LIFE, LIBERTY, AND THE PURSUIT OF GENETIC INFORMATION

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ABSTRACT

The Supreme Court's decision in Association for Molecular Pathology v. Myriad Genetics, Inc. *has sparked a nationwide debate on the merits of gene patents. It furthermore has led to discussion of how gene patents prevent patients from making informed decisions regarding whether to undergo major medical procedures, such as mastectomies. Although the* Myriad *litigation was based on the Patent Act's patentable subject matter requirement under § 101,, this case has highlighted a more fundamental flaw in the patent system. Using gene patents as an example, this Article argues that the Patent Act—as applied to laboratories, doctors, and patients—may violate the Fifth Amendment's Due Process Clause. Gene patents and other broad diagnostic patents can create a de facto monopoly over bodily information such as genetic mutations. Consequently, they can prevent patients from uncovering critical details of their own genetic and other bodily information and thus interfere with their ability to make informed healthcare decisions. This Article argues that the U.S. Patent & Trademark Office's grant of broad diagnostic patents has directly violated individual liberty interests. These patents confer monopoly rights over diagnostic tests, and consequently bodily information, making the harm they cause the direct result of a government actor. This Article does not propose abolishing diagnostic patents. Rather, it suggests that Congress narrowly tailor the Patent Act to promote a compelling government interest, thereby avoiding a constitutional violation.*

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INTRODUCTION

In the past year, much attention has been paid to how diagnostic testing can help patients make informed medical decisions. For example, in May 2013, Angelina Jolie announced in a *New York Times* op-ed that she chose to have a double mastectomy after learning that she carries the BRCA 1 genetic mutation.[1] BRCA 1 and BRCA 2 genetic mutations dramatically raise a woman's risk of contracting breast and ovarian cancer.[2] "I feel empowered that I made a strong choice," Ms. Jolie stated.[3] Stories such as hers have helped contribute to a discussion on the ability of patients to learn about the information in their own bodies and therefore to make better decisions regarding medical treatment.

These stories have drawn attention to an important problem: that gene patents and other patents on diagnostic testing impact public health.[4] Myriad Genetics ("Myriad") has a monopoly on these diagnostic tests due to its various patents pertaining to BRCA 1 and BRCA 2, which has allowed Myriad to limit the scope of testing available to patients.[5] But in June 2013, the Supreme Court struck down Myriad's isolated gene claims under § 101 of the Patent Act,[6] and competitors began offering gene testing for the BRCA mutations at significantly lower prices.[7]

Patients everywhere had won. Or had they? Notwithstanding the Supreme Court's opinion, Myriad sued the competitors and claimed to *still*

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1. Angelina Jolie, *My Medical Choice*, N.Y. TIMES (May 14, 2013), http://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html.

2. *See generally* Robert Cook-Deegan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers*, 12 GENETICS MED. S15 (2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3047448/.

3. Jolie, *supra* note 1, at A25.

4. Arti K. Rai, Essay, *Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development*, 61 DUKE L.J. 1237, 1240 (2012) ("The extent to which basic discoveries in genetics may be patented is a question of great importance to the national economy, to medical science, and to the public health.").

5. *See generally*, DEP'T OF HEALTH & HUMAN SERVS., REP. OF THE SEC'Y ADVISORY COMM. ON GENETICS, HEALTH & SOC'Y, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 46–48 (2010) [hereinafter, HHS REPORT], *available at* http://oba.nih.gov.oba/sacghs_patents_report_2010.pdf (discussing how gene patents have limited patient access to genetic testing); *see also* Brenda M. Simon, *Patent Cover-Up*, 47 HOUS. L. REV. 1299, 1308 (2011) ("By using licensing restrictions to limit research and testing, companies are hindering the ability to assess the quality of genetic testing.").

6. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013).

7. *See, e.g.*, AMBRY GENETICS, *BreastNext*, http://www.ambrygen.com/tests/breastnext (last visited Dec. 6, 2013) ("Please note, all samples received starting June 13, 2013 for BreastNext, CancerNext, and OvaNext will automatically include *BRCA1/2* gene sequencing and deletion/duplication analyses at no additional cost. Additionally, Ambry will contact clinicians to discuss any clinically-significant *BRCA1/2* incidental findings on all in-house samples.").

hold a monopoly over BRCA testing based on its remaining cDNA and method patents.[8] The Supreme Court's decision had changed nothing.

In the gene patent debate, scholars and judges have focused primarily on the Patent Act, a statute designed to protect inventors and promote innovation.[9] This discourse has largely overlooked the broader issue of how to promote innovation without compromising individual patient rights. Using gene patents as an illustrative example, this Article argues that the Patent Act may allow the Patent & Trademark Office ("PTO") to violate the due process rights of patients. The Fifth Amendment prevents the Federal Government from depriving individuals of "life, liberty, or property, without due process of law."[10] The Supreme Court has furthermore established a fundamental right to make medical decisions in consultation with one's physician.[11] This raises the question of whether strong diagnostic patent rights have compromised the liberty interests of individuals, given the lack of patient safeguards in the Patent Act.

This Article is the first to examine how patent issuance under the Patent Act can lead to due process violations.[12] Diagnostic patents may

8. *See* Andrew Pollack, *2 Competitors Sued by Genetics Company for Patent Infringement*, N.Y. TIMES (July 10, 2013), http://www.nytimes.com/2013/07/11/business/2-competitors-sued-by-genetics-company-for-patent-infringement.html (noting that Myriad sued Ambry Genetics and Houston-based Gene by Gene for infringement of Myriad's remaining BRCA 1 and BRCA 2 patents); *Myriad Genetics sues Bio-Reference Laboratories and Quest Diagnostics for Patent Infringement*, PATHOLOGY BLAWG (Oct. 25, 2013), http://pathologyblawg.com/pathology-news/pathology-vendors/myriad-genetics/myriad-genetics-sues-bio-reference-laboratories-quest-diagnostics-patent-infringement/ (reporting that Myriad sued Quest Diagnostics and Bio-Reference Laboratories' wholly-owned subsidiary GeneDX for infringing Myriad's remaining BRCA 1 and BRCA 2 patents, plus other patents). There are also two declaratory judgments that have been filed against *Myriad* in California federal courts. *Counsyl, Inc. Challenges Eight Myriad Genetics BRCA Patents*, PATHOLOGY BLAWG (Oct. 11, 2013), http://pathologyblawg.com/pathology-news/pathology-vendors/myriad-genetics/counsyl-inc-challenges-eight-myriad-genetics-brca-patents/ (reporting that Counsyl, Inc.—which provides genetic testing—has brought a declaratory judgment against Myriad in the Northern District of California); *Quest Diagnostics Brings the Fight to Myriad Genetics with BRCA Patent Suit*, PATHOLOGY BLAWG (Oct. 15, 2013), http://pathologyblawg.com/pathology-news/pathology-vendors/myriad-genetics/quest-diagnostics-brings-fight-myriad-genetics-brca-patent-suit/ ("Quest Diagnostics filed suit against Myriad Genetics in US District Court in the Central District of California on October 10, 2013, asking for a declaration that multiple patents held by Myriad Genetics involving BRCA testing are invalid and that Quest is not infringing on any of the specified patents.")

9. Article 1, Section Eight of the 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[.]" U.S. CONST. Art. I, § 8, cl. 8.

10. U.S. CONST. amend. V.

11. *See infra* Part II.C.

12. Professor Jennifer Rothman has applied a liberty framework to copyright law. *See* Jennifer E. Rothman, *Liberating Copyright: Thinking Beyond Free Speech*, 95 CORNELL L. REV. 463, 493 (2010). She uses the Due Process Clause to develop an affirmative theory to support use rights. *Id*. at 474–75. A student note briefly touched on the idea that gene patents may have due process implications. *See* Morgan Geller, Note, *Every Woman Deserves Her Own Pair of Genes: The Constitutionality of Patenting The BRCA Gene in* Association for Molecular Pathology v. U.S. Patent & Trademark Office, 34 NOVA L. REV. 765 (2010). Also, Professor John Thomas explored patent enforcement as a state

confer inventors with de facto monopolies on bodily information, such as DNA mutations. When misused, such patents can prevent patients from learning about key information in their own bodies, preventing them from making informed medical decisions and depriving them of a fundamental liberty interest. Moreover, the Patent Act is not narrowly tailored to serve a compelling governmental interest due to a lack of patient safeguards. Consequently, the Patent Act—as applied to laboratories, doctors, and patients— may be unconstitutional.[13]

There are several reasons why due process problems persist, notwithstanding the *Myriad* Court's ruling. As mentioned above, Myriad continues to assert a monopoly over all BRCA 1 and BRCA 2 testing. Furthermore, researchers have already identified other gene-related diagnostic patents that may be broad enough to bar testing for particular diseases.[14] Finally, the problem of patient access to bodily information encompasses diagnostic testing patents in general, not simply the patentability of isolated genes.

Part I of this Article examines the role of the Constitution in patent law with regard to protecting individual rights. It examines the shortcomings in Article I, Section Eight of the Constitution, which authorized Congress to create the patent system.[15] It also discusses attempts by scholars to secure protection under the First Amendment for the communication of diagnostic test results. Part II of this Article provides an overview of gene patents and the gene patent controversy.

Part III looks at whether the Due Process Clause can be used to protect access to one's own bodily information. It argues, based on existing precedent, that there exists a fundamental right to learn about one's own bodily information to make informed medical decisions in consultation with one's physician. Notwithstanding the relatively young age of the field of genetics, the core right of bodily integrity is deeply rooted in the history and tradition of our nation.[16]

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action but focused on the fact that patentees would not be considered state actors. *See* John R. Thomas, *Liberty and Property in the Patent Law*, 39 HOUS. L. REV. 569, 606 (2002).

13. An argument can be made that gene patents also violate the First Amendment. The existence of gene patents can prevent doctors and researchers from communicating to their patients when a genetic mutation is discovered. *See* Part I.B. This issue was before the district court in *Myriad* but was not appealed. This argument merits further analysis.

14. *See infra* notes 133–34 and accompanying text.

15. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3242 (2010) ("In 1790, Congress passed the first Patent Act, an 'Act to promote the progress of useful Arts' that authorized patents for persons who had 'invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used,' if 'the invention or discovery [was] sufficiently useful and important.'" (quoting 1 Stat. 109–10 (1790) (alteration in original)).

16. *See* Washington v. Glucksberg, 521 U.S. 702, 721 (1997) (noting that fundamental rights must be "'deeply rooted in this Nation's history and tradition'" (quoting Moore v. City of E. Cleveland, 431 U.S. 494, 503 (plurality opinion))). This severe limitation on fundamental rights is controversial.

Part IV discusses how the PTO's issuance of gene patents can violate individual liberty rights. It examines how patent holders predictably use their monopoly rights to block testing and to prevent more comprehensive tests from being offered to the public. This Part argues that diagnostic patents can be distinguished from patents on drugs or medical devices, because only the former can lead to a de facto monopoly on information which cannot be invented around. It further observes that a patient's access to his or her own bodily information merely requires freedom from government interference, which is wholly consistent with the Due Process Clause. This Part does not make a cost-based argument regarding access to diagnostic testing. Rather, it argues that the government should not facilitate the creation of monopolies on information without including safeguards to protect patient rights.

Part V examines the larger institutional design problem of protecting patients from broad diagnostic patents. Part V makes two legislative suggestions to prevent future constitutional violations. First, it recommends that Congress amend the Patent Act to facilitate compulsory licensing of diagnostic patent holders where individual rights have been compromised. It also advocates for granting the National Institute of Health (NIH) power to promulgate regulations on compulsory licensing and to authorize such licenses. Second, it suggests that the Patent Act be amended to provide an experimental use exception to medical researchers. These changes would help protect individuals from the unconstitutional side-effects of promoting innovation.

I. CONSTITUTIONAL PATENT LAW

Patents related to diagnostic testing can directly harm patients. Broad diagnostic patents, such as those at issue in *Myriad*, do not block merely a particular method or medical procedure. Instead, they have the effect of granting a complete monopoly on underlying bodily information.[17] Such patents can block patients from accessing information in their own body and prevent patients from receiving proper medical treatment.[18]

Yet, the patent system is ill-equipped to deal with these public-policy issues. Although anyone may challenge the validity of a patent in the PTO, third parties may not challenge patents on public policy grounds. The Patent Act, in general, does not have provisions to protect the public

See David M. Smolin, *Fourteenth Amendment Unenumerated Rights Jurisprudence: An Essay in Response to* Stenberg v. Carhart, 24 HARV. J.L. & PUB. POL'Y 815, 821–24 (2001) (discussing the controversy of the Supreme Court relying on history to define unenumerated fundamental rights).

17. *See* Complaint, Myriad Genetics, Inc. v. Ambry Genetics (D. Utah 2013) (No. 2:13-cv-00640-RJS) (arguing that genetic testing of BRCA 1 and BRCA 2 violates its gene patents).

18. *See generally* HHS REPORT, *supra* note 5.

welfare. Although a common-law experimental use exception once existed, it was eviscerated by the Federal Circuit.[19] Moreover, there is still debate over whether strong patent rights always benefit the public.[20]

By contrast, other intellectual property statutes generally contain safeguards against public harm. For example, the Copyright Act permits some unlicensed but socially beneficial use under the doctrine of fair use.[21] Likewise, under § 337 of the Tariff Act, a product that violates a U.S. patent may not be blocked from entering the country[22] if the benefits to a patent holder are outweighed by concerns regarding "public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers."[23]

This raises the question of how we can protect individual rights from the harsher effects of patents. Although a statutory solution is clearly needed,[24] Congress has yet to offer one.[25] Likewise, although the Executive Branch can use eminent domain and other powers to seize or override patent rights,[26] it seldom does.

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19. *See* Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) ("[U]se does not qualify for the experimental use defense when it is undertaken in the 'guise of scientific inquiry' but has 'definite, cognizable, and not insubstantial commercial purposes.'" Rather, the defense is limited to "actions performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'" (quoting Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000))).

20. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1629–30 (2003) (discussing how a one-size-fits-all approach to patent law fails to maximize innovation and ultimately hurts the public); Sarah R. Wasserman Rajec, *Tailoring Remedies to Spur Innovation*, 61 AM. U. L. REV. 733, 747 (2012) (discussing how patent trolls coupled with strong patent rights result in less public access to products).

21. 17 U.S.C. § 107 (2006). *See* Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 918 (2004).

22. 19 U.S.C. § 1337(a)(B)(ii) (2006).

23. 19 U.S.C. § 1337(c) (2006).

24. *See, e.g.*, Mueller, *supra* note 21, at 918 (calling for a statutory experimental use exception to promote scientific research). *See generally* Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247 (2009) (arguing in favor of compulsory licensing of patented pharmaceuticals to protect public health).

25. When the America Invents Act passed, Congress offered no legislative solution but instead, instructed the PTO to hold a series of roundtables on the effects of gene patents on patients.

26. In 1912, the Supreme Court held that the government has the right to use eminent domain to seize patents. *See* Crozier v. Aktiengesellschaft, 224 U.S. 290, 304–05 (1912) (holding that patents are subject to the government's eminent domain power). Likewise, if a federal agency finances research that results in a patent, it can exercise "march-in rights" to obtain a license when a patent holder fails to satisfy the "health or safety needs" of the public. 35 U.S.C. § 203(b) (2006). However, the government prefers to use a softer approach, using threats of march-in rights or the like to obtain a compromise or concession from the patent holder. For example, when terrorist attacks necessitated that the government obtain a supply of Bayer's patented Cipro antibiotic, the Secretary of Health and Human Services threatened to disregard the patent and pursue generic alternatives if Bayer did not lower its price. Bayer chose to comply with the Secretary's request. Cynthia M. Ho, *Inoculation Inventions: The Interplay of Infringement and Immunity in the Development of Biodefense Vaccines*, 8 J. HEALTH CARE L. & POL'Y 111, 112–114 (2005).

Consequently, to protect the rights of individuals, we must turn to the Constitution. Subpart A maintains that Article I, Section Eight, Clause Eight of the Constitution ("IP Clause") is an inadequate form of protection for individual rights. Subpart B discusses how the First Amendment has been used in patent proceedings and addresses its weaknesses. Finally, Subpart C argues in favor of using the Due Process Clause to protect a patient's liberty interests.

A. The Intellectual Property Clause

Both patent and copyright law are grounded in Article I, Section Eight, Clause Eight of the Constitution ("IP Clause"), which grants Congress the right "[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."[27] The IP Clause is viewed generally as a limitation on Congress's power to regulate intellectual property. For example, in *Graham v. John Deere Co.*, the Supreme Court noted that the clause is not just a grant of power, but also a limitation.[28] It maintained that Congress may neither "overreach the restraints imposed by the stated constitutional purpose" nor "enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby."[29] Professor Jeanne Fromer noted that a textual analysis of the clause suggests that the IP Clause further limits Congress's ability to use *other* constitutional powers to promote the progress of the useful arts.[30]

The IP Clause does not protect individual rights. In *Eldred v. Ashcroft*, the Supreme Court addressed the issue of the Sonny Bono Copyright Term Extension Act, which extended the term for existing and future copyrights.[31] The petitioners, who published works in the public domain, argued that the extension violated the IP Clause's "limited Tim[e]" language.[32] The Court held that the copyright term could be retroactively extended, even though the extension did not provide any incentive to past authors to innovate.[33] The Court did distinguish copyrights from patents, maintaining that "patents and copyrights do not entail the same exchange,

27. U.S. Const. Art. I, § 8, cl. 8.

28. Graham v. John Deere Co., 383 U.S. 1, 4 (1966).

29. *Id*. at 6.

