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The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law

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THE “PROGRESS CLAUSE”: AN EMPIRICAL ANALYSIS BASED ON THE CONSTITUTIONAL FOUNDATION OF PATENT LAW

Lori B. Andrews

When the Founding Fathers promulgated the Progress Clause of the U.S. Constitution, they recognized the potential for certain types of patents to impede rather than promote innovation. The drafting of the Patent Act and its interpretation by the U.S. Supreme Court similarly recognized that abstract ideas, laws of nature, and products of nature do not represent patentable inventions and that innovation requires that these tools be available to all researchers. In three recent cases, the Supreme Court has revisited the Progress Clause. Its most recent case on the issue, Association for Molecular Pathology v. Myriad Genetics, Inc., raises not only legal issues, but also empirical ones. This Article puts the goals of the Progress Clause in context by analyzing all of the studies that have addressed whether gene patents promote or impede progress. It demonstrates that the Founders’ concerns were warranted and an exemption for abstract ideas, laws of nature, and products of nature is necessary.

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# Table of Contents

I. Introduction ........................................................................................................... 539

II. The Patent System and Patentable Subject Matter ........................................... 543

III. What Do Gene Patents Cover? ................................................................. 552

IV. The Unique Challenges Gene Patents Pose for Innovation ......................... 554
   A. Genes as Information .............................................................................. 555
   B. Genes as Interactive Entities ................................................................. 556
   C. Gene Patents and Exclusivity ................................................................. 559
   D. The Difficulties of Challenging Gene Patents ........................................ 560

V. Analyses of the Effects of Gene Patents on Innovation ..................................... 561
   A. Are Gene Sequence Patents Necessary for the Initial Innovation? ........... 562
   B. Are Genetic Sequence Patents Necessary for Subsequent Innovation? .... 567
      1. Effects of Gene Patents on Researchers’ Undertaking of Genetic Research ........................................................................ 568
      2. Effects of Gene Patents on Epidemiological Research ......................... 573
      3. Effects of Gene Patents on Research on Diagnostics ........................... 576
   C. What Are The Effects of Gene Patents on Researchers’ and Research Subjects’ Willingness to Participate in Research? .......... 582
      1. Effects of Gene Patents on Researchers’ Withholding or Delaying Public Disclosure of Data ......................................................... 582
      2. Effects of Academic Researchers’ Lack of Awareness of the Potential Impact of Patents ............................................................... 586
      3. Effects of Gene Patents on People’s Willingness to Participate in Genetic Research and Donate Biological Samples For Research .......... 589

VI. Conclusion ........................................................................................................... 592
I. INTRODUCTION

When the Founding Fathers were drafting the U.S. Constitution, they thought about how best to encourage innovation in their new nation. The result was the Progress Clause of the U.S. Constitution, Article I, Section 8, Clause 8. The Progress Clause provides that Congress shall have 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 . . . .”

This clause, designed to reward the creation and sharing of new knowledge, is the constitutional basis for the intellectual property system in existence today.

The nation’s Founders engaged in extensive analyses about the scope of the clause and its appropriate limits. Thomas Jefferson, the first administrator of the patent system and author of the 1793 Patent Act, was concerned about the power of monopolies over science. He stated, “Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.”

Jefferson was adamant that abstract ideas, as well as the handiwork of nature, not be restricted by patents. He wrote:

