] fragments held by different owners seems inevitably to require costly future transactions to bundle licenses together before a firm can have an effective right to develop these products.”).

³ See Simone A. Rose, *Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles?*, 38 *AM. J. L. & MED.* 113, 134 (arguing that a *sui generis* form of intellectual property protection is needed for basic isolated stem cells and genes to avoid a “progress gap” in research); Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 *UMKC L. REV.* 295, 352 (2007) (discussing and dismissing concerns regarding gene patents impacting personal autonomy).

⁴ See DEPT. OF HHS, REP. OF THE SEC’Y ADVISORY COMM. ON GENETICS, HEALTH, AND SOC’Y, *GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 2* (2010) (hereinafter, “HHS Report”) (“The Committee found that the prospect of patent protection of a genetic research discovery does not play a significant role in motivating scientists to conduct genetic research.”), available at http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.

which involves the validity of Myriad's BRCA 1 and 2 gene patents.⁵ But largely overlooked in the debate is a discussion on how gene patents impact the constitutional rights of patients.

In particular, scholars have not considered whether gene patents violate the Fifth Amendment's Due Process Clause⁶ by impeding the liberty rights of patients. In this paper, I contend that patients have a fundamental liberty right to make informed medical decisions. In some cases, the only way to make an informed decision is for a patient to learn whether she carries a particular genetic mutation. By issuing gene patents, the government is directly interfering with a patients' ability to obtain this information. Consequently, the Patent Act as applied to gene patents is unconstitutional.

2. Gene Patents and Fundamental Due Process Rights

The Due Process Clause protects the right to bodily integrity. The Supreme Court has observed that "[t]he integrity of an individual's person is a cherished value of our society."⁷ Justice O'Connor observed in a concurrence that

[b]ecause our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination, the Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause.⁸

This key right often manifests itself with regard to medical treatment. The Supreme Court has generally supported individual rights to make medical treatment decisions in consultation with a

⁵ This case is currently before the Supreme Court. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398, 2012 WL 4508118, at *1 (Nov. 30, 2012).

⁶ This amendment prevents the Federal Government from depriving individuals of "life, liberty, or property, without due process of law." U.S. Const. amend. V.

⁷ *Schmerber v. Cal.*, 384 U.S. 757, 772 (1966) (holding that a drunk driving suspect's blood being forcibly taken did not violate the suspect's due process rights because it was a "minor intrusion" under "stringently limited circumstances," but emphasizing that substantial bodily intrusions are not permitted).

⁸ *See Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 287 (1990) (O'Connor, J. concurring).

physician,⁹ so long as it does not run counter to the public welfare or general morality concerns.¹⁰ Bodily integrity is a fundamental right. Consequently, the government cannot impinge upon it unless it can show that the infringement is narrowly tailored to serve a compelling governmental interest.¹¹

The right of bodily integrity can furthermore be linked to the fundamental right to knowledge. One cannot meaningfully make an informed medical decision without having access to information. In the context of the right to contraception, the Supreme Court reaffirmed that states may not “contract the spectrum of available knowledge.”¹² Similarly, several Courts of Appeal have found that a person cannot exercise the right to refuse medical treatment without receiving adequate information regarding the procedure. The Third Circuit observed that the right to bodily integrity includes:

the right to be free from unjustified intrusions into the body, the related right to refuse unwanted medical treatment, and, as we decide today, *the right to sufficient information to intelligently exercise those rights*.¹³

These cases present a compelling argument that the right to make informed medical treatment decisions includes the right to information about one’s own body.