30. Jeanne C. Fromer, *The Intellectual Property Clause's External Limitations*, 61 DUKE L.J. 1329, 1344 (2012) ("[T]he IP Clause's text and the constitutional structure volunteer a suggestive—but not ironclad—argument that the Clause's unique construction operates externally to forbid Congress from using its other powers to promote the progress of science and useful arts beyond the means specified in the Clause.").

31. *See* Eldred v. Ashcroft, 537 U.S. 186 (2003).

32. *Id*. at 193 (alteration in original) (internal quotations omitted).

33. *Id*. at 203–04.

and that our references to a *quid pro quo* typically appear in the patent context."[34]

In *Golan v. Holder*, the Court addressed whether a Uruguay Round Agreement Act provision, which permitted copyrights on works that had recently passed into the public domain, violated the IP Clause.[35] The Court held that no violation had occurred, disregarding individual harm in favor of Congress's ability to shape a copyright regime that promoted innovation overall.[36]

In his dissent, Justice Breyer, joined by Justice Alito, argued that U.S. copyright and patent jurisprudence has followed a utilitarian approach.[37] Discussing the IP Clause, the dissent observed the Court's earlier emphasis on the purpose of the IP Clause:

> "[T]he monopoly privileges that Congress may authorize are . . . [not] primarily designed to provide a special private benefit. Rather, the *limited grant is a means by which an important public purpose may be achieved*. It is intended *to motivate the creative activity of authors . . . by the provision of a special reward*."[38]

Notwithstanding the limiting language regarding patents, *Eldred* revealed a fundamental limitation in the role that the IP Clause plays in IP law. Although the *Golan* dissent emphasizes a public well-being angle, it is concerned with the protection of rights of the public as a whole, not those of individuals. If one person is harmed by a law, but the public generally thrives, the law would be justified under such a utilitarian analysis. No precedent supports the idea that the IP Clause provides affirmative protection for third parties who are harmed, such as the book publishers who printed public domain works in *Eldred*.

Several scholars believe that the IP Clause should play a stronger role in how courts look at biotechnology patent law issues. Professor Oskar Liivak maintained that the IP Clause contains an originality requirement that "mandates narrow claim scope for inventions low in originality."[39] He argued that the scope of gene patents should be narrowed by looking to originality for guidance.[40] Professor Simone Rose contends that the IP Clause mandates examining whether patent protection for isolated

34. *Id*. at 216.
35. Golan v. Holder, 132 S. Ct. 873, 878 (2012).
36. *Id*. at 878.
37. *Id*. at 901–02 (Breyer, J., dissenting).
38. *Id*. at 902 (some alteration in original) (internal citations omitted) (quoting Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 429 (1984)).
39. Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 41 U.C. DAVIS L. REV. 177, 188 (2007).
40. *Id*. at 223.

bioproducts "allows for reasonable access to basic knowledge."[41] But neither of these views has been adopted by the courts.

B. The First Amendment

Other petitioners and scholars have attempted to invoke the First Amendment to protect individuals from the negative effects of patents. When the *Myriad* case was filed in the Southern District of New York, the petitioners raised a First Amendment argument,[42] arguing that broad gene patents have a number of detrimental speech effects. Patents can prevent doctors from communicating with their patients and researchers from communicating with research participants.[43] Because the district court held that Myriad's isolated DNA patents were "unpatentable subject matter under 35 U.S.C. § 101,"[44] the court found it unnecessary to reach the plaintiffs' constitutional claims.[45] The First Amendment argument was raised on appeal and has not yet been addressed by the courts.[46]

The interplay between the First Amendment and copyright law, unlike patent law, is much clearer. In *Golan*, the Supreme Court emphasized that copyright law has "'built-in First Amendment accommodations'" such as fair use and the idea/expression dichotomy.[47] Professors Kali Murray and Erika George maintain that analogous First Amendment accommodations are built into the Patent Act.[48] Although the Supreme Court has established

41. Simone A. Rose, *Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles?*, 38 AM. J.L. & MED. 113, 133 (2012). Professor Rose further notes that the "balancing of access and innovation is the basis for excluding products of nature and abstract ideas from patentable subject matter under section 101 of the Patent Act" and that access to such knowledge "is crucial to our progress as a society." *Id*.

42. Complaint at 3, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 1:09-cv-04515), 2009 WL 1343027.

43. *See* Brief for Kali N. Murray & Erika R. George as Amici Curiae in Support of Petitioners, Ass'n for Molecular Pathology v. Myriad Genetics, Inc. at 2, 16–17, 133 S. Ct. 2107 (2013) (No.12-398), 2013 WL 432954, at *2, 16–17; *see also* Krysta Kauble, *Patenting Everything Under the Sun: Invoking the First Amendment to Limit the Use of Gene Patents*, Comment, 58 UCLA L. REV. 1123, 1128 (2011) (arguing that the First Amendment "may serve as a helpful lens for distinguishing laws of nature from patentable objects"); Geller, *supra* note 12, at 776–77 (discussing First Amendment concerns in gene patents).

44. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010), *rev'd*, 689 F.3d 1303 (Fed. Cir. 2012).

45. *Id*. at 237–38.

46. It is possible that as a matter of appellate procedure, the petitioners were unable to cross-appeal the First Amendment issue because there was no negative ruling on it.

47. Golan v. Holder, 132 S. Ct. 873, 889–90 (2012) (quoting Eldred v. Ashcroft, 537 U.S. 186, 219 (2003))..

48. Murray & George, *supra* note 43, at 7–8. Professors Murray and George also raised a Thirteenth Amendment challenge against gene patents. *Id*. at 21–24.

that laws of nature, physical phenomenon and abstract ideas are not embodied in § 101,[49] Murray and George contend:

> These exclusionary principles suggest that ours is a constitutional system with dual objectives. Our constitutional patent regime seeks not only to incentivize the creative activity of a patent claimant but also to protect the preconditions for creative activity by preserving certain types of information . . . from aggressive claims that would serve to block access to these basic building blocks of scientific inquiry and information exchange.[50]

As the Court in *Eldred* notes, unlike a copyright, a patent "does prevent full use by others of the inventor's knowledge," thereby conferring the patentee with a monopoly on knowledge.[51]

Even if we assume that the First Amendment provides some protection to third parties against overly broad patents, it is cannot block patents on diagnostic testing that prevent individuals from learning about their own medical information. However, combined with other Constitutional violations, the First Amendment could be part of a penumbral rights argument. This argument is briefly discussed in Part V.

C. The Due Process Clause

The Due Process Clause protects individuals against the "arbitrary action of government."[52] Under the doctrine of substantive due process, a court considers whether a regulation or government action is justified notwithstanding the effect on an individual life, liberty, or property interest.[53] Scholars describe the doctrine as having "waxed and waned" over the last century, with disputes remaining over the scope of these unwritten rights.[54]

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49. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

50. Murray & George, *supra* note 43, at 7 (citing *Eldred*, 537 U.S. at 217).

51. *Eldred*, 537 U.S. at 217.

52. County of Sacramento v. Lewis, 523 U.S. 833, 845 (1998) (quoting Wolff v. McDonnell, 418 U.S. 539, 558 (1974)).

53. *See, e.g.*, *id*. at 840.

54. John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 939, 959 n.64 (1986) ("Although the fortunes of substantive due process have waxed and waned since Lochner v. New York, 198 U.S. 45 (1905), and considerable dispute exists over the scope of unwritten rights, even conservative members of the Court recognize some irreducible substratum of unwritten rights."). For the early history of substantive due process, see Alex Kozinski & Stuart Banner, *The Anti-History and Pre-History of Commercial Speech*, 71 TEX. L. REV. 747, 761–63 (1993).

In contrast to property rights, which have diminished over the years,[55] liberty rights remain strong. As the Supreme Court noted in *Lawrence v. Texas*, "[l]iberty protects the person from unwarranted government intrusions" and "presumes an autonomy of self."[56] As discussed in Part III, under the right of bodily integrity, patients have the right to make informed health care decisions. This arguably includes the right to access information about our own bodies without interference from the government.

The Fifth Amendment's Due Process Clause could play a powerful role in shaping patent law. Unlike the IP Clause, the Due Process Clause protects individuals whose liberty interests have been harmed by a federal government actor. Therefore, the protection extends beyond speech, covering intrusions into a patient's right to bodily integrity.[57]

But the most difficult obstacle to using due process in a patent context is establishing that the government's actions directly harm patients. To trigger due process rights, there must be a state or federal action, and not merely a private harm.[58] As Professor John Thomas has observed, a court

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55. *See* Robin Feldman, *Whose Body is it Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law*, 63 STAN. L. REV. 1377, 1381 (2011) (discussing how courts have been reluctant to recognize property rights in cell lines); Ronald J. Krotoszynski, Jr., *Fundamental Property Rights*, 85 GEO. L.J. 555, 555 (1997) (discussing how property rights have been the "poor relation" compared to liberty rights under modern substantive due process jurisprudence).

Note that there is some limited protection for genetic information as property. The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits health insurance issuers from using genetic information to deny coverage, raise premiums, or impose pre-existing condition exclusions; it also prohibits employers from discriminating against employees on the basis of genetic information. *See* Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110-233, 122 Stat. 881. But GINA does not confer individuals with a property interest, nor does it protect genetic information as property. Five states have passed legislation protecting an individual's genetic information as property. *See* ALASKA STAT. ANN. § 18.13.010(a) (West 2012) ("Except as provided in (b) of this section . . . a DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed."); COLO. REV. STAT. ANN. § 10-3-1104.7(1)(a) (West 2012) ("Genetic information is the unique property of the individual to whom the information pertains."); FLA. STAT. § 760.40(2)(a) (2010) (noting that the results of DNA analysis, "whether held by a public or private entity, are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested"); GA. CODE ANN. § 33-54-1 (2005) ("The General Assembly . . . finds and declares that: (1) Genetic information is the unique property of the individual tested" and further, limits the use, disclosure, and availability of such information); LA. REV. STAT. ANN. § 22:1023.E (2011) ("An insured's or enrollee's genetic information is the property of the insured or enrollee."). However, these statutes focus on preventing unauthorized disclosures of genetic information and not on creating a knowledge right in one's own genetic information. *See* W. Peter Guarnieri, Note, *Prince Harry and the Honey Trap: An Argument for Criminalizing the Nonconsensual Use of Genetic Information*, 48 AM. CRIM. L. REV. 1789, 1802 (2011) (observing that even in states with property protection for genetic information, "courts have been reluctant to recognize property rights in a person's genetic information"). Some scholars and practitioners have advocated for stronger property rights in genetic information. *See* Samantak Ghosh, *The Taking of Human Biological Products*, 102 CALIF. L. REV. (forthcoming 2014), *available at* http://ssrn.com/abstract=2244097.

56. Lawrence v. Texas, 539 U.S. 558, 562 (2003).

57. *See infra* Part III.

58. *See* Paul R. Verkuil, *Privatizing Due Process*, 57 ADMIN. L. REV. 963, 964 (2005) ("[P]rocess is only *due* when the public sector, rather than the private, takes action."); *see also* Deshaney v.

would be highly unlikely to find a patent holder to be a government actor.[59] This high standard likely explains why no one has attempted to utilize this clause in the context of patent law.[60]

Consequently, a preliminary question must be answered: does the PTO's issuance of a diagnostic patent directly harm patients? If so, the PTO's action could invoke due process protection. By contrast, if the patentee causes the harm, the patient has no recourse under the Fifth Amendment. This Subpart argues that the harm from diagnostic patents stems directly from the PTO's actions, making the Due Process Clause applicable, while acknowledging the weaknesses inherent in this argument.

1. Overview

The issue of when a state action has deprived a person of due process rights is complex. In *Shelley v. Kraemer*, a landowner attempted to enforce a restrictive covenant prohibiting non-whites from living on fifty-seven parcels of land in St. Louis.[61] The Supreme Court confronted the question of whether a state action had occurred, given it was a private landowner attempting to enforce the covenant. It held "[t]hat the action of state courts and of judicial officers in their official capacities is to be regarded as action of the State within the meaning of the Fourteenth Amendment."[62] Similarly, in *New York Times v. Sullivan*, the Supreme Court held that a state court's application of libel law to block protected speech constituted a state action.[63]

Under this line of cases, federal court enforcement of patents that violate the due process rights of individuals would be sufficient to give rise to state action. But over time, the state action doctrine has been narrowed substantially. *Shelley* was found to be untenable because it created a state action every time that a court acted.[64]

Winnebago Cnty. Dep't of Soc. Servs., 489 U.S. 189, 196 (1989) ("Its purpose was to protect the people from the State, not to ensure that the State protected them from each other. The Framers were content to leave the extent of governmental obligation in the latter area to the democratic political processes.").

59. *See* Thomas, *supra* note 12, at 606.

60. There is also a separate problem of obtaining standing to sue. *See* Sapna Kumar, *Public Law, Standing, and the Federal Circuit* (draft on file with author).

61. Shelley v. Kraemer, 334 U.S. 1, 4–5 (1948).

62. *Id*. at 14.

63. N.Y. Times Co. v. Sullivan, 376 U.S. 254, 265 (1964) ("Although this is a civil lawsuit between private parties, the Alabama courts have applied a state rule of law which petitioners claim to impose invalid restrictions on their constitutional freedoms of speech and press. It matters not that that law has been applied in a civil action and that it is common law only, though supplemented by statute.").

64. *See* Shelley Ross Saxer, *Judicial State Action:* Shelley v. Kraemer*, State Action, and Judicial Takings*, 21 WIDENER L.J. 847, 852–53 (2012).

In *Lugar v. Edmondson Oil Co.*, the Supreme Court noted that it had "affirmed the essential dichotomy set forth in the [Due Process Clause] between deprivation by the State, subject to scrutiny under its provisions, and private conduct, however discriminatory or wrongful, against which the [Due Process Clause] offers no [protection]."[65] However, the Court found that conduct is fairly attributed to the government where the deprivation is "caused by the exercise of some right or privilege created by the State" and that "the party charged with the deprivation must be a person who may fairly be said to be a state actor."[66]

The second part of the *Lugar* test—when a third party can be fairly said to be a state actor—has been criticized as "one of the more slippery and troublesome areas of civil rights litigation."[67] The Seventh Circuit has noted that "[b]oth the Supreme Court and the lower federal courts have acknowledged the difficulty of determining whether a private entity has acted under the color of state law."[68] At least five separate tests exist for determining when state action is found, none of which completely captures the PTO's behavior.[69]

2. Analysis

Some scholars argue that patent rights are not intrinsically different from real property rights.[70] For example, Professor Adam Mossoff has

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65. Lugar v. Edmondson Oil Co., 457 U.S. 922, 936 (1982) (quoting Jackson v. Metro. Edison Co., 419 U.S. 345, 349 (1974)) (internal quotation marks omitted).

66. *Id*. at 937; *see also* Shelley Ross Saxer, Shelley v. Kraemer*'s Fiftieth Anniversary: "A Time for Keeping; a Time for Throwing Away"?*, 47 U. KAN. L. REV. 61, 69–75 (1998) (discussing theories for when a liberty violation constitutes a state action).

67. *See* Rodriguez v. Plymouth Ambulance Serv., 577 F.3d 816, 823 (7th Cir. 2009) (quoting Int'l Soc'y for Krishna Consciousness v. Air Canada, 727 F.2d 253, 255 (2d Cir. 1984)) (internal quotations omitted).

68. *Id*.

69. *See* Jackson, 419 U.S. at 351 (1974) (discussing the close nexus test); Burton v. Wilmington Parking Auth., 365 U.S. 715, 725 (1961) (discussing the symbiotic relationship test, where "[t]he state has so far insinuated itself into a position of interdependence . . . that it must be recognized as a joint participant in the challenged activity"); Edmonson v. Leesville Concrete Co., 500 U.S. 614 (1991) (discussing the public function test, where the private party is exercising a power that is traditionally exclusively the function of government); Dennis v. Sparks, 449 U.S. 24 (1980) (discussing the joint participation test, where private parties conspire with government actors to such an extent they are held to be acting under color of law); Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass'n, 531 U.S. 288 (2001) (discussing the pervasive entwinement test, where the private actor is substantially entwined with the state via a combination of function, personnel, influence and funding).

70. *See* Emily Michiko Morris, Res *or Rules? Patents and the (Uncertain) Rules of the Game*, 18 MICH. TELECOMM. & TECH. L. REV. 481, 484 (2012) (observing that "critics most often seem to compare patent claims to fences or the metes and bounds of real property, rather than to easements, leaseholds, or other legal interests in property"); Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J.L. & TECH. 321, 323 (2009) (arguing that "defining a property right in terms of the right to exclude is not distinctive to patent law" because patent rights are derived "from a conception of property in land that was first promulgated within American law by the legal realists in the early

argued that patents are constitutional private property, subject to the takings clause.[71] This view is attractive, given that like real property holders, patent holders do not appear to be state actors.[72] Patent holders do not have government-like powers; rather, they hold something akin to an entitlement. Patent holders furthermore do not provide a public function, nor do their actions directly benefit the government. Thus, it is difficult to argue that they act in any quasi-governmental fashion.

However, when a broad patent is issued, it is possible to show that the PTO directly caused the deprivation. Unlike real property ownership, patents are an entitlement that has been created *in toto* by the government. When the PTO issues a patent, it grants an inventor a right to exclude others from making, using, or selling the patented technology.[73] The claim language of a patent, and consequently the scope of the patent, is heavily dependent on the PTO's examination procedure. This is in contrast to copyright law, where copyright exists from the moment of fixation[74] and government registration does not involve a substantive examination.