1 U.S. CONST. art. I, § 8, cl. 8.
2 SETH SHULMAN, OWNING THE FUTURE 29 (1999).
3 6 WRITINGS OF THOMAS JEFFERSON 181 (Henry A. Washington ed.). Similarly, for Nobel Laureate economist Joseph Stiglitz, the issue is not “whether the patent system encourages or discourages innovation . . . [but] whether the particular category of patents under discussion does so, and does so to a sufficient extent to justify the large social costs of the restrictions on the use of knowledge and the extension of monopoly power.” Declaration of Joseph E. Stiglitz ¶ 40, Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. Jan. 20, 2010) (No. 09-4515). Stiglitz identifies three ways gene patents such as those at issue in Ass’n for Molecular Pathology v. USPTO impede basic research: (1) the “patent race” to patent particular genetic sequences reduced the available public funds for other research; (2) the “socially unproductive race to be first” to patent genes diverted scarce talent from other more productive pursuits; and most significantly (3) gene patents pose a substantial impediment to follow up research. Id. at ¶¶ 37–39.
That ideas should freely spread from one to another over the globe, for
the moral and mutual instruction of man, and improvement of his
condition, seems to have been peculiarly and benevolently designed by
nature, when she made them, like fire, expansible over all space,
without lessening their destiny in any point, and like the air in which
we breathe, move, and have our physical being, incapable of
confinement or exclusive appropriation.¹

Patents are not granted for all useful products or processes that
result from human ingenuity. For instance, mental processes and
abstract ideas are not patentable because “they are . . . basic tools
of scientific and technological work.”⁵ Patenting other raw
materials of scientific and technological work, such as laws of
nature or products of nature, similarly raises the danger of
inhibiting future innovation and “foreclose[ing] more future
invention than the underlying discovery could reasonably justify.”⁶

In a series of cases over the past 150 years, the Supreme Court
has held that one cannot patent abstract ideas, laws of nature,
products of nature, or materials isolated from products of nature if
those materials behave in the same way they would in nature.⁷ In
1853, when Samuel Morse convinced the Patent Office to grant
him a patent on all uses of electromagnetic waves to write at a
distance, the Supreme Court said that he could not patent the law
of nature that covers every such use of electromagnetic waves.⁸ He
could only patent his invention—the telegraph.⁹

The Supreme Court, in O’Reilly v. Morse,¹⁰ was concerned that
granting Morse broad rights to a law of nature beyond his

¹ Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 9 n.2 (1966) (quoting
6 WRITINGS OF THOMAS JEFFERSON 180–81 (Henry A. Washington ed.)).
⁶ Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1292
(2012).
Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); American Fruit
Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11–12 (1931); Cochrane v. Badische
Anilin & Soda Fabrik, 111 U.S. 293, 311 (1884); American Wood-Paper Co. v.
Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566, 594 (1874); O’Reilly v. Morse,
⁸ Morse, 56 U.S. at 113.
⁹ Id.
¹⁰ 56 U.S. 62 (1853).
particular invention would overcompensate him by giving him rights to subsequent inventions that he did not himself create:

If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Nor is this all, while he shuts the door against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light.\textsuperscript{11}

In 1980, the first Supreme Court case dealing with biotechnology made clear that the exemption is just as relevant in the modern biotech age. \textit{Diamond v. Chakrabarty}\textsuperscript{12} involved a man-made (genetically engineered) bacterium, which the Court carefully described as \textit{not} naturally occurring.\textsuperscript{13} In that case, the Court stated:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.”\textsuperscript{14}

The \textit{Chakrabarty} Court held that an invention from a product of nature is only patentable if it is “markedly different” from nature.\textsuperscript{15} The reason it is important not to have patents on products of nature or laws of nature is that it would give inventors “\textit{too much} patent

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\textsuperscript{11} Id. at 113.
\textsuperscript{12} 447 U.S. 303 (1980).
\textsuperscript{13} Id. at 309.
\textsuperscript{14} Id. (alteration in original) (citations omitted) (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).
\textsuperscript{15} Id. at 310.
protection” and “impede rather than ‘promote . . . ’ the constitutional objective of patent and copyright protection.”