⁹ See, e.g., *Griswold v. Conn.*, 381 U.S. 479, 482 (1965) (holding that the State may not “contract the spectrum of available knowledge,” including “the right to distribute, the right to receive, the right to read and freedom of inquiry, freedom of thought, and freedom to teach”) (internal citations omitted); *Doe v. Bolton*, 410 U.S. 179, 197 (1973) (holding unconstitutional a statute that “substantially limited” a “woman’s right to receive medical care in accordance with her licensed physician’s best judgment and the physician’s right to administer it”); *Rust v. Sullivan*, 500 U.S. 173, 203 (1991) (finding an abortion regulation to be constitutional, in part, because “a doctor’s ability to provide, and a woman’s right to receive, information concerning abortion and abortion-related services outside the context of the Title X project remain[ed] unfettered”).

¹⁰ See *Gonzales v. Carhart*, 550 U.S. 124, 168 (2007) (affirming a ban on partial-birth abortion); *Jacobson v. Mass.*, 197 U.S. 11, 21 (1905) (affirming a mandatory vaccination program for smallpox).

¹¹ *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997).

¹² *Griswold*, 381 U.S. at 482.

¹³ *White v. Napoleon*, 897 F.2d 103, 112 (3d Cir. 1990) (emphasis added, internal citations omitted).

By issuing gene patents, the PTO directly hinders patients' ability to obtain critical information about their genes. Patents grant an inventor the right to exclude, but impose no obligation on the patent holder to provide the invention to the public. Gene patent holders can therefore exclude others from offering a diagnostic test, and yet not offer the test themselves.¹⁴

If the patent holder does offer testing, it may be limited in scope compared to what other laboratories could provide. Moreover, the patent holders can deny individuals the right to get secondary confirmatory testing. Accordingly, the issuance of a gene patent has the potential to impede a patient's ability to obtain genetic information necessary to make an informed medical decision.

Note that gene patents are not narrowly tailored to serve a compelling government interest. First, the Patent Act currently lacks any means for compelling reluctant patent holders to license patents, in contrast to patent statutes in other countries.¹⁵ Second, the Patent Act does not permit experimental use for researchers. Companies such as Myriad have a well-documented history of blocking testing by not-for-profit research laboratories, such as those at Yale and the University of Pennsylvania.¹⁶ This behavior slows the refinement and further development of genetic tests.¹⁷

Because the Patent Act prevents patients from making informed healthcare decisions and is not narrowly tailored, it is unconstitutional as applied. Congress and the PTO should take

¹⁴ For example, for eighteen months, the diagnostic test for Long QT syndrome was not available in the U.S. because the exclusive licensee was in bankruptcy. Julia Carbone, et al., *DNA Patents and Diagnostics: Not a Pretty Picture*, 28 NATURE BIOTECH. 784–91 (August 2010).

¹⁵ HHS Report, *supra* note 4, at 89.

¹⁶ *See, e.g., Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 205 (S.D.N.Y. 2010), *rev'd*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted in part*, 133 S. Ct. 694 (2012) (noting that Myriad forced laboratories at Yale and the University of Pennsylvania to stop offering BRCA 1 and 2 testing).

¹⁷ *See* HHS Report, *supra* note 4, at 2–3.

immediate steps to ensure that patients can make informed medical decisions without government hindrance.

Note that gene patents need not be abolished to remedy the constitutional violation. The government merely needs to take measures to ensure that gene patents do not block a patient's ability to learn about his or her genetic information in the context of medical decisionmaking. One approach is to follow the HHS Advisory Committee's recommendations and create a statutory research exemption, as well as an exemption from liability for "anyone who infringes a patent on a gene while making, using, ordering, offering for sale, or selling a genetic test for patient care purposes."¹⁸ Another option is for Congress to require the compulsory licensing of gene patents for research and diagnostic testing purposes.¹⁹

In conclusion, I advise the PTO and Congress to examine how gene patents impact patient liberty interests and to implement appropriate changes. Patent law does not operate in a vacuum; it has the potential to hinder and interfere with core rights protected by the Constitution.

¹⁸ *Id.* at 94.

¹⁹ See Janice M. Mueller, *Facilitating Patient Access to Patent-Protected Genetic Testing*, 6 J. BUS. & TECH. L. 83, 98–100 (2011).