Professor Mossoff has observed that courts once had a strong role in shaping the scope of real property rights, making patents and real property analogous.[75] However, in post-*Shelley* caselaw, a court's mere enforcement of a property right does not play a role in creating a state action.[76] Thus the court's role for enforcement, either in real property or in patents, cannot serve as a basis for a state action. But again, unlike with real property, a government agency is involved in shaping the scope of the patent right at the outset. Indeed, patent rights do not exist without agency involvement.

But how can the mere creation of a patent right give rise to a due process violation? If an inventor patents an invention, it is not an unforeseeable or unintended consequence of the patent system for that inventor to exclude everyone else from making or using that invention. It is exactly what we would expect, given that patent rights are exclusionary.[77]

Thus, when the PTO issues a broad diagnostic testing patent to an inventor, and that inventor proceeds to shut down all laboratories offering

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twentieth century"). *But see* Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1097 (2009) (noting that patents can be distinguished from real property on several grounds, including the fact that patents can impede access to medicine, where as real property cannot).

71. Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 700 (2007).

72. *See* Thomas, *supra* note 12, at 606.

73. *See* Mossoff, *supra* note 70, at 322–23 (noting that the "conventional wisdom" is that "patents secure only a right to exclude," but arguing that such a construal of patent rights is inaccurate and causes problems in patent law).

74. 17 U.S.C. § 102(a) (2006).

75. *See* Mosoff, *supra* note 70, at 350–51.

76. *See* Saxer, *supra* note 64, at 851–52, 854–55.

77. What is out of the norm is for an inventor to obtain a patent and then dedicate the patent to the public domain, or grant free licenses to non-profit entities.

the test, *the PTO itself* causes the deprivation. The patent owner is acting in a manner that is wholly consistent with the entitlement that it has been granted. The patent system does not require inventors to sell their inventions, nor does it anticipate a benevolent inventor who allows competitors to stay in business. In that regard, the PTO is the proximate cause of the harm.

One might argue that individuals are not harmed unless a patent holder chooses to enforce a patent. However, the mere issuance of a patent by the PTO can have a chilling effect on third parties, because competitors expect patent holders to exercise their rights. Laboratories would rather not offer a test than risk expensive litigation, even if the laboratory has a good chance at prevailing.[78] The fact that all issued patents are presumed valid furthers this harm.[79]

In the context of gene patents, Professor Holman noted that "this chilling effect is based on an unwillingness to challenge the patents."[80] Taken one step further, the chilling effect is based on third parties not having the vast financial resources needed to challenge the patents. In other words, laboratories will cease research in the face of a patent, even one of dubious validity, rather than risk costly litigation.

For example, Ambry Genetics ("Ambry") offers next-generation genetic testing for breast cancer genes, a form of testing that does not require isolation of genes, which should not violate any of Myriad's past or present patents.[81] It had the capability to offer BRCA 1 and BRCA 2

78. Laboratories are generally not willing to speak on the record about how patents affect their decision to offer testing. Consequently, the chilling effect is very difficult to measure. *See* Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1082–83 (2003) (noting that smaller firms which lack "a portfolio of defensive patents may be dissuaded from entering a particular research area," which can lead to a chilling effect, but acknowledging that the effect is difficult to measure). However, Professor Chandrasekharan and Cook-Deegan's research shows that the mere existence of patents affects laboratory behavior. *See infra* note 120 and accompanying text; *see also* Ian Ayres & Gideon Parchomovsky, *Tradable Patent Rights*, 60 STAN. L. REV. 863, 867–68 (2007) ("The dramatic growth in the number of issued patents has prompted a concern that the modern patent system hinders technological progress, and hence retards dynamic efficiency. In particular, the desire of patentees to build strong patent portfolios, coupled with the poor quality of review by the USPTO and the laxity with which it grants patents, have dramatically increased the cost of follow-on innovation in our society."); Robert Cook-Deegan et al., *supra* note 2, at S29 (maintaining that Myriad's gene patents may be responsible for a chilling effect on further development of genetic tests).

79. *See* Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2239 (2011) ("In asserting patent invalidity as a defense to an infringement action, an alleged infringer must contend with § 282 of the Patent Act of 1952 (Act), under which '[a] patent shall be presumed valid' and '[t]he burden of establishing invalidity . . . shall rest on the party asserting' it." (quoting 35 U.S.C. § 282 (2006) (alteration in original)).

80. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patents Litigation*, 76 U. MO. KAN. CITY L. REV. 295, 347 (2007).

81. *See generally* Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 U. MO. KAN. CITY L. REV.

testing, but did not do so until the day of the Supreme Court's *Myriad* decision.[82] There is no evidence that Ambry was contacted or threatened by Myriad. Rather, the mere existence of the patent was likely enough to prevent them from offering a test that was arguably not infringing.[83] Indeed, Ambry's fears proved well-founded, given that they were promptly sued by Myriad once they began offering the testing.[84]

Consequently, the mere existence of patents can deprive patients of their right to learn about their own bodily information. This is in contrast with cases where the deprivation did not occur at the point of issuance by the state, but only at some later point of enforcement by the private party.[85]

In this regard, even if we assume patents are property rights, they are created in a way that is distinct from real property and other forms of intellectual property. The PTO is the architect of the patent right—shaping the claim language of the patent, thus molding the metes and bounds of the exclusionary right. This is not a right that is created instantly, like copyright, nor a mere recordation of a transaction that occurred, like the sale of land. Consequently, the issuance of patents by the PTO constitutes a government action, which can give rise to a due process violation. Parts III and IV explain in detail how the Due Process Clause can be used to protect patients from overly broad diagnostic patents.

II. GENE PATENTS AS A REPRESENTATIVE CASE

Gene patents provide a clear example of how a due process violation can directly result from the issuance of broad diagnostic patents. This Part gives an overview of the basic science behind genes and explains the application of gene patents. Part III then creates a framework for a due process analysis, and Part IV applies it to gene patents and shows why the Supreme Court's *Myriad* decision was inadequate.

563 (2012) (discussing, in general, why next-generation genetic diagnostic testing does not infringe isolated gene patents).

82. *See* AMBRY GENETICS, *supra* note 7.

83. A counterargument could be made that Ambry Genetics recognized that Myriad aggressively enforced their patent rights and acted accordingly. Nevertheless, one can argue that it is not Myriad's direct behavior but the mere existence of the patent that caused Ambry Genetics to not offer the test.

84. *See* Pollack, *supra* note 8.

85. *See, e.g.*, Am. Mfrs. Mut. Ins. Co. v. Sullivan, 526 U.S. 40, 43 (1999) (holding a private insurer's decision to withhold payment did not constitute state action because the deprivation occurred, not at the time of delegation of the exclusionary right to the private insurer, but at the choice of the private insurer to exclude coverage).

A. A Brief Overview of DNA

To understand gene patents, it is useful to understand some of the underlying science. Genes carry hereditary traits and are comprised of DNA, which provides instructions on how to make "functional molecules" such as RNA and proteins.[86] The DNA sequences are collectively referred to as "nucleotides," which provide information regarding the precise order for a protein's "building block"—amino acids.[87] Not all DNA actually encodes amino acids, thus providing the building blocks for cells to manufacture proteins. Coding sequences of DNA are called "exons"; the non-coding pieces of DNA between the exons are called "introns."[88]

To make a protein, transcription occurs, during which time the information coded in the DNA is copied into RNA.[89] At this point, the non-coding introns must be removed and the exons joined together. This splicing process yields mRNA, which transfers information to the ribosomes that produce the proteins from mRNA.[90] During this process, errors can occur, such as the deletion of a nucleotide in the exon, or the addition of a nucleotide in the intron. Although many of these mutations are harmless, they can cause abnormal or missing proteins that can sometimes lead to diseases such as Alzheimer's.[91]

In the laboratory, scientists can isolate strands of natural DNA. From isolated strands, they can create mRNA, as well as complimentary DNA, or cDNA. cDNA is essentially an edited man-made copy of the information contained in regular DNA.[92] It is synthesized in a laboratory from messenger RNA. Unlike regular DNA, cDNA is stripped of all of its introns and is therefore different from naturally-occurring DNA.[93] Although isolated DNA is no longer patentable, cDNA remains patentable subject matter under § 101 of the Patent Act.[94]

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86. *How Genes Work*, NAT'L INST. FOR HEALTH, http://publications.nigms.nih.gov/thenewgenetics/chapter1.html#dnastr (last updated June 9, 2011).

87. *Id*.

88. *Id*.

89. *Id*.

90. *Id*.

91. *Id*.

92. Megan Krench, *New Supreme Court Decision Rules That cDNA Is Patentable—What It Means for Research and Genetic Testing*, SCI. AM. (July 9, 2013), http://blogs.scientificamerican.com/guest-blog/2013/07/09/new-supreme-court-decision-rules-that-cdna-is-patentablewhat-it-means-for-research-and-genetic-testing/.

93. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013); *see also* Feldman, *supra* note 55, at 1388 ("As a cell goes through the complex process of translating the DNA sequence through messenger RNA and into the proper protein, certain portions of the sequence are spliced away. cDNA is the mirror image of the sequence at the point at which all noncoding regions have been removed.").

94. *Myriad*, 133 S. Ct. at 2111.

B. The Government's Response

Gene patents are one of the most controversial categories of patents in the United States and abroad[95] and have received attention from all three branches of government. Yet, though many concerns have been raised regarding patient rights, no branch has had the desire or the means to fully protect patients from the harsh effects of gene patents.

1. The Executive Branch

The PTO has generally spoken out in favor of gene patents. In 2001, it issued examination guidelines responding to comments that "genes are discoveries rather than inventions."[96] The PTO maintained that "an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it."[97] It further stated: "where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable."[98] In recent years, the PTO has taken a harder look at the impact of gene patents on diagnostic testing and genetic research, but only at Congress's behest.[99]

In contrast, the Department of Justice has stood firmly against gene patents. In the *Myriad* litigation, the Office of the Solicitor General submitted an amicus brief to the Supreme Court, stating that isolated DNA "is not patent-eligible because it has merely been 'isolated' . . . rather than significantly altered by human intervention."[100] The government argued

95. *See, e.g.*, Timothy Caulfield, *Human Gene Patents: Proof of Problems?*, 84 CHI.-KENT L. REV. 133, 133 (2009) (discussing the controversy of gene patenting); Rebecca Goulding et al., *Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research*, 16 B.U. J. SCI. & TECH. L. 194, 196 (discussing the controversy of gene patents, and observing that they raise "concerns about ethics, the norms of science and university values, and the impact on further research and innovation").

96. USPTO Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092 (Jan. 5, 2001).

97. *Id*. at 1093.

98. *Id*.

99. *See supra* notes 109–110 and accompanying text.

100. Brief for the U.S. as Amicus Curiae for Petitioner at 12, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2013) (No. 12-398). Notably, this case marked the first time that a solicitor general argued before the Federal Circuit. *See* Courtenay C. Brinckerhoff et al., *The Federal Circuit Hears Oral Arguments in Myriad Isolated DNA Case*, LEXOLOGY (April 4, 2011), http://www.lexology.com/library/detail.aspx?g=3fb58b6f-c91a-4af0-a382-28b1872ef604 (discussing Solicitor General Neal Katyal's argument before the court); Alison Frankel, *U.S. Solicitor General to Make Unprecedented Federal Circuit Appearance, Opposing Gene Patentability in* Myriad *Case*, THE AM. LAWYER, Feb. 2011, http://www.americanlawyer.com/PubArticleTAL.jsp?id=1202482853884&slreturn=20131123000421 (noting that Katyal's argument appears to mark the first time that a solicitor general has argued before the Federal Circuit).

that "extending patent eligibility to a modified natural substance may risk 'tying up' the underlying natural substance" when the only modification is "removing the substance from its natural environment."[101] During oral arguments before the Supreme Court, the Solicitor General urged the Court to strike down patents on isolated genes.[102]

The Department of Health and Human Services had a more mixed reaction to gene patents. In 2010, it released the Report of the Secretary's Advisory Committee on Genetics, Health, and Society ("HHS Report").[103] The Committee's detailed study found that gene patents "pose serious obstacles" to both genetic diagnostic tests and therapeutic treatments designed for people with particular gene variations.[104] It further noted that "U.S. patent law not only threatens medical progress, it may also drive valuable genetic research to countries with a more hospitable legal climate."[105] The Committee ultimately recommended that the Patent Act be amended to provide "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" as well as a research exemption.[106]

However, in response to the Committee report, HHS Secretary Kathleen Sebelius dissolved the Committee.[107] The premature termination of the Committee raised the question of whether the Obama administration was turning its back on the problems raised by gene patents.[108]

2. The Legislative Branch

Congress has only managed baby steps towards examining the issue of gene patents. Under the America Invents Act ("AIA"), Congress mandated that the PTO report to Congress regarding gene patents. Congress asked the PTO to focus on four topics: (1) the impact that the lack of independent second opinion testing has had on patient care and on innovation, (2) the

101. *See* Brief for the U.S. as Amicus Curiae for Petitioner at 17–18, *Myriad*, 133 S. Ct. 694 (2013) (No. 12-398).

102. Transcript of Oral Argument at 25–26, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398).

103. The Committee had 18 members, who were experts in a wide range of fields including genetics, legal and medical academia, nursing, and public policy. *See* HHS REPORT, *supra* note 5, at i–ii.

104. HHS REPORT, *supra* note 5, at 89. The HHS Report notes that Belgium allows for research on or with isolated genes exempt from infringement of any patents. *Id*. at 90.

105. *Id*. at 90.

106. *Id*. at 94.

107. Dan Vorhaus, *HHS Pulls the Plug on Genetics Advisory Committee*, GENOMICS LAW REPORT (Sept. 23, 2010), http://www.genomicslawreport.com/index.php/2010/09/23/hhs-pulls-the-plug-on-genetics-advisory-committee/.

108. *Id*.

effect that second opinion genetic diagnostic testing would have on existing patent holders' rights, (3) the "impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine," and (4) the "role that cost and insurance coverage have on access to and provision of genetic diagnostic tests."[109] This led the PTO to hold a series of hearings regarding genetic diagnostic testing.[110]

Representative Lamar Smith introduced legislation in 2011 that would have created a new subsection under the Patent Act establishing a safe harbor for second opinion genetic diagnostic testing.[111] However, the proposed legislation died after it was opposed by the ACLU and other groups that feared that the amendment was too narrow and risked legitimizing the patentability of genes.[112] This incident highlights that Congress ultimately controls the scope of § 101 of the Patent Act.

3. The Courts

The Federal Circuit first weighed in on the gene patent debate in the early 1990s. In *Amgen, Inc. v. Chugai Pharmaceutical Co.*, the court found a "purified and isolated DNA sequence" to be novel.[113] The *Amgen* court, however, did not address whether genes were patentable under § 101.

This opportunity came in the *Myriad* litigation. At issue were patents held by Myriad Genetics, which is a corporation that was spun off by the University of Utah. These patents claimed the isolated BRCA 1 and 2 genes, along with related cDNA and method claims. A patient with one or both of these BRCA mutations has an elevated risk of contracting breast and ovarian cancer.[114] Once the patents were issued, Myriad began sending cease-and-desist letters to laboratories that offered BRCA 1 and BRCA 2

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109. America Invents Act, Pub. L. No. 112-29, § 27, 125 Stat. 284, 338–39 (2011).

110. *See* U.S. PATENT & TRADEMARK OFFICE, *AIA Studies and Reports—Genetic Testing*, http://www.uspto.gov/aia_implementation/aia_studies_reports.jsp (providing public comments and transcripts of hearings regarding genetic testing).

111. Dan Vorhaus, *House Introduces Patent Reform Proposal to Permit Second Opinions in Genetic Diagnostic Testing*, GENOMICS LAW REPORT (June 15, 2011), http://genomicslawreport.com/index.php/2011/06/15/house-introduces-patent-reform-proposal-to-permit-second-opinions-in-genetic-diagnostic-testing/.

112. Dan Vorhaus, *Update: Proposed Second Opinion Safe Harbor for Genetic Diagnostic Testing Withdrawn*, GENOMICS LAW REPORT (June 16, 2011), http://www.genomicslawreport.com/index.php/2011/06/16/update-proposed-second-opinion-safe-harbor-for-genetic-diagnostic-testing-withdrawn/.

113. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) (internal quotation marks omitted).

114. *See* D. Ford et al., *Genetic Heterogeneity and Penetrance Analysis of the BRCA1 and BRCA2 Genes in Breast Cancer Families*, 62 AM. J. HUM. GENETICS 676, 676 (1998) (discussing BRCA mutation link to breast and ovarian cancer).

testing, including those at educational institutions including Yale and the University of Pennsylvania.[115]

In 2011, the Federal Circuit held that patents on isolated, purified genes meet the patentability requirement under § 101 of the Patent Act.[116] The opinion was fractured, with Judge Lourie writing for the majority, Judge Moore concurring in the judgment, and Judge Bryson dissenting in part.

The Supreme Court issued a grant-vacate-remand decision in light of the Court's decision in *Mayo*.[117] In that case, the Supreme Court held that a patent covering a medicine dosing process was not patentable under § 101 because the process was effectively a law of nature.[118]

In response, in 2012, the Federal Circuit issued an opinion nearly identical to its prior decision, once again finding gene patents to meet the patentability requirement.[119] The Federal Circuit refused to address public policy concerns, noting that the question before it was not "whether [it is] desirable for one company to hold a patent or license covering a test that may save people's lives."[120]

The Supreme Court granted certiorari on the issue of "[w]hether human genes are patent-eligible subject matter under 35 U.S.C. 101."[121] The Court held that isolated, purified DNA is not patentable, while holding that man-

115. *See id*. (noting that as a result of Myriad's efforts to enforce its patents against the University of Pennsylvania Genetic Diagnostic Lab and the Yale DNA Diagnostics Lab, both labs ceased testing); *see also* Julia Carbone, et al., *DNA Patents and Diagnostics: Not a Pretty Picture*, 28 NATURE BIOTECH. 784, 785–86 (2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3026778/ (noting that "Myriad's enforcement actions coupled with broad patent claims, its fairly narrow conception of what constituted acceptable research and its failure to clearly state that it would not pursue those conducting such research, [resulted in] university and private laboratories ceasing to offer the [BRCA] test publicly in the United States.").

116. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1354 (Fed. Cir. 2011).

117. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012). The Supreme Court in *Mayo* held that Prometheus' medicine dosing process was not patentable subject matter under § 101 of the Patent Act because the process was effectively a law of nature. *Id*.

118. *Id*. This decision clarified that a process can cover a law of nature even if meets the Federal Circuit's machine-or-transformation test.

119. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012), *rev'd in part*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

120. *Id*. at 1324 ("The question is also not whether is it desirable for one company to hold a patent or license covering a test that may save people's lives, or for other companies to be excluded from the market encompassed by such a patent—that is the basic right provided by a patent, *i.e.,* to exclude others from practicing the patented subject matter."); *see also* Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1103–08 (2003) (arguing that the Federal Circuit has taken a formalist approach to decisionmaking, disregarding a policy-oriented approach).

121. Brief for the U.S. as Amicus Curiae Supporting Petitioners at I, Ass'n for Molecular Pathology v. Myriad, 133 S. Ct. 694 (2012) (No. 12-398), 2013 WL 390999.

made cDNA is patentable. [122] The implications of the Court's ruling are discussed below.

C. Monopolies on Information

When an inventor discovers a gene that causes a disease, he or she generally isolates, extracts, and purifies the gene. To do this, the gene is isolated in a laboratory and "separated from proteins and other DNA sequences."[123] Part of the gene is then removed from the cell and separated from non-DNA materials and then further processed to separate the part of the DNA that is of interest from the rest of the DNA.[124] This process allows the DNA to be used for biotechnological applications that naturally occurring DNA is not suitable for.[125]

Prior to the Supreme Court's *Myriad* decision, an inventor could determine the function of a gene or mutation and then patent isolated nucleic acid molecules with sequences that correspond to fragments of the gene.[126] Because such patents covered information, they gave the inventor exclusive control over virtually all forms of diagnostic testing for the gene sequence.[127] Consequently, patents regarding isolated genes blocked all diagnostic testing for the gene at issue.[128]

Indeed, even after *Myriad*, it still appears that inventors can maintain a total monopoly on testing for a particular mutation. As discussed above, companies that have attempted to offer BRCA 1 and BRCA 2 testing using

122. *Myriad*, 133 S. Ct. at 2111.

123. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 196 (S.D.N.Y. 2010).

124. *Id*.

125. *Id*.

126. *See id*. at 211.

127. The Supreme Court recognized this problem in *Myriad*, observing that isolating DNA "does not change the information-transmitting quality of the DNA." *Myriad*, 133 S. Ct. at 2115.

128. *See* Amy Maxmen, *How the Myriad Genetics Gene-Patent Case Might Affect Personalized Medicine*, NATURE (July 20, 2012), http://www.nature.com/news/the-great-gene-patent-debate-1.11044 (noting how some of the isolated DNA genes subject to U.S. patents "form the basis of diagnostic tests that determine when someone might respond well to a given therapy, or whether they're at risk of a disease or a drug side effect"); *Molecular Pathology*, 702 F. Supp. 2d at 204–05 (discussing how two of the plaintiffs offered BRCA testing using a method not patented by Myriad, but were blocked by Myriad's patents because the method required the use of isolated DNA encoding the BRCA mutations). Note that it was unclear whether isolated gene patents blocked more advanced forms of testing. *Compare* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1348 (Fed. Cir. 2012) (Bryson, J., dissenting) (arguing isolated gene patents block full genomic sequencing), *with* Christopher M. Holman, *Debunking the Myth that Whole-Genome Sequencing Infringes Thousands of Gene Patents*, 30 NATURE BIOTECH. 240 (2012) (arguing that next-generation genomic testing does not infringe patents on isolated genes).

next-generation testing technology have been sued by Myriad, notwithstanding the Supreme Court's decision.[129]

Broad gene patents have had many implications for patients. First, patent holders have limited the scope of available testing and shut down laboratories that attempted to offer broader or more advanced versions of a genetic test.[130] In one extreme case, the patent holder failed offer the test at all.[131] Second, patent holders have prevented patients from obtaining a second opinion on their diagnostic test by choosing not to license the test to other laboratories.[132] Third, patent holders have withheld licenses to researchers, thereby limiting further innovation in diagnostic testing. Consequently, gene patents have limited individual access to bodily information.

These problems are not theoretical. In a 2003 study, 25% of laboratories surveyed reported that they stopped performing a genetic test because of patent-related issues, and 53% reported that they were unable to develop a new test because of patents.[133] Genetic law and policy researchers Robert Cook-Deegan and Subhashini Chandrasekharen argue that exclusive licensing of gene patents has reduced the availability of genetic testing to patients.[134]

Moreover, the Supreme Court's decision leaves two types of gene patents still permissible: cDNA patents and method patents. As discussed above, cDNA is essentially an edited man-made copy of the usable information contained in regular DNA.[135] Method patents cover a process

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129. *See* Howard Wolinsky, *Gene Patents and Capital Investment*, 14 EUR. MOLECULAR BIO. REP. 871, 871 (2013) ("Myriad Genetics has not given up defending its patents, however. On 9 and 10 July 2013, it slapped Ambry and Gene by Gene with lawsuits in the US District Court in Salt Lake City for allegedly infringing on patents covering synthetic DNA and methods-of-use related to the *BRCA1* and *BRCA2* genes.").

130. *See infra* Part IV.A.1.b.

131. *See infra* Part IV.A.1.a.

132. This has been a particular problem with patents controlled by Myriad Genetics and Athena Diagnostics. *See generally* Sean O'Connor, *The Use of MTAs to Control Commercialization of Stem Cell Diagnostics and Therapeutics*, 21 BERKELEY TECH. L.J. 1017 (2006) (discussing Myriad Genetics and Athena Diagnostics' use of exclusive licensing); *see also* Robert Cook-Deegan et al., *Observations from Studies of Patenting and Licensing Practices that Affect DNA-Based Clinical Testing*, Statement at the U.S. Patent and Trademark Office Roundtable (Jan. 10, 2013), http://www.genomics.duke.edu/centers/cpg/sec-27-study/documents/Cook-DeeganstmtUSPTO10Jan2013Roundtable10Jan2013onlinesupplement-1.pdf ("Both Athena and Myriad established sole provider standing for some of their tests because of very broad patent rights.").

133. Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, J. MOLECULAR DIAGNOSTICS, Feb. 2003, at 3–8, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1907368/.

134. *See* Subhashini Chandrasekharan & Robert Cook-Deegan, *Gene Patents and Personalized Medicine—What Lies Ahead?*, 1 GENOME MED. 92, 92 (2009) ("When the provider does not offer all forms of genetic testing . . . or does not have coverage and reimbursement agreements with insurers or health plans, patients cannot turn elsewhere to get a test.").

135. *See* Krench, *supra* note 92.

or series of steps for doing something, such as testing for a genetic disorder. Broad method patents can also block patient access to genetic information; indeed, several broad method patents appear to cover all forms of testing for a particular gene.[136] Although the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[137] promises some form of a limit on broad method patents involving diagnostic testing, it is unclear where that boundary lies.[138]

These two types of patents are now at issue in a lawsuit Myriad filed against Ambry. When *Myriad* was handed down, Ambry immediately began offering BRCA 1 and BRCA 2 testing. Myriad has now sued them in the District of Utah, arguing that their remaining cDNA and method patents give them a monopoly on that testing.[139] In Myriad's motion for a preliminary injunction, it maintained that "Ambry is able to offer testing at this discounted price by unfairly and improperly 'free-riding' off of the hundreds of millions of dollars invested by Myriad Genetics in developing the science and market for clinical diagnostic testing for hereditary cancers."[140] Consequently, even after the *Myriad* decision, Myriad is still attempting to assert a monopoly right over bodily information.

III. DUE PROCESS AND GENETICS

All individuals possess a fundamental right to bodily integrity, including the right to make informed medical decisions in consultation with their physicians.[141] Yet, in the debate regarding diagnostic patents, no attention has been paid to the interplay between patents and the fundamental liberty rights of individuals. In particular, gene patents provide a clear illustration of how diagnostic patents have violated the due process rights of patients.

It is important to emphasize that in many circumstances, diagnostic patents do not violate the Constitution. For example, an inventor may obtain a method patent on a diagnostic test that reveals information about a patient's ancestry and has nothing to do with medical treatment. Likewise,

136. HHS REPORT, *supra* note 5, at 13–14.

137. 132 S. Ct. 1289 (2012).

138. *See* Rebecca S. Eisenberg, Prometheus *Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341, 342–43 (2013), http://yalelawjournal.org/2013/04/01/eisenberg.html (noting that the Supreme Court's decision "cast[s] a shadow of uncertainty over the validity of patents on diagnostic inventions," but offers "only vague guidance" to lower courts on how to handle validity challenges).

139. Complaint at 5–16, Myriad Genetics Inc. v. Ambry Genetics (D. Utah 2013) (No. 2:13-cv-00640-RJS) (2013 WL 3810321).

140. Motion for Preliminary Injunctive Relief at 5, *Myriad* (D. Utah 2013) (No. 2:13-cv-00640-RJS).

141. *See infra* Part III.B.

a diagnostic patent may be narrow, allowing for alternative forms of testing. For this reason, one cannot argue that the Patent Act is facially unconstitutional.[142]

This Article, instead, argues that the Patent Act may be unconstitutional as applied to individual patients, to laboratories attempting to offer testing where none is available, or to laboratories attempting to offer secondary testing. An as-applied challenge may be used when a statute is unconstitutional as applied to a particular circumstance. A successful challenge does not render the entire statute unconstitutional. Rather, the court will hold that the part of the statute as applied to the plaintiff is unconstitutional.[143]

Subpart A provides an overview of the scope of substantive liberty interests in a broader context. Subpart B then considers a hypothetical case of a patient who requires access to her genetic information when seeking medical treatment. It then shows that for situations that do not jeopardize public health or offend the morals of the court, a fundamental liberty right exists to make informed medical decisions in consultation with one's physicians. Subpart B also discusses how a right to personal information, when used to make informed health care decisions, can be inferred from Supreme Court and appellate court precedent. This Part concludes that a patient has a right to access her genetic information to make informed medical decisions.

A. Overview of Liberty Interests

In *Board of Regents of State Colleges v. Roth*, the Supreme Court noted that it "has not attempted to define with exactness the liberty" that is guaranteed by the Due Process Clause.[144] However, over a long line of cases, the Court has articulated liberty rights that are fundamental, including "the rights to marry, to have children, to direct the education and

142. To make a facial challenge, "the challenger must establish that no set of circumstances exists under which the Act would be valid." United States v. Salerno, 481 U.S. 739, 745 (1987). A successful challenge invalidates the statute. Members of City Council of City of L.A. v. Taxpayers for Vincent, 466 U.S. 789, 796 (1984) (observing, in a First Amendment context, that a statute is "invalid 'on its face'" if "it is unconstitutional in every conceivable application"). However, facial challenges are heavily disfavored. *See* Wash. State Grange v. Wash. State Republican Party, 552 U.S. 442, 450 (2008) (noting that facial challenges "run contrary to the fundamental principle of judicial restraint" by anticipating a constitutional question, and circumvent the democratic process).

143. *See* Field Day, LLC v. Cnty. of Suffolk, 463 F.3d 167, 174 (2d Cir. 2006) ("An 'as-applied challenge' . . . requires an analysis of the facts of a particular case to determine whether the application of a statute, even one constitutional on its face, deprived the individual to whom it was applied of a protected right.").

144. Bd. of Regents of State Colls. v. Roth, 408 U.S. 564, 572 (1972) (internal quotation marks omitted). Note that this case involves the Fourteenth Amendment, but the due process protection against state encroachments parallels that of federal encroachments under the Fifth Amendment.

upbringing of one's children, to marital privacy, to use contraception, to bodily integrity, and to abortion."[145]

A statute cannot infringe upon a fundamental right unless the infringement is narrowly tailored to serve a compelling government interest.[146] This is regarded as a high bar for the government to clear. By contrast, to prevail against infringement of a non-fundamental right, the burden rests on the affected individual to show that the legislation in question is not rationally related to a legitimate government interest.[147]

Although existing fundamental rights are very powerful, the Supreme Court has resisted further expansion. In *Washington v. Glucksberg*, the Supreme Court held that Washington State's ban on physician-assisted suicide did not violate the Due Process Clause.[148] It emphasized its reluctance to broaden substantive liberty interests, "lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court."[149]

The Supreme Court noted that to establish new substantive liberty rights, one must first examine whether the asserted interest is "deeply rooted in this Nation's history and tradition."[150] Additionally, there must be a "'careful description' of the asserted fundamental liberty interest."[151] The Court held that because the right to physician-assisted suicide was not backed by history or tradition, it was not fundamental.[152]

This rigid definition of fundamental liberty interests is problematic in cases such as this where technological advances allow the government to compromise our bodily integrity in new ways. The framers of the

145. Washington v. Glucksberg, 521 U.S. 702, 720 (1997) (citations omitted).

146. *Id*. at 721 (quoting Reno v. Flores, 507 U.S. 292, 302 (1993))

147. *See id*. at 728 (holding that the right to assisted suicide is not a fundamental right, and that Washington's assisted-suicide ban was rationally related to legitimate government interests). The Supreme Court has never enumerated what constitutes non-fundamental liberty rights, though it appears to be a catch-all including the right to education and to contract and engage in business. *See* Plyler v. Doe, 457 U.S. 202, 223 (1982) ("Nor is education a fundamental right; a State need not justify by compelling necessity every variation in the manner in which education is provided to its population."); Nebbia v. New York, 291 U.S. 502, 527–28 (1934) ("The Constitution does not guarantee the unrestricted privilege to engage in a business or to conduct it as one pleases . . . [and] statutes prescribing the terms upon which those conducting certain businesses may contract, or imposing terms if they do enter into agreements, are within the state's competency.").

148. *Glucksberg*, 521 U.S. at 735.

149. *Id*. at 720.

150. *Id*. at 721 (quoting Moore v. City of E. Cleveland, 431 U.S. 494, 503 (1977)) (plurality opinion). Note that there are disputes over whether this is the sole metric for determining a fundamental right. *See* Nan D. Hunter, *Living with* Lawrence, 88 MINN. L. REV. 1103, 1119–22 (2004) (noting that under *Glucksberg*, "fundamental rights constituted a frozen category and a limiting principle that operated to bar any meaningful protection for interests that could not meet its eligibility criteria" and that the opinion "illustrated the fractured and uncertain nature of the opposition on the Court to the Rehnquist-Scalia-Thomas approach to substantive due process analysis").

151. *Glucksberg*, 521 U.S. at 721 (internal quotation marks omitted).

152. *Id*. at 723–24.

Constitution clearly did not contemplate that detailed information from our body would enable us to make better decisions regarding our health, nor did they foresee that the government would be able to hinder our access to such information though the patent system. Because of the Supreme Court's controversial limitation on the expansion of liberty interests, the only way to prevent new forms of liberty violations is to link the violation to an existing fundamental right. Subpart B accomplishes this by linking patient access to genetic information to the existing fundamental right of bodily integrity.

B. Bodily Integrity

Consider the following pre-*Myriad* hypothetical: Alice experiences severe pain and goes to see her physician, Dr. Smith. Dr. Smith believes that Alice might be suffering from a treatable disease but cannot be sure without learning whether she carries a particular genetic mutation. However, the isolated, purified gene has been patented, and the diagnostic test for the mutation is not offered by any laboratory. Suppose that Dr. Smith can either perform the test in-house, but knows that this action will infringe upon the patent. Can Alice and Dr. Smith bring an as-applied constitutional challenge to the Patent Act?

The first question that must be asked is *how* would Alice and Dr. Smith challenge the patent. The Patent Act contains no citizen-suit provision allowing third parties to directly challenge a patent. During the *Myriad* litigation, a group of plaintiffs attempted to sue under the Declaratory Judgment Act. However, the Federal Circuit denied standing to all but one of the parties, claiming that the patients who were merely denied access to testing suffered no real or immediate injury.[153] The only harm the court recognized was being sued for patent infringement, as opposed to bodily harm.[154] The issue of standing in the Federal Circuit merits further attention.[155]

Assuming Alice and Dr. Smith did have standing, under what constitutional theory could they sue? As discussed above, the Intellectual Property Clause provides little protection, and the problems they face do not directly pertain to speech.

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153. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1319 (Fed. Cir. 2012).

154. *Id*.

155. *See generally* Michael J. Burstein, Rethinking Standing in Intellectual Property Challenges (November 2013) (unpublished manuscript) *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2359873; Sapna Kumar, Public Law, Standing, and the Federal Circuit (unpublished manuscript) (draft on file with author).

Consequently, we must then understand the scope of the fundamental right to bodily integrity. Among various liberty interests, the right to bodily integrity has remained one of the strongest.[156] As discussed below, it has been expanded by the Supreme Court to include rights originally cast under privacy, such as the right to contraception and abortion.[157]

Justice Blackmun noted in his concurrence in *Planned Parenthood v. Casey* that "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual *to the possession and control of his own person, free from all restraint or interference of others*."[158] Over the years, the Court has reiterated this principle, observing that "[t]he integrity of an individual's person is a cherished value of our society."[159] Justice O'Connor has observed 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."[160] This right often arises in medical treatment cases. As discussed below, the Supreme Court has generally supported a patient's right to make medical treatment decisions in consultation with her physician, albeit with some restrictions.

There are three lines of cases regarding medical treatment: public health cases, moral values cases, and autonomy cases.[161] The public-health line of cases focuses on the state's duty to protect public health.[162] In such cases, the Supreme Court prioritizes protecting the public over the rights of

156. Seth F. Kreimer, *Rejecting "Uncontrolled Authority Over the Body": The Decencies of Civilized Conduct, the Past and the Future of Unenumerated Rights*, 9 U. PA. J. CONST. L. 423, 452–55 (2007) (arguing that the right of bodily integrity is likely to remain strong going forward, and maintaining that "federal courts cannot abandon the bodies of the citizenry to the convenience of the state and refuse to grapple with the issues on the grounds that the constitutional text enumerates no cognizable rights").

157. *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 849–50 (1992) (plurality opinion) (discussing the constitutional limits on the state's right to interfere with bodily integrity); Kreimer, *supra* note 156 at 439 ("In the ensuing decade and a half, it has become increasingly difficult to refuse to discern rights against bodily violation as part of the constitutional fabric.").

158. *Casey*, 505 U.S. at 927 (Blackmun, J., concurring in part) (emphasis added) (quoting Union Pac. R.R. Co. v. Botsford, 141 U.S. 250, 251 (1891)); *see also* Christopher Richins, Jacobson *Revisited: An Argument for Strict Judicial Scrutiny of Compulsory Vaccination*, 32 J. LEGAL MED. 409, 433 (2011) (discussing the right to bodily integrity).

159. *See* Schmerber v. California, 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, but emphasizing that substantial bodily intrusions were not permitted); *see also* Deana Pollard Sacks, *Elements of Liberty*, 61 SMU L. REV. 1557, 1581 (2008) ("Physical autonomy, referred to as 'bodily integrity,' has consistently been protected as a liberty right integral to self-determination.").

160. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 287 (1990) (O'Connor, J., concurring).

161. *See* B. Jessie Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 281–82 (2007) (discussing the "public health" versus "autonomy" line of Supreme Court cases regarding the right to make medical treatment choices).

162. *See, e.g.*, Jacobson v. Massachusetts, 197 U.S. 11, 39 (1905) (affirming a mandatory vaccination program for smallpox).

individuals to make health care decisions.[163] Courts of appeals decisions rejecting access to unapproved medical treatments have also emphasized protecting public health.[164] These cases are not applicable to Alice, because she is not seeking medical treatment that is potentially harmful to herself or others; she is instead trying to learn whether she carries a particular mutation to make an informed decision in consultation with her physician.

Moral-values cases involve government interference with the physician–patient relationship for moral or ethical reasons. Cass Sunstein maintains that the Supreme Court rejected physician-assisted suicide because of "due process traditionalism" in which courts utilize "morals of tradition."[165] The Court's decision to ban partial-birth abortion, even when a physician deems the procedure necessary, further illustrated moral values prevailing over the right to make medical decisions.[166] However, this line of cases is not applicable to Alice, because there is no strong moral concern with regard to a patient learning about her own genetic information.[167]

The third line of cases emphasizes the rights of bodily integrity and dignity interests,[168] and is *highly* relevant to Alice's situation. These cases include the right to refuse medical treatment and the right to choose appropriate medical treatment in consultation with one's physician.[169] In these cases, the Supreme Court has endeavored to protect patient rights to make these decisions and to limit the government's intrusion into the physician–patient relationship.[170]

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163. *See, e.g.*, Roe v. Wade, 410 U.S. 113, 150 (1973) ("The prevalence of high mortality rates at illegal 'abortion mills' strengthens, rather than weakens, the State's interest in regulating the conditions under which abortions are performed.").

164. *See, e.g.*, Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) ("It is apparent in the context with which we are here concerned that the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health.").

165. *See* Cass R. Sunstein, *Due Process Traditionalism*, 106 MICH. L. REV. 1543, 1544, 1558 (2008) (arguing that the Supreme Court, in rejecting physician-assisted suicide, "appeared to settle on a kind of due process traditionalism, captured in the view that long-standing cultural understandings are both necessary and sufficient for the substantive protection of rights under the Due Process Clause").

166. *See* Gonzales v. Carhart, 550 U.S. 124, 138–39 (2007) (using loaded descriptions of partial birth abortions, such as referring to the fetus as a "baby," to frame the issue of why such abortions can be banned without a health exception for women).

167. There are, perhaps, two examples where there might be moral concerns regarding access to genetic information. First, prenatal genetic testing might result in a woman having an abortion. Second, many bioethicists have taken the paternalistic position that if an individual learns that he or she is predisposed to some horrible disease, the individual will not be able to cope with the information. In that regard, they view providing such information to individuals to be unethical. *See generally* Evans, *supra* note 13.

168. Hill, *supra* note 161, at 278.

169. *Id*. at 305–13.

170. Note that the right of bodily integrity goes beyond the medical context. Many cases involve the right of prisoners to be free from invasive procedures that are not medically needed. *See, e.g.*, Winston v. Lee, 470 U.S. 753, 766 (1985) (rejecting state's request for surgery to remove bullet from chest of man to determine whether he was involved in an attempted robbery as an invasion of privacy);

1. The Right to Make Health Care Decisions

In *Griswold v. Connecticut*, the Supreme Court considered a state statute that prohibited individuals from distributing contraception or assisting someone in obtaining contraception.[171] The appellant was charged with providing information to married persons regarding how to prevent conception, as well as with prescribing contraception.[172] The Court noted that the case involved "a wide range of questions that implicate the Due Process Clause," and observed that the statute in question "operates directly on an intimate relation of husband and wife and their physician's role in one aspect of that relation."[173]

Griswold established a sphere of constitutional protection for the physician–patient relationship that the Court continued to build on. Seven years later, in *Eisenstadt v. Baird*, the Supreme Court struck down several Massachusetts statutes that limited the availability of contraception to anyone other than married couples.[174] Although this case was decided on equal protection grounds, the Court noted that "[i]f the right of privacy means anything, it is the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[175] *Eisenstadt* thus emphasized that the Court would not tolerate unwarranted governmental intrusion in the physician–patient relationship.

Abortion rights are also grounded in the right to make sound medical decisions. In *Roe v. Wade*, the Supreme Court discussed the mental and physical harm that a woman might experience by carrying a pregnancy to term.[176] It then noted, "[a]ll these are factors the woman and her responsible physician necessarily will consider in consultation."[177]

In *Doe v. Bolton*, the Supreme Court struck down 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."[178] The Court noted that it had not been "cited to any

Rochin v. California, 342 U.S. 165, 172 (1952) (holding that a group of officers' act of forcibly removing drugs from a criminal suspect's stomach "shock[ed] the conscience" and constituted "[i]llegally breaking into the privacy of the petitioner").

171. Griswold v. Connecticut, 381 U.S. 479, 480 (1965).

172. *Id*.

173. *Id*. at 481–82.

174. Eisenstadt v. Baird, 405 U.S. 438, 454–55 (1972).

175. *Id*. at 453.

176. Roe v. Wade, 410 U.S. 113, 153 (1973).

177. *Id*.

178. Doe v. Bolton, 410 U.S. 179, 197 (1973).

other surgical procedure made subject to committee approval as a matter of state criminal law."[179]

These early physician–patient cases were decided on First Amendment, equal protection, and privacy grounds. However, in the 1992 case *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the Supreme Court recast the above cases as relating to liberty.[180] Reiterating its earlier precedent, the Court stated that "[t]hese matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment [Due Process Clause]."[181]

These cases emphasize that the Constitution limits the government's ability to interfere with the physician–patient relationship. The Supreme Court's decisions in *Griswold*, *Eisenstadt*, and *Doe* also emphasized this relationship in permitting physicians to bring constitutional claims for interference with their ability to provide care to their patients.[182]

2. The Right to Information

The right to information relates to the right to make medical decisions, which was implicitly recognized by the Supreme Court in *Rust v. Sullivan*.[183] In that case, the Court considered a health regulation that limited the ability of health care providers who received government funds to provide information regarding abortions.[184] The petitioners argued that the regulations "violate a woman's Fifth Amendment right to medical self-determination and to make informed medical decisions free of government-imposed harm."[185] The Court held that while there was no constitutional violation, "a doctor's ability to provide, and a woman's right to receive information concerning abortion . . . outside the context of the [government-funded] project remains unfettered."[186]

In *Griswold*, the Supreme Court was more explicit, stating that the government "may not, consistently with the spirit of the First Amendment, contract the spectrum of available knowledge."[187] Within this right of

179. *Id*.

180. Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 851 (1992) (noting that *Griswold*, *Eisenstadt*, and other cases "support the reasoning in *Roe* relating to the woman's liberty because they involve personal decisions concerning not only the meaning of procreation but also human responsibility and respect for it").

181. *Id*.

182. *See* Singleton v. Wulff, 428 U.S. 106, 114–15 (1976) (discussing cases).

183. 500 U.S. 173 (1991).

184. *Id*. at 177.

185. *Id*. at 202.

186. *Id*. at 203.

187. Griswold v. Connecticut, 381 U.S. 479, 482 (1965).

knowledge, it acknowledged "the right to distribute, the right to receive, the right to read and freedom of inquiry, freedom of thought, and freedom to teach."[188] Justice White also emphasized a knowledge right in medical decisionmaking, noting that the statute at issue would prevent "disadvantaged citizens" who lacked "adequate knowledge or resources to obtain private counseling" from accessing "medical assistance and up-to-date information in respect to proper methods of birth control."[189]

With *Rust* and *Griswold*, we see the beginning of a right for a physician to disseminate knowledge so that the patient can make an informed medical treatment decision. Both of those cases recognized that a suppression of information compromises the physician–patient relationship.

This right was then expanded in the context of freedom from unwanted medical treatment. In *Cruzan v. Director, Missouri Department of Health*, the Supreme Court recognized "a general liberty interest in refusing medical treatment."[190] Three Courts of Appeals have subsequently linked the right to refuse medical treatment with the right to knowledge.[191] The Third Circuit held that the Due Process Clause protects "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*."[192] It noted that "[a] prisoner's right to refuse treatment is useless without knowledge of the proposed treatment,"[193] and that "[p]risoners have a right to such information as is reasonably necessary to make an informed decision to accept or reject proposed treatment, as well as a reasonable explanation of the viable alternative treatments that can be made available in a prison setting."[194] The Court therefore held the State's failure to disclose that the proposed treatment involved penicillin violated the Due Process Clause.[195]

188. *Id*. (citations omitted).

189. *Id*. at 503 (White, J., concurring).

190. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 278 (1990) (citing Vitek v. Jones, 445 U.S. 480, 494 (1980)); *see also Developments in the Law—Medical Technology and the Law*, 103 HARV. L. REV. 1519, 1644–45 (1990) (discussing the right of competent patients to refuse medical treatment).

191. No appellate court has denied the existence of the right to information in this context. However, at least one scholar has been skeptical of these appellate cases. *See* Robert Gatter, *A Prisoner's Constitutional Right to Medical Information: Doctrinally Flawed and a Threat to State Informed Consent Law*, 45 WAKE FOREST L. REV. 1025, 1026 (2010) (arguing that "individuals likely have a substantive due process right to avoid unwanted bodily invasions, but not a right to well-informed treatment decisions" and that this line of cases conflicts with state informed consent laws).

192. White v. Napoleon, 897 F.2d 103, 111 (3d Cir. 1990) (emphasis added) (internal citations omitted).

193. *Id*. at 113.

194. *Id*.

195. *Id*.

The Second Circuit adopted a slightly narrower approach. Like the Third Circuit, the Second Circuit held "that an individual cannot exercise his established right to refuse medical treatment in a meaningful and intelligent fashion unless he has sufficient information about proposed treatment."[196] It noted that "[a]bsent knowledge of the risks or consequences that a particular treatment entails, a reasoned decision about whether to accept or reject that treatment is not possible."[197]

The Second Circuit emphasized, however, that "the right to medical information is not, in and of itself, an independent right."[198] It noted that it is instead "a derivative of the right to refuse treatment and extends only to those circumstances in which it will effectuate a patient's exercise of that underlying right."[199] The court emphasized that this right is grounded in the Due Process Clause.[200]

In an unpublished decision, the Ninth Circuit denied summary judgment to the State in a medical treatment refusal case involving the Due Process Clause.[201] Relying on the Second and Third Circuit opinions, the court held that a question of fact existed as to whether the plaintiff was provided with sufficient information to give informed consent to medical treatment.[202]

Even if we assume that the right to information is merely a derivative right, as the Second Circuit asserts,[203] it should attach to the right to make medical decisions just as it does for the right to refuse medical treatment.[204] The *Bolton* Court emphasized that the government cannot substantially limit 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."[205] Blocking a physician from gathering necessary information from a

196. Pabon v. Wright, 459 F.3d 241, 249 (2d Cir. 2006).

197. *Id*.

198. *Id*. at 251.

199. *Id*.

200. *Id*. at 253.

201. Rainwater v. Alarcon, 268 Fed. App'x 531, 533 (9th Cir. 2008).

202. *Id*. at 534.

203. *See Pabon*, 459 F.3d at 251–52 (noting that the right to medical knowledge is not a right in and of itself, but is derivative of the right to refuse medical treatment).

204. This article does not address the use of genetic material to make the decision of whether to have children. The Supreme Court in *Eisenstadt* found the decision of "whether to bear or beget a child" to be a fundamental one. Eisenstadt v. Baird, 405 U.S. 438, 453–55 (1972). To the extent that a person is a potential carrier of a genetic mutation that can cause health problems in future offspring, the right of knowledge should likewise attach. Individuals should have a right to knowledge that will help them make informed choices regarding whether to have children.

205. Doe v. Bolton, 410 U.S. 179, 197 (1973).

patient prevents the physician from being able to exercise good judgment and limits the patient's ability to make an informed decision.[206]

Thus, to the extent that Alice's access to her genetic information is necessary for her physician to exercise judgment with regard to treatment, and is necessary for Alice to make an informed medical decision, such a right is protected as a liberty interest. Part IV examines how far such a right extends.

IV. THE RIGHT TO ONE'S OWN BODILY INFORMATION

Technology has dramatically increased our ability to understand our own bodies. Genotyping for one million genetic variants is currently available for only $99.[207] Several laboratories and researchers have reported that they expect the cost of full-genome sequencing to fall below $1,000 by 2015.[208] This cost decrease will likely increase demand for genetic testing over time, given that such information can increasingly help guide a physician's treatment of his or her patient.

The *Myriad* litigation has highlighted the impact that bodily information has on a patient's medical decisionmaking. Numerous women filed declarations in the district court stating that they could not make informed decisions to have mastectomies and hysterectomies without knowing whether they carried a BRCA mutation.[209] BRCA is only the tip of the iceberg; there are many other diseases that can be diagnosed through genetic testing, leading to better medical treatment.[210]

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206. An argument could also be made that such a limitation violates informed consent laws. Many states require informed consent either by statute or under the common law. *See* William J. McNichols, *Informed Consent Liability in a "Material Information" Jurisdiction: What Does the Future Portend?*, 48 OKLA. L. REV. 711, 714–17 (1995). A cause of action is "based on an unintentional failure to disclose information," and can be characterized as negligence. Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 OKLA. L. REV. 697, 707 (2012). One can argue that patents which prevent physicians from providing all relevant information to their patient regarding medical treatment run afoul of such laws.

207. *See* 23ANDME, *Discover Your Ancestral Origins and Lineage with a Personalized Analysis of Your DNA*, http://www.23andme.com/ (last visited June 30, 2013) (offering $99 genotyping).

208. *See* Alex Planes, *The $1,000 Genome Marks the Start of a New Phase in Human Evolution*, THE MOTLEY FOOL (Jan. 22, 2014), http://www.fool.com/investing/general/2014/01/22/the-1000-genome-marks-the-start-of-a-new-phase-in.aspx(observing that based on statistical data of genome sequencing costs, full-genome sequencing should fall to $1000 in 2015, and to $100 by no later than 2024).

209. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 189 (S.D.N.Y. 2010).

210. *See, e.g.*, Anne Marie Comeau et al., *Population-Based Newborn Screening for Genetic Disorders when Multiple Mutation DNA Testing is Incorporated: A Cystic Fibrosis Newborn Screening Model Demonstrating Increased Sensitivity but More Carrier Detections*, 113 PEDIATRICS 1573, 1573–74 (2004); Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577 (discussing how genetic testing can allow for early detection and treatment of hemochromatosis and how patents have hindered laboratories from offering testing); Karel Pacak et al., *Recent Advances in Genetics,*

If there is a fundamental right to make an informed decision about medical treatment, it follows that as a part of that right, individuals must be permitted to learn about their own genetic and bodily information without government hindrance. The unique makeup of each individual is playing a growing role in medicine, both in the diagnosis and treatment of diseases.[211] Pharmacogenomics, which is the practice of pharmaceutical companies developing treatments based on an individual's genetic makeup, is an emerging field in medical research.[212] Because method claims involving genetic material remain patent eligible, modern technologies to diagnose disease cannot reach their full potential.

Likewise, microbiomics is expected to play an increasingly important role in diagnostic testing personalized medicine.[213] Each person carries a unique mix of microorganisms in his or her body.[214] Variations in that flora can contribute to obesity, inflammatory bowel disease, and other conditions.[215] There is also further evidence of epigenetic inheritance, that is, variations of inherited traits outside of changes in our DNA.[216] Research in these areas could one day lead to better diagnostic testing for various health conditions, all of which would be potentially patentable.

Our unique bodily information will continue to play a growing role in making medical decisions. Therefore, blocking access to it has the potential to prevent patients from making informed medical decisions and from

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Diagnosis, Localization, and Treatment of Pheochromocytoma, 134 ANNALS INTERNAL MED. 315, 315–16 (2001) (discussing how identification of a cancer gene has provided a method of genetic diagnosis of a particular type of tumor and has allowed for early treatment).

211. *See, e.g.*, Charles J. Epstein, *Medical Genetics in the Genomic Medicine of the 21st Century*, 79 AM. J. HUM. GENETICS 434 (2006) (discussing the growing role of genomic medicine).

212. *See generally* HUMAN GENOME PROJECT, *Human Genome Project Information Archive*, http://web.ornl.gov/sci/techresources/Human_Genome/index.shtml (last visited Dec. 16, 2013). Life Technologies recently acquired Navigenics, which offers physicians "an analysis of your patient's genetic predispositions for a wide variety of health conditions and pharmacogenomic outcomes." *See* NAVIGENICS, *Navigenics Results*, http://www.navigenics.com/visitor/for_physicians/ (last visited Dec. 16, 2013).

213. *See* Alan Dove, *Microbiomics: The Germ Theory of Everything*, 340 SCI. 763 (2013), *available at* http://www.sciencemag.org/site/products/lst_20130510.xhtml (discussing the growing understanding of how changes in the microbiomic ecosystem can cause illness); Alexander Statnikov et al., *A Comprehensive Evaluation of Multicategory Classification Methods for Microbiomic Data*, 1 MICROBIOME 11 (2013), *available at* http://www.microbiomejournal.com/content/1/1/11 (noting that one of the promises of microbiomics is linking these organisms to changes in the body, which could lead to breakthroughs in diagnostic testing and personalized medicine).

214. *See* Sharon Greenblum et al., *Metagenomic Systems Biology of the Human Gut Microbiome Reveals Topological Shifts Associated with Obesity and Inflammatory Bowel Disease*, 109 PROC. NAT'L ACAD. SCI. U.S. 594, 594 (2012), *available at* http://www.pnas.org/content/109/2/594.full ("Microbial communities populate numerous sites in the human anatomy and harbor over 100 trillion microbial cells. This complex ensemble of microorganisms, collectively known as the human microbiome, plays an essential role in our development, immunity, and nutrition, and has a tremendous impact on our health.") (citations omitted).

215. *Id*.

216. *See* Bing Zhu & Danny Reinberg, *Epigenetic Inheritance: Uncontested?*, 21 CELL RES. 435 (2011), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3193423/.

receiving appropriate treatment from their physicians. Subpart A discusses the spectrum of liberty harm that can arise from gene patents. Subpart B discusses why patient access to bodily information differs from access to drugs.

A. A Spectrum of Harm

Diagnostic patents can hinder a person's ability to make medical decisions in a variety of ways. Patent holders may limit the scope of available testing and prevent individuals from obtaining secondary testing. In extreme cases, a patent holder may be unable or unwilling to offer the analogous test.

These problems should not exist. In 1980, the Bayh-Dole Act was passed, which allowed inventions developed from federally-funded grants to be patented.[217] The Act created "march-in rights" that allow a government agency that funded the initial research, such as the National Institutes of Health, to intervene and grant licenses to third parties in order to protect the health and safety of consumers.[218] However, there have only been a handful of petitions for the government to exercise this right, and no petition has ever been successful.[219] Moreover, not all patents stem from federally-funded research.

Using isolated gene patents as an example, this Subpart looks at the types of harm that arise from diagnostic patents and argues that the PTO's grant of these patents may cause due process violations. It then discusses how patients are harmed when no testing is available for the patented gene, when limited testing is offered, or when secondary or confirmatory testing is unavailable. It then discusses how this harm extends beyond gene patents.

1. Three Categories of Harm

a. No Testing Permitted

The situation most harmful to patients is when the patent holder fails to make a diagnostic test available and yet, refuses to permit others to provide testing. In such a case, a strong argument can be made that patient liberty interests are violated. Patients who need diagnostic testing for treatment purposes would not be permitted to access their bodily information, even if

217. Bayh-Dole Act, Pub. L. 96-517, 94 Stat. 3018 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)).

218. *See* 35 U.S.C. § 203(a) (2006).

219. John H. Raubitschek & Norman J. Latker, *Reasonable Pricing—A New Twist for March-In Rights Under the Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 149, 151–62 (2005).

they had a personal means of obtaining access. This lack of access would hinder people's ability to make informed medical treatment decisions.

A similar situation occurred with regard to testing for Long QT Syndrome (LQTS), a condition that can cause sudden death in younger adults.[220] People who carry the gene but do not receive treatment are at risk for severe heart problems.[221] The University of Utah patented the purified, isolated gene that causes LQTS and awarded DNA Sciences an exclusive license for testing. DNA Sciences offered no genetic test for the gene at any point. Nevertheless, it shut down competitor GeneDX, which did offer a test, and refused to issue a license.[222] DNA Sciences subsequently entered into bankruptcy, leading to an eighteen-month period when LQTS testing was unavailable in the U.S.[223] In a statement before the PTO, Marc Grodman attributed the death of a ten-year old girl to the lack of available testing.[224]

In this case, there were other methods of diagnosing LQTS, although the genetic test was considered to be "the gold standard."[225] Consequently, this case was not as egregious as the hypothetical case. However, treatment of LQTS may vary with the type of mutation present, making genetic testing a key part of developing a proper treatment plan.[226] Thus, the issuance of the broad LQTS patents caused a direct interference with the physician–patient relationship and prevented some patients from making informed decisions regarding medical treatment. Consequently, a due process violation likely occurred.

A related situation arises when the patent holder fails to offer prenatal testing for a diagnosable medical condition. For example, the two licensed LQTS test providers have refused to provide prenatal testing, arguing that the disease is treatable and that the test can be done at infancy.[227] Likewise, Athena Diagnostics was the sole licensee for the genes that cause spinocerebellar ataxia but failed to offer pre-implantation or prenatal

220. *See* Misha Angrist et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome*, 12 GENETICS MED. S111 (2010), *available at* http://www.nature.com/gim/journal/v12/n1s/pdf/gim2010145a.pdf.

221. *See id*.

222. *See* Brandon L. Pierce et al., *The Impact of Patents on the Development of Genome-Based Clinical Diagnostics: An Analysis of Case Studies*, 11 GENETICS MED. 202, 202–09 (2009), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2873842/#R36; *see also Stifling or Stimulating—The Role of Gene Patents in Research and Genetic Testing*: *Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 110th Cong. 37 (2007) (statement of Marc Grodman, CEO Bio-Reference Labs.) [hereinafter *Statement of Grodman*].

223. *See* Angrist, *supra* note 220; Carbone et al., *supra* note 115.

224. *Statement of Grodman*, *supra* note 222, at 40.

225. Angrist, *supra* note 220, at S115.

226. *Id*. at S116.

227. *Id*. at S127.

testing.[228] This is notwithstanding the fact that notice to the parent of a medical condition could allow for advance planning.[229] Professor Rochelle Dreyfus has suggested that prenatal testing remains controversial because of its relationship to abortion.[230]

The case of unavailable prenatal testing is more complicated than testing for adults. In recent years, abortion-related cases have fallen into the moral-values line of cases.[231] Because some women who have a prenatal test may choose to abort the fetus, the court may disregard the physician–patient relationship under some form of due process traditionalism.

b. Testing Is Limited in Scope

Another possibility arises when the patent holder permits only limited testing. This problem was illustrated with Myriad's control over BRCA 1 and 2 testing. In the United Kingdom, where Myriad held fewer patent rights,[232] NewGene and others "utilize so-called next-generation sequencing technology" for BRCA testing.[233] Researchers claim that this technology can "detect far more deleterious mutations in far more relevant genes than the Myriad test detects . . . at a fraction of the cost."[234] Such tests were unavailable in the U.S. prior to the Supreme Court's decision.

Myriad also refused to let other laboratories offer diagnostic tests that Myriad itself did not offer. In 2005, the Yale DNA Diagnostic Lab contacted Myriad to ask if it could offer large rearrangement testing, which could predict cancer risks missed by Myriad's then-existing test.[235] Myriad refused, arguing that such a test would infringe their patents.[236] But they failed to offer such a test until a year later,[237] leaving women without

228. Ashton Powell et al., *Spinocerebellar Ataxia: Patient and Health Professional Perspectives on Whether and How Patents Affect Access to Clinical Genetic Testing*, 12 GENETICS MED. S83, S88 (2010).

229. Rochelle C. Dreyfuss, *The Patentability of Genetic Diagnostics in U.S. Law and Policy* 6 (N.Y. Univ. Sch. of Law Pub. Law & Legal Theory Research Paper Series, Working Paper No. 10-68, 2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1678123.

230. *Id*.

231. *See supra* notes 165–67 and accompanying text.

232. Note that after the *Myriad* decision, Myriad now holds *more* patent rights in the UK and EU.

233. John Conley et al., *How Will Myriad Respond to the Next Generation of BRCA Testing?*, GENOMICS LAW REPORT (March 1, 2011), http://www.genomicslawreport.com/index.php/2011/03/01/how-will-myriad-respond-to-the-next-generation-of-brca-testing/.

234. *Id*.

235. Declaration of Ellen T. Matloff, M.S. at 3–4 , Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09-4515), *available at* http://www.aclu.org/files/pdfs/freespeech/brca_Matloff_declaration_20090826.pdf.

236. *Id*.

237. *See Testing for Hereditary Breast and Ovarian Cancer Syndrome*, 3 CLINICAL SUMMARY (Myriad Genetics, Inc.), no. 3, 2012, at 1, https://www.myriad.com/lib/clinical-summaries/v9n3_Judkins.pdf; *see also* Form letter from Myriad to Physicians and Healthcare Providers (on file with author), http:// myriad.com/lib/brac/BART-Letter.pdf.

valuable information regarding their risk of cancer. Throughout all of this, the government failed to exercise the march-in rights afforded under Bayh-Dole, despite having contributed roughly one-third of the funding for the discovery of BRCA 1 and having provided $2 million for BRCA research.[238]

A related problem is that patent holders may block new research and the development of new tests.[239] As discussed above, Myriad shut down BRCA testing at Yale, the University of Pennsylvania, and other academic institutions.[240] This was in spite of the fact that the co-assignee for several of the BRCA patents is the University of Utah, a publically-funded entity.[241] Likewise, Athena Diagnostics blocked university laboratories from offering tests for Alzheimer's disease,[242] though the Alzheimer genes were patented by Duke University and other academic institutions.[243]

Professor Rebecca Eisenburg observes that "[a]rguments that gene patents interfere with the practice of medicine beg the question of why medical practitioners should be treated differently from any other providers of goods and services under the patent laws."[244] However, a distinction can be made if a diagnostic patent interferes with the physician–patient relationship and causes a due process violation. That being said, it seems unlikely that due process would require a broad experimental research right.

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238. *See* Sandra S. Park & Tania Simoncelli, *Making the Case Against Gene Patents*, THE SCITECH LAWYER, Fall 2012, at 14; John Conley, *Government Refuses to March-In Under Bayh-Dole—Again*, GENOMICS LAW REPORT (January 18, 2011), http://www.genomicslawreport.com/index.php/2011/01/18/government-refuses-to-march-in-under-bayh-dole-again/ (calling for the government to exercise its march-in rights for BRCA 1 and 2 to permit confirmatory testing).

239. Rebecca S. Eisenburg, *Why the Gene Patenting Controversy Persists*, 77 ACAD. MED. 1381, 1383 (2002).

240. *See* Complaint at 2–3, Univ. of Utah Research Found. v. Ambry Genetics (D. Utah 2013) (No. 2:13-cv-00640-RJS) ("The University of Utah is the owner or co-owner of United States Patent Nos. 5,709,999; 5,747,282; 5,753,441; 5,837,492; and 6,033,857."); Carbone, *supra* note 115. Note that Myriad claims that the University of Pennsylvania's Genetic Diagnostic Laboratory was commercial and not a research service. *See* Carbone et al., *supra* note 115.

241. E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S41 (2010). Myriad has a total of nine patents on the BRCA 1 and 2 genes. *Id*.

242. *Id*.

243. *Id*.

244. Eisenburg, *supra* note 239, at 1383. Duke University's "Policy on Inventions, Patents, and Technology Transfer" states that "the university does not undertake research or developmental work principally for the purpose of developing patents and commercial applications" and notes for the patentable inventions resulting from research, "[i]t is the policy of the university to assure the utilization of such inventions for the common good and, where necessary, to pursue patents and licenses to encourage their development and marketing." DUKE UNIV., POLICY ON INVENTIONS, PATENTS, AND TECHNOLOGY TRANSFER 7 (2008), *available at* http://olv.duke.edu/Inventors/PoliciesAndProcedures/policy_on_inventions.pdf.

c. Unavailability of Confirmatory Testing

Gene patents and other diagnostic patents can also harm patients by limiting patient access to confirmatory testing. Such tests are important because laboratory mistakes in the original test can cause patients to undergo unnecessary major surgery, such as a mastectomy.[245] For the BRCA genes, no form of confirmatory testing was available prior to 1999. Myriad gradually allowed other laboratories to offer confirmatory testing, but only a subset of their BRCA tests.[246] There are numerous reported cases of individuals who were unable to obtain any confirmatory testing, including some of the original plaintiffs in the *Myriad* litigation.[247]

It is unclear whether this type of interference is sufficient to constitute a due process violation. If a physician does not trust the results from the single laboratory offering the test, one could argue that the physician should be able to seek retesting to make a proper recommendation to the patient. At the same time, so long as one test is available, one can argue that patients are not being denied access to their bodily information.

2. Beyond Isolated Genes

The harm discussed above extends beyond isolated genes. Myriad has sued several competing laboratories for patent infringement, based on its remaining cDNA and method claims. Myriad continues to maintain that it holds a monopoly on BRCA 1 and BRCA 2 testing.[248]

Also within genetics, researchers have suggested that patents on pathogenic mutations and fundamental methods of determining the association between a gene and an inherited disorder can effectively cover all information pertaining to a particular genetic mutation.[249] For example, a group of U.S. patents claim methods of diagnosing spinocerebellar ataxia type 6 (SCA6) by examining the patient's gene sequence.[250] A group of

245. *See* HHS REPORT, *supra* note 5 at 44 ("The ability to obtain a confirmatory test from a second laboratory is important because genetic test results can have implications for major medical decisions, such as whether to have a mastectomy or surgical removal of the ovaries.").

246. *See* Myriad Genetics, Inc., Written Comments on Genetic Diagnostic Testing Study at 8, (Mar. 26, 2012), *available at* http://www.uspto.gov/aia_implementation/gene-comment-myriad-gen.pdf (discussing second-opinion testing for the BRCA genes).

247. *See, e.g.,* John Schwartz, *Cancer Patients Challenge the Patenting of a Gene*, N.Y. TIMES, (May 12, 2009), www.nytimes.com/2009/05/13/health/13patent.html (discussing a patient who was unable to get confirmatory testing in 2006).

248. *See supra* note 8 and accompanying text.

249. Nele Berthels et al., *Impact of Gene Patents on Diagnostic Testing: A New Patent Landscaping Method Applied to Spinocerebellar Ataxia*, 19 EUR. J. HUM. GENETICS 1114, 1117 (2011), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3198141/.

250. *See* U.S. Patent No. 7,329,487 (filed May 12, 2003); U.S. Patent No. 6,303,307 (filed Apr. 23, 1999); U.S. Patent No. 5,853,995 (filed Jan. 7, 1997).

researchers have argued that one of the methods is so fundamental that "it appears to be very difficult to circumvent the patent when performing [any type of] SCA6 genetic diagnosis."[251]

Moreover, the *Myriad* Court's distinction between isolated DNA and cDNA was confusing at best. Although the Court struck down patents on isolated DNA because it contains the same information as DNA in the body, similar arguments can be made about cDNA. It is now unclear how much modification is enough for a protein, organism, or other material from the body to get a patent.[252]

Beyond genetics, other patents may block diagnostic tests. In *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*, the Federal Circuit affirmed a patent on a method of detecting certain vitamin B deficiencies that did so by assaying a patient's total homocysteine levels.[253] In this case, alternative tests existed so no due process concerns were raised. However, in Justice Breyer's dissent from the denial of certiorari, he noted that "special public interest considerations reinforce my view that we should decide this case."[254] He maintained that failing to consider the case threatens to restrict the medical profession:

> Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of health care while inhibiting its effective delivery.[255]

Furthermore, because the *Myriad* Court focused only on isolated genes, it leaves open the possibility that isolated bacteria, proteins, and organisms could receive patents in the short-term. Such patents could block future microbiomic research, which could lead to tests for predispositions to obesity and diabetes.[256] Likewise, method patents could block epigenetic

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251. Berthels et al., *supra* note 249, at 1117. The researchers in this article are discussing EP 1,015,628, which is similar to what is claimed in the U.S. patent. Note that it is unclear whether these claims are still valid in light of *Mayo*.

252. *See* Heidi Ledford, *Myriad Ruling Causes Confusion*, 498 NATURE 281, 281–82 (2013), *available at* http://www.nature.com/news/myriad-ruling-causes-confusion-1.13226 (noting that there is confusion among attorneys as to how much modification is enough for a biological product to be patentable).

253. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1364 (Fed. Cir. 2004).

254. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 138 (2006) (Breyer, J., dissenting).

255. *Id*.

256. *See* Patrice Cani et al., *Metabolic Endotoxemia Initiates Obesity and Insulin Resistance*, 56 DIABETES 1761, 1761–72 (2007) (showing that in mice, high concentrations of bacterial

testing for predispositions to depression and other illnesses.[257] While patents of this nature should eventually fail in court,[258] until that time, they could still negatively impact patients.

B. Distinction from Access to Medicine and Medical Devices

One important question to address is how patients seeking bodily information is different from patients seeking an expensive drug or a non-FDA approved medical device. BRCA testing has generally been available for a price, albeit a high one until recently. However, there are several salient differences between these types of access.

1. Patents on Information

Intellectual property protection for information is typically limited to copyright and trade secrecy law. Moreover, information that occurs in nature cannot, in theory, be patented under § 101 of the Patent Act. However, numerous patents in the diagnostic arena have crossed the line into claiming naturally-occurring bodily information. Myriad continues to claim de facto ownership of the BRCA 1 and BRCA 2 genes, arguing that no form of testing can occur without infringing its patents.[259]

This is in sharp contrast to patents on tools, such as drugs or medical devices. Although drugs can help treat a medical condition and medical devices can help patients access information in their bodies, the utility patents that cover drugs and medical devices do not block others from creating new forms of treatment or new means of discovery.

The issuance of gene patents and other broad diagnostic patents are potential due process violations because such patents are absolute. There is no way to invent around Myriad's patents, because Myriad has a de facto claim to the information in BRCA 1 and 2. In contrast, new drugs can be developed and new medical devices can be invented.

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lipopolysaccharides cause inflammation, which can trigger diabetes and obesity); Michael Pollan, *Some of My Best Friends Are Germs*, N.Y. TIMES MAGAZINE (May 15, 2003), http://www.nytimes.com/2013/05/19/magazine/say-hello-to-the-100-trillion-bacteria-that-make-up-your microbiome.html?adxnnl=1&adxnnlx=1382133071-h/4ooGnbWKrQ2Whg3LEHAA ("Disorders in our internal ecosystem—a loss of diversity, say, or a proliferation of the 'wrong' kind of microbes—may predispose us to obesity and a whole range of chronic diseases, as well as some infections.").

257. *See* Dan Hurley, *Grandma's Experiences Leave a Mark on Your Genes*, DISCOVER (June 11, 2013), http://discovermagazine.com/2013/may/13-grandmas-experiences-leave-epigenetic-mark-on-your-genes.

258. *See* Ledford, *supra* note 252, at 281 ("Although the Supreme Court case was limited to human DNA, the ruling will probably be applied to other molecules such as proteins, as well as to other organisms . . . .").

259. *See* Pollack, *supra* note 8.

2. Due Process as a Negative Right

Additionally, there is a distinction between using the Due Process Clause to obtain something from the government and using it to prevent government intrusions in protected spheres. Scholars such as David Currie have observed that "the due process clause is phrased as a prohibition, not an affirmative command," and therefore does not require the government to act affirmatively.[260] Consequently, positive rights, such as the right of access to drugs, are far more difficult to establish, as the right must be "unusual and exceptionally well-justified."[261]

Several circuits have expressed the view of the Constitution as "a charter of negative rather than positive liberties."[262] The en banc D.C. Circuit held that the Due Process Clause does not guarantee a substantive right of access to medicine.[263] The court found that no evidence had been presented "of a right to procure and use experimental drugs that is deeply rooted in our Nation's history and traditions."[264] It observed that "other courts have rejected arguments that the Constitution provides an *affirmative right of access* to particular medical treatments reasonably prohibited by the Government"[265] and cited to cases from the Third, Fifth, Seventh, and Tenth Circuits.[266] Consequently, as the D.C. Circuit held, the right to make

260. David P. Currie, *Positive and Negative Constitutional Rights*, 53 U. CHI. L. REV. 864, 865 (1986).

261. *See* Archie v. City of Racine, 847 F.2d 1211, 1213 (7th Cir. 1988) (en banc):

> Implication of a "positive" right (to have the government do something) out of the constitutional "negative" right (to be let alone) often depends on arguments about policy rather than on the text, structure, or history of the document; it may depend on seeing things from the perspective of collective benefits rather than the autonomy of the individual, a perspective that potentially increases the role of government in society, contrary to the plan of the Bill of Rights. Such a step therefore must be unusual and exceptionally well-justified.

262. *See, e.g.*, DeShaney v. Winnebago Cnty. Dep't of Soc. Servs., 812 F.2d 298, 301 (7th Cir. 1987), *aff'd*, 489 U.S. 189 (1989); *see also* Naomi R. Cahn, *Models of Family Privacy*, 67 GEO. WASH. L. REV. 1225, 1226 (1999) (discussing the conventional view that the Due Process Clause does not require the government to act affirmatively). *But see* Susan Bandes, *The Negative Constitution: A Critique*, 88 MICH. L. REV. 2271, 2280–86 (1990) (arguing against the negative interpretation of the Due Process Clause).

263. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 711 (D.C. Cir. 2007) (en banc).

264. *Id*.

265. *Id*. at 710 (emphasis added) (citations omitted).

266. *Id*. at 710 n.18 (citing Mitchell v. Clayton, 995 F.2d 772, 775 (7th Cir. 1993)) ("[M]ost federal courts have held that a patient does not have a constitutional right to obtain a particular type of treatment or to obtain treatment from a particular provider if the government has reasonably prohibited that type of treatment or provider."); Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980) ("Constitutional rights of privacy and personal liberty do not give individuals the right to obtain [the cancer drug] laetrile free of the lawful exercise of government police power."); Rutherford v. United States, 616 F.2d 455, 457 (10th Cir. 1980) ("[T]he patient['s] . . . selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health. The premarketing requirement of the [FDCA], 21 U.S.C. § 355, is an exercise of Congressional authority to limit the patient's choice of medication. This is clear under the [Supreme Court's] decisions . . . .").

health care decisions does not trigger an affirmative right for the government to provide something, such as medicine.[267]

Likewise, courts have not recognized a common law property right in one's blood or tissue. In *Moore v. Regents of California*, the California Supreme Court addressed the issue of ownership of cellular material that is removed during surgery.[268] The state court established that a patient has no proprietary right in a cell line that was derived from the patient's own blood and tissue removed during surgery.[269] The court expressed concern that if such an act was deemed conversion, it would hamper medical research.

Access to bodily information is arguably a negative right. At its core, the debate is not about a right to low-cost or free diagnostic testing.[270] Rather, the right is to be free from governmental interference in learning about one's own biological information for medical decisionmaking. This is not a request for the government to provide something to patients, but rather, for the government not to interfere by granting overly broad patents that cover bodily information without ensuring safeguards to patient rights.

The role of the patent holder and third parties differ in the access to medicine debate versus the right to bodily information. As Professor Eisenburg observes, the cost of producing a drug and obtaining FDA approval are high. Consequently, doctors and patients are not in a position to supply themselves with drugs, even in the absence of patents.[271] As a result, litigants in such cases are ultimately seeking an affirmative liberty right—the right to be provided with a particular drug by the patent holder.

Thus, the negative versus positive right distinction becomes relevant. Individuals seeking access to their bodily information are merely attempting to secure a negative right—the right to access their own information without government interference. And unlike access to experimental drugs, access to biological information under the supervision of a physician does not have potential negative public-health consequences.

To protect this negative right, Congress must either strike the parts of the Patent Act that permit the patenting of diagnostic patents, or narrowly tailor the Patent Act to side-step a due process violation. Part V makes suggestions for the latter.

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267. *Abigail*, 495 F.3d at 711.

268. Moore v. Regents of Univ. of Cal., 793 P.2d 479 (Cal. 1990).

269. *Id*. at 494–96.

270. To the extent people do argue for low-cost or free genetic tests, these arguments should be grouped together with the access to medicine debate. The high cost of medical treatment is a distinct problem from patient access to genetic information.

271. *See* Eisenburg, *supra* note 239.

3. Ethical Considerations

Biological information, including DNA, is an integral part of the human body that cannot be permanently excised. Even if a cell line is developed from a patient's tissue, the information remains a part of the patient's body.[272] In 1997, the European Parliament issued a Resolution on Cloning, in which it "[s]tresse[d] that each individual has a right to his or her own genetic identity."[273] The Vatican has likewise stressed the importance of genetic identity. In arguing against the genetic modification of humans, the International Theological Commission stated that "[t]he uniqueness of each human person, in part constituted by his biogenetic characteristics and developed through nurture and growth, belongs intrinsically to him."[274] Anthropologist Paul Brodwin has argued that genetic knowledge has the potential to transform group identity by giving groups a means to identify those who genetically share their identity.[275]

One context in which ethical and moral concerns have been examined is with regard to the return of research results to patients. When individuals participate in research studies, it is sometimes possible for the researchers to discover important information about a particular individual's health. A highly controversial question remains as to whether the individual in such a case is entitled to that information.[276] A majority of international guidelines suggest that individuals should be entitled to such results, to the extent that preventative or therapeutic measures are available.[277]

In the European Union and United Kingdom, the importance of access to one's genetic and biological information has wider recognition. In 1999, the Human Genetics Commission (HGC) was tasked by the UK Health and Science Ministers to review the consequences of offering genetic testing to

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272. *See generally* Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U. L. REV. 359 (2000). Rao views privacy as being synonymous with the right to bodily integrity and right to liberty.

273. Resolution on Cloning, Eur. Parliament, 1997 O.J. (C 115) 14.4/92 (Mar. 12, 1997), *available at* http://www1.umn.edu/humanrts/instree/cloning1.html.

274. International Theological Commission, *Communion and Stewardship: Human Persons Created in the Image of God*, VATICAN (2002), http://www.vatican.va/roman_curia/congregations/cfaith/cti_documents/rc_con_cfaith_doc_20040723_communion-stewardship_en.html.

275. Paul Brodwin, *Genetics, Identity, and the Anthropology of Essentialism*, 75 ANTHROPOLOGICAL Q. 323, 324–25 (2002) (noting that genetics can effect "personal esteem and self-worth, group cohesion, access to resources, and the redressing of historical injustice").

276. *See, e.g.*, Fiona Alice Miller et al., *What is a Meaningful Result? Disclosing the Results of Genomic Research in Autism to Research Participants*, 18 EUR. J. HUM. GENETICS 867 (2010), http://www.nature.com/ejhg/journal/v18/n8/pdf/ejhg201034a.pdf.

277. Annelien L. Bredenoord & Johannes J. M. van Delden, *Research Ethics in Genomics Research: Feedback of Individual Genetic Data to Research Participants*, *in* HUMAN MEDICAL RESEARCH: ETHICAL, LEGAL AND SOCIO-CULTURAL ASPECTS 127, 127 (Jan Schildmann et al. eds., 2012); *see also* Bartha Maria Knoppers et al., *The Emergence of an Ethical Duty to Disclose Genetic Research Results: International Perspectives*, 14 EUR. J. HUM. GENETICS 1170, 1173–74 (2006), *available at* http://www.nature.com/ejhg/journal/v14/n11/pdf/5201690a.pdf.

the public.[278] HGC surveyed individuals, academics, companies, consumer groups, and individual researchers; they also held evidence-gathering meetings with key groups.[279] The majority of the respondents stated that individuals were entitled to high quality genetic information through direct testing. A subset "felt that this was a natural extension of individual autonomy (or liberty)," so long as proper consent was obtained.[280]

Article 8, paragraph 1 of the European Convention on Human Rights states: "Everyone has the right to respect for his private and family life . . . ."[281] The HGC observed that Article 8 "might be interpreted as preventing unnecessary restrictions on the right to find out information about oneself in order to make informed decisions about private matters."[282] Article 8 allows for this right to be balanced against public safety, health, and morals. In this regard, Article 8 is similar to the protection for fundamental liberty rights that has evolved in the U.S. common law.

The HGC raised a concern, echoed by the U.S. and European scientific community, that "the right to know information about oneself is an important right," which must be balanced against preventing individuals from being exploited.[283] This is certainly important. However, this type of safeguard is not built into the U.S. patent system. These concerns show how our biological information may be viewed as being intertwined with the core of human identity and demonstrate the importance of treading carefully in this area of intellectual property.

V. REFORM

Parts II, III, and IV discussed how the issuance of broad diagnostic patents can violate the liberty interests of patients. As noted earlier, the government may infringe on a fundamental liberty interest if it can show that the infringement is narrowly tailored to serve a compelling government interest.[284] Generally, diagnostic patents may serve a compelling interest in promoting the development of tailored gene therapy treatments that could

278. *See* HUM. GENETICS COMM'N, GENES DIRECT 11 (2003), *available at* http://web.archive.org/web/20080311071232/http:/www.hgc.gov.uk/UploadDocs/DocPub/Document/genesdirect_full.pdf.

279. *Id*. at 12.

280. *Id*. at 28.

281. Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, art. 8, 213 U.N.T.S. 221, *available at* http://www.echr.coe.int/Documents/Convention_ENG.pdf.

282. HUM. GENETICS COMM'N, *supra* note 278, at 48.

283. *Id*.

284. Reno v. Flores, 507 U.S. 292, 302 (1993) (noting that substantive due process "forbids the government to infringe certain 'fundamental' liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest").

revolutionize medical care.[285] More generally, patents arguably promote innovation.

But to meet the requirements of the Fifth Amendment, the government must show that diagnostic patents are narrowly tailored to serve a compelling government interest.[286] Under the Patent Act, inventors are under no obligation to offer diagnostic tests that are the subject of the patent. Furthermore, they are not obligated to permit secondary testing or to permit experimental use of the patent. Consequently, there is a strong argument that the Patent Act is unconstitutional as applied to laboratories, doctors, and patients.

Although a full discussion of how to prevent due process violations goes beyond the scope of this Article, this Part makes initial suggestions of what the government can do narrowly tailor the Patent Act. Subpart A critiques the scope of the Supreme Court's *Myriad* decision. It then suggests constitutional options that future courts can utilize to force Congress to act. Subpart B provides general suggestions for amending the Patent Act. In particular, it argues for the use of compulsory licensing for diagnostic-testing patents and recommends that an experimental use exception be added to the Patent Act. Subpart C then considers what role the executive branch can play. It suggests that Congress grant rulemaking authority to HHS to implement compulsory licensing for cases where the patent holder refuses to offer the covered diagnostic test or confirmatory testing.

A. The Courts

As discussed above, the Supreme Court invalidated Myriad's isolated gene claims. The fact that Myriad has subsequently sued multiple laboratories offering BRCA 1 and BRCA 2 testing shows that the Court's decision did not go far enough. Myriad's cDNA and method claims permit it to continue to monopolize an area of diagnostic testing.

The Supreme Court missed an opportunity to spur broader legislative reform by failing to utilize the judicial canon of constitutional avoidance. There is precedent for courts to minimize constitutional violations when interpreting statutory language. The nondelegation doctrine, for example, was once used to strike down overly broad delegations of power from

285. *See* John K. Flanagan, *Gene Therapy and Patents*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 739, 740–46 (1998) (discussing how somatic cell gene therapy could be used for medical treatment); Andrew W. Torrance, *Family Law and the Genomic Revolution*, 79 UMKC L. REV. 271, 272–73, 282 (2010) (arguing that the availability of gene patents could facilitate the growth of targeted gene therapy).

286. *See* U.S. CONST. amend V; *Flores*, 507 U.S. at 302.

Congress to administrative agencies.[287] Now the doctrine exists exclusively as a canon of construction to avoid serious constitutional questions.[288] Similarly, when a court is faced with competing interpretations of a statute, one of which renders the statute unconstitutional, the court will choose the interpretation that avoids the constitutional violation.[289]

Professor Cass Sunstein describes these doctrines as "decisional minimalism," in which judges "make deliberate decisions about what should be left unsaid."[290] He observes that courts may use decisional minimalism to spark greater deliberation. For example, a court may interpret an ambiguous statute to avoid a constitutional violation so that a decision is made by a politically accountable body.[291] Likewise, it may use the nondelegation doctrine to force the legislature to act.[292]

A strong argument exists that gene patents violate patient due process rights. By employing the canon of constitutional avoidance, the Supreme Court could have interpreted § 101 of the Patent Act narrowly, thereby prohibiting all gene patents. In doing this, the Court could have recognized that a broad interpretation of § 101 raises potential constitutional concerns. Such a decision would have invited Congress to amend the Patent Act to permit gene patents with additional safeguards to protect patient rights.

So what can the Supreme Court do going forward? As discussed in Part I, Congress asked the PTO hold roundtables on the implications of gene patents. But Congress has shown no motivation to act in terms of legislative reform. Moreover, neither the PTO nor HHS appear to have sufficient authority to act in this area. This means that changes must be initiated by the Supreme Court.

The most direct way to do this would be for the Supreme Court to strike down the Patent Act as unconstitutional as applied to patients using the Due Process Clause. It could then instruct Congress of the changes that are needed in the Patent Act to adequately protect patient liberty rights. Those needed changes are discussed in Subpart B.

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287. *See* Lisa Schultz Bressman, Essay, Schechter Poultry *at the Millennium: A Delegation Doctrine for the Administrative State*, 109 YALE L.J. 1399, 1404–05 (2000) (discussing two 1935 Supreme Court decisions that struck down overly broad delegations as "the high-water mark for the nondelegation doctrine").

288. John F. Manning, *The Nondelegation Doctrine as a Canon of Avoidance*, 2000 SUP. CT. REV. 223, 223 (2000).

289. *See* Alexander M. Bickel & Harry H. Wellington, *Legislative Purpose and the Judicial Process: The Lincoln Mills Case*, 71 HARV. L. REV. 1, 31 (1957) (noting that when constitutional doubts "are seriously entertained and are of major proportions the rule rests on reasons of its own which have little to do with what may inoffensively be described as the function of remanding legislation to Congress for a new look").

290. Cass R. Sunstein, *Foreword: Leaving Things Undecided*, 110 HARV. L. REV. 4, 6–7 (1996).

291. *Id*. at 38.

292. *Id*.

A weakness in the above argument is that the Supreme Court has been extremely reluctant to expand the scope of fundamental rights, fearing that the scope of the Due Process Clause will be limitless. Although biological information is arguably part of a much older right of making informed medical treatment decisions, it may choose to view it as a new concept that is not "deeply rooted in this Nation's history."[293]

However, the Supreme Court has recently begun blurring the distinction between fundamental and non-fundamental rights, perhaps to side-step the "deeply rooted" requirement. When the Court struck down the Defense of Marriage Act, it never referred to the right to marry a partner of the same sex as "fundamental."[294] The Alito dissent observed that the majority's treatment of the right of same-sex marriage was as if it were fundamental, even though the dissent believed it did not meet the "deeply rooted" requirement.[295]

Even if the Supreme Court does not find a perfect fit with substantive due process, it may recognize a penumbral right under substantive due process. Penumbral rights protect fundamental rights that are implicitly derived from the Constitution[296] and are consistent with the Ninth Amendment's protection of unenumerated rights.[297] Such rights are viewed in two different ways: as auxiliary protection for core constitutional rights and as a method of discerning additional rights based on rights enumerated

293. U.S. v. Windsor, 133 S. Ct. 2675, 2707 (2013) (Alito, J., dissenting) (quoting Washington v. Glucksberg, 521 U.S. 702, 720–21 (1997)).

294. *See generally id*.

295. *Id*. at 2707 (Alito, J., dissenting) (maintaining that the majority implies substantive due process underlies its decision, notwithstanding the fact that gay marriage is not "deeply rooted in this Nation's history and tradition").

296. *See* San Antonio Indep. Sch. Dist. v. Rodriguez, 411 U.S. 1, 33 (1973) (holding that the answer to whether education is a fundamental right "lies in assessing whether there is a right to education explicitly or implicitly guaranteed by the Constitution"); Quill v. Vacco, 80 F.3d 716, 726 (2d. Cir. 1996), *rev'd on other grounds*, 521 U.S. 793 (1997) ("[F]undamental rights are those explicitly or implicitly derived from the Constitution itself.").

297. U.S. CONST. amend. IX ("The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people."); *see also* United States v. Criden, 675 F.2d 550, 556 (3d. Cir. 1982) ("[B]oth the concept of penumbral guarantees and the ninth amendment support the existence of rights not explicitly mentioned in the Constitution.") (citing Richmond Newspapers, Inc. v. Virginia, 448 U.S. 555, 579 n.15 (1980) (plurality opinion)).

in the Constitution.[298] In recent years, penumbras have been used by the Supreme Court to fortify state sovereignty.[299]

Penumbral rights may be useful in two regards. First, to the extent that the right to genetic and other biological information is not explicitly a liberty right, it may be viewed as an implicit right under the Constitution. Second, as discussed in Part I, there is a growing body of literature asserting that diagnostic patents may violate other parts of the Constitution. Even if these arguments alone are not strong enough to support protection, one could nevertheless argue that the right to biological information falls within the overlap of the First, Fifth, and Ninth Amendments.[300]

B. Congress

Congress's policymaking in the area of diagnostic patents has been inadequate, and scholars have been wary of any legislative solution in this area.[301] However, if Congress can be compelled to act, two changes to the Patent Act should be carefully considered. The first would be to add a compulsory licensing provision to the Patent Act for situations where patients have no access to diagnostic testing or confirmatory testing. The second change would be adding a long-overdue statutory experimental use exception.

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298. *See* LAURENCE H. TRIBE, 1 AMERICAN CONSTITUTIONAL LAW 43 (3d ed. 2000) ("[Penumbral rights] reveal that the gaps between the rights-defining provisions enumerated in the Bill of Rights are only apparent and do not represent substantively empty space but instead serve to juxtapose, in an almost Impressionist fashion, individual commitments in combinations also showing additional guarantees."); Stephen Kanter, *The Griswold Diagrams: Toward a Unified Theory of Constitutional Rights*, 28 CARDOZO L. REV. 623, 626 (2006) (characterizing penumbras as described in *Griswold* as "a protective shell" that surrounds "each textually explicit core right"); Glenn Harlan Reynolds, Essay, *Second Amendment Penumbras: Some Preliminary Observations*, 85 S. CAL. L. REV. 247, 248 (2012).

299. *See* Helen Hershkoff, *Horizontality and the "Spooky" Doctrines of American Law*, 59 BUFF. L. REV. 455, 480 (2011) (discussing the Rehnquist Court's use of penumbras to support state sovereignty as a limit on national power).

300. *See* Roe v. Wade, 410 U.S. 113, 153 (1973) ("This right of privacy, whether it be founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action, as we feel it is, or, as the District Court determined, in the Ninth Amendment's reservation of rights to the people, is broad enough to encompass a woman's decision whether or not to terminate her pregnancy."); Griswold v. Connecticut, 381 U.S. 479, 484–85 (1965) (discussing how "[v]arious guarantees create zones of privacy," including the penumbra of the First Amendment, as well as those of the Fourth, Fifth, and Ninth amendments); *see also* Lynn D. Wardle, *Protection of Health-Care Providers' Rights of Conscience in American Law: Past, Present, and Future*, 9 AVE MARIA L. REV. 1, 24 n.83 (2010) ("The notion of a constitutionally protected right of privacy has at times been conceived of as a hybrid concept involving overlapping 'penumbras' of several amendments in the Bill of Rights . . . .").

301. *See* Rai, *supra* note 4, at 1266–68 (noting that "patent-law scholars have often found the congressional option unsatisfactory" and discussing the problems of "vetogates" and congressional capture).

1. Compulsory Licensing

The HHS Report made suggestions for statutory changes to protect patient rights. The first suggestion is "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."[302] The rationale for the change is to restore free-market conditions and eliminate problems regarding access to genetic testing.[303] The HHS Report argues that this would allow the development of new testing, including next-generation testing that can lead to low-cost genetic sequencing.

There are a few problems with this suggestion. The goal of the HHS Report was to promote greater patient access to testing, and not to address constitutional violations. As discussed above, however, all diagnostic patents can potentially lead to due process violations. The exception should be broadened to provide a shield to people providing such services where it infringes a diagnostic patent that covers all forms of testing for a medical condition. This would provide greater protection for health care professionals against infringement of patents that do not fall into the narrow category of "gene patents."

A second problem with the HHS Report is that it does not provide the patent holder with compensation.[304] Rather than granting amnesty from infringement, the Patent Act could be amended to require compulsory licensing in limited cases.[305] It is unclear how broad such a right should be. One possibility would be to keep the right narrow, requiring compulsory licensing in only three circumstances. The first circumstance would be where a diagnostic test is not made available at all by the patent holder, as we saw with LQTS testing. The second circumstance would be where the diagnostic test being offered is incomplete compared to what another laboratory could offer, as we saw with Myriad failing to offer large rearrangement testing when Yale had the capability to do so. The third circumstance would be where only a single laboratory is offering the testing, with no availability for confirmatory testing, as we have seen with several tests. As discussed in Subpart C, an agency would need to have power to administer such a provision and to set compulsory licensing rates.

Unfortunately, the suggestion that compulsory licensing be used to protect patient rights is likely to be met with resistance. Although

302. HHS REPORT, *supra* note 5, at 94.

303. *Id*.

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

305. *Id*.

compulsory licenses are common outside the U.S.[306] and are consistent with our international treaty obligations,[307] there is limited use of it in the U.S. Most U.S. compulsory licensing occurs under the Copyright Act.[308] For example, a musician seeking to record another artist's song can obtain a compulsory license under § 115 of the Copyright Act.[309] By contrast, compulsory licensing of patents in the U.S. is rare and employed only under a few narrow circumstances.[310] It is not favored by the patent community[311] due to fears that diluting rights for patent holders will reduce innovation.

Nevertheless, given the existence of a constitutional violation, some alteration in the scope of diagnostic patent rights is inevitable. With compulsory licensing, patent holders would at least receive compensation

306. *See, e.g.*, Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1069 (2009) (noting that compulsory licenses for patents are common in "developing countries and their sympathizers"); Jerome H. Reichman, *Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow*, 46 HOUS. L. REV. 1115, 1139 (2009) (discussing how several European countries have codified compulsory licensing for dependent patents that are blocked by a dominant patent).

307. *See* Ho, *supra* note 306, at 1069; Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 98 (2007) (discussing the leeway allowed for TRIPS members to utilizing compulsory licensing).

308. The Copyright Act employs statutory licensing to collect royalty fees from cable operators that retransmit television and radio broadcasts, satellite operators that retransmit network and non-network signals, and from importers or manufacturers for distributing digital audio recording products. *See* 17 U.S.C. § 111(c)(1) (2006) ("[S]econdary transmissions to the public by a cable system of a performance or display of a work embodied in a primary transmission made by a broadcast station licensed by the Federal Communications Commission or by an appropriate governmental authority of Canada or Mexico shall be subject to statutory licensing . . . ."); 17 U.S.C. § 119(a)(1) (2006) ("[S]econdary transmissions of a performance or display of a work embodied in a primary transmission made by a non-network station shall be subject to statutory licensing under this section if the secondary transmission is made by a satellite carrier . . . ."); 17 U.S.C. § 1003(a) (2006) ("No person shall import into and distribute, or manufacture and distribute, any digital audio recording device or digital audio recording medium unless such person records the notice specified by this section and subsequently deposits the statements of account and applicable royalty payments for such device or medium specified in section 1004."). The Copyright Act also utilizes compulsory licensing. For example, a musician seeking to record another artist's song can obtain a compulsory license under § 115 of the Copyright Act.

309. *See* 17 U.S.C. § 115(a)(1) (2006) (permitting, after initial distribution, others to "obtain a compulsory license to make and distribute phonorecords of the work"); 42 U.S.C. § 7608 (2006) (allowing for compulsory licensing of patents related to the implementation of clean air laws under three sections of the Clean Air Act).

310. *See* 42 U.S.C. § 2183 (2006) (allowing for compulsory licensing of patents that are "of primary importance in the production or utilization of special nuclear material or atomic energy" and are "of primary importance to effectuate the policies and purposes" related to the development and control of nuclear energy); 42 U.S.C. § 7608 (2006) (allowing for compulsory licensing of patents related to the implementation of clean air laws under three sections of the Clean Air Act); Mueller, *supra* note 21, at 967–68 (discussing how the Federal Trade Commission and the Department of Justice use compulsory licensing as a remedy).

311. *See* Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 608 (2000).

for the loss of their diagnostic-testing monopoly. They would, moreover, retain a monopoly with regard to therapeutic treatments. As Subpart C notes, this Article recommends that rulemaking authority for compulsory licensing be given to HHS and not to the PTO.

2. Research Exemption

The second suggestion made in the HHS Report is "[t]he creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research."[312] A statutory research exemption is long overdue. In *Madey v. Duke University*, the Federal Circuit eviscerated the common-law experimental use defense.[313] The court held that Duke's use of a former researcher's patented devices did not constitute experimental use because Duke's use comprised a legitimate business interest.[314] The Supreme Court declined to grant certiorari.[315]

The fallout from the *Madey* case was significant. Scholars have observed that patents are routinely ignored and infringed by academic researchers.[316] However, as *Myriad* illustrates, this non-permissible research shuts down upon the arrival of a cease-and-desist letter. Myriad and Athena Diagnostics have been especially aggressive in this regard, shutting down academic research relating to their exclusive licenses.

At its root, the problem is that academic research in biotechnology can be commercialized. The *Madey* court made clear that even non-commercial projects can "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects."[317] Even when the original patented work was funded by government grants, researchers can still patent—and therefore commercialize—their work.[318] Consequently, current protection for experimental use is practically non-existent.

An experimental use provision in the Patent Act would remedy this problem. Such an exemption could be limited to patents with medical

312. HHS REPORT, *supra* note 5, at 97.

313. *See generally* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).

314. *See id*. at 1362 ("Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications.").

315. Duke Univ. v. Madey, 539 U.S. 958 (2003).

316. *See* Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 21 (2008) ("Universities and academic researchers continue to engage in experimentation with patented inventions despite the now clear rule that they are not immune from liability for doing so.").

317. *Madey*, 307 F.3d at 1362.

318. The Bayh-Dole Act of 1982 allows grant recipients to "elect to retain title to any subject invention." 35 U.S.C. § 202(a) (2006); *see also* Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188, 2192–93 (2011) (discussing the Bayh-Dole Act).

applications to allow researchers to continue to expand upon diagnostic tests under patent protection. If the researcher consequently discovers a superior test and patents it, the new test would fall under a compulsory licensing requirement benefitting the original patent holder. But to have a measurable effect, the HHS Report's suggestion would need to be broadened to go beyond patented genes to allow for any diagnostic patent that creates a monopoly over bodily information.

It is unclear, however, whether an experimental use provision is necessary to avoid a constitutional violation. Compulsory licensing alone would prevent patent holders from blocking patient access to genetic information. It is also uncertain whether the government's hindering of further innovation in genetic testing, in and of itself, constitutes a due process violation.

C. The Executive Branch

If compulsory licensing is implemented, who will administer it? Congress will not have the resources or expertise to work out the details of when compulsory licensing should be triggered and what compensation should be paid out. After the courts and Congress, this leaves an administrative agency as the best option for making policy decisions regarding how to best implement compulsory licensing.[319]

The PTO would be a poor administrator of such a provision. The agency has not been entrusted with notice-and-comment rulemaking authority over the substantive provisions of the Patent Act;[320] nor does it have experience in dealing with issues of public policy and health. The PTO's power is gradually expanding. Under the AIA, Congress granted the PTO the ability to conduct post-grant review proceedings that scholars note resembles formal adjudication[321] and notice-and-comment rulemaking.[322] However, the agency currently lacks the expertise to engage in health-law policy rulemaking and adjudication.

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319. See Rai, *supra* note 4, at 1237.

320. *See* Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 297 (2007) ("First, unlike most significant agencies, the PTO does not have any significant substantive rulemaking authority."). Melissa Wasserman argues that the PTO has received substantive rulemaking authority under the America Invents Act, but it remains to be seen whether the PTO will utilize notice-and-comment rulemaking and whether courts will grant appropriate deference. *See generally* Melissa F. Wasserman, *The Changing Guard of Patent Law:* Chevron *Deference for the PTO*, 54 WM. & MARY L. REV. 1959 (2013).

321. *See* Rai, *supra* note 4, at 1239 ("[T]he AIA did confer upon the PTO the ability to conduct postgrant review proceedings that resemble formal adjudications.").

322. *See* Sarah Tran, *Administrative Law, Patents, and Distorted Rules*, 80 GEO. WASH. L. REV. 831, 859–60 (2012) (arguing that the AIA granted the PTO substantive rulemaking authority).

But as the Solicitor General noted, the issue of patents on basic discoveries in genetics "is a question of great importance to the national economy, to medical science, and to the public health," and therefore "implicates the expertise and responsibilities of a wide array of federal agencies," including the National Institute for Health (NIH).[323] Professor Rai has observed that the NIH has played a major role in gene-patent jurisprudence since the early 1990s and has a stake in the outcome given its role in funding genomics research.[324] Although the NIH initially was in favor of broad gene patent rights, a change in directorship resulted in the agency backing away from such patents, fearing that they would chill research.[325]

Consequently, the NIH is the natural choice for administering a new provision. The agency is under the HHS, which already administers a broad range of public-health programs and research grants associated with diagnostic testing.

A counter-argument to this proposal is that the NIH does not have expertise in promoting innovation.[326] However, the main objective of creating rules regarding compulsory licensing would be to create narrow rules to protect the public health, not to promote innovation. Congress could take into account innovation when passing the enabling legislation.

CONCLUSION

The *Myriad* litigation helped reveal two levels of problems caused by the PTO's issuance of broad diagnostic patents. It highlighted how patients are harmed when patent holders prevent laboratories from developing and offering competing tests. But *Myriad* also revealed a more fundamental problem—that the PTO's issuance of broad diagnostic patents can violate patients' due process rights. The PTO is a government actor, and it plays an extensive role in shaping the scope of diagnostic patent claim language. Patent holders then use these patents in a wholly foreseeable way—to exclude competitors from offering tests and from conducting research.

The solution to these problems is not to abolish diagnostic patents, but to narrowly tailor the Patent Act to promote the compelling governmental interest of fostering innovation. Congress must consider the interplay

323. Brief for the United States as Amicus Curiae Supporting Neither Party at 1, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406).

324. *See* Rai, *supra* note 4, at 1241.

325. *Id*. at 1250–53.

326. *Id*. at 1273 (noting that the "NIH is not necessarily the ideal sister agency to engage with the PTO" and observing that the "NIH is not necessarily an expert in the law and economics of transforming life-science research into commercial invention").

between government-issued patent rights and individual liberty interests. It should start by adding safeguards to the Patent Act to allow for compulsory licensing when a patent holder fails to offer a diagnostic test or when confirmatory testing is not available. Such a change could be overseen by HHS. More generally, Congress needs to recognize that changes to the Patent Act directly impact individual rights. These proposals would allow inventors to continue to patent innovations in diagnostic testing without unduly sacrificing patient health.

It is unlikely such a change will be made voluntarily by Congress. The Supreme Court would likely need to intervene and hold the Patent Act, as applied, to be unconstitutional. To do this, the Court must revisit the scope of liberty interests in health care, because these rights have been eroded by controversial abortion cases. If the Court remains inactive, fundamental rights will continue to diminish as technology advances.