In three recent cases—Bilski v. Kappos,17 Mayo Collaborative Servs. v. Prometheus Labs., Inc.,18 and Ass’n for Molecular Pathology v. Myriad Genetics, Inc.19—the Supreme Court reiterated that some patents can thwart innovation. Myriad, the most recent decision, provides the perfect case study about whether a particular class of patents impedes or promotes progress. Myriad focuses on whether the claimed inventions—isolated human genes—are “markedly different” from products of nature.20 In addition to extensive briefing about whether there was sufficient human ingenuity involved to consider an isolated human gene a patentable invention,21 the affidavits and amicus briefs in the case gathered all existing data on whether gene patents encourage or discourage innovation. Over ninety affidavits were filed,22 including two from Nobel Laureates.23 Over 102 amicus groups filed briefs arguing for the invalidation of gene patents,24 including medical organizations such as the American Medical Association25 and patient advocacy groups such as the March of Dimes.26 Industry organizations such as the Biotechnology Industry

17 130 S. Ct. 3218 (2010).
19 133 S. Ct. 2107 (2013).
20 Id. at 2109.
22 Ass’n for Molecular Pathology v. USPTO (USPTO), 702 F. Supp. 2d 181 (S.D.N.Y. Mar. 29, 2010).
Organization filed briefs arguing that gene patents were valid. Also weighing in were prominent scientists, various companies, numerous law professors, and the intellectual property bar. The briefs and affidavits submitted in the case cover every study undertaken about the impact of human gene patents. These analyses provide the ideal raw material for a conceptual exploration of how to determine whether the allowance of patents on a particular class of materials furthers or hinders progress, and to discern how to draw the line between unpatentable and patentable subject matter.

In Part II, this Article analyzes the patent system and courts’ roles in addressing patent subject matter eligibility. Part III explains what gene patents cover. Part IV outlines some of the special challenges that genes raise for patent law and why it might be expected that patents on genes might impede innovation. Part V assesses the effects of gene patents on innovation, including: (1) the role human gene patents play in assuring the initial innovation of identifying genetic sequences; (2) the role human gene patents play in sequential innovation such as the undertaking of epidemiological research, creation of diagnostic kits, and development of new treatments to prevent or ameliorate genetic diseases; and (3) the impact of gene patents on researchers’ and research subjects’ willingness to participate in research. The concluding section assesses whether gene patents are likely to encourage or restrict innovation—that is, whether or not they “promote progress.” That analysis concludes that the rationale behind the Progress Clause supports the Court’s assessment that genes are unpatentable products of nature.

II. THE PATENT SYSTEM AND PATENTABLE SUBJECT MATTER

Patents are designed as a government-granted privilege and not as a right entitled to inventors for their discoveries. As the

References:

Supreme Court has noted, the patent privilege is powerful in that its “very exclusivity can impede the flow of information that might permit, indeed spur, invention.”

Thus, a foundational question in analyzing patent eligibility is whether a class of patents will “promote the Progress of Science and useful Arts.”

The mechanism by which Congress chose to encourage innovation was to grant an inventor a patent—a monopoly on any use of the patented invention in exchange for a disclosure in the patent application of how the invention can be made. This is thought to encourage innovation by stimulating people to invent in the first place, often by making a better, cheaper, more interesting, and more effective alternative to an existing invention. Thus, if a person patents a mousetrap made of wood, when the patent application later becomes public (a condition of the patent grant), other inventors can read about how the inventor made the mousetrap and can create variations using significantly different materials or processes.

Under the Patent Act, a patent is a limited legal monopoly given to an inventor who meets certain constitutional and statutory requirements. The invention must be novel, non-obvious, and useful. But Section 101 of the Patent Act and the Progress Clause in the Constitution also require an assessment that the purported invention is not an abstract idea, law of nature, or product of nature. Simply meeting the requirements of non-obviousness,

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31 See Myriad, 133 S. Ct. at 2116.
36 The patent application must have a detailed written description of the invention and must demonstrate how to make the invention. 35 U.S.C. § 101; 35 U.S.C. § 112.
novelty, and usefulness is not enough because, for example, a product of nature (such as a new mineral discovered in the ground) might meet all three and yet not be an “invention.” This is true no matter how much money or intellect is spent finding this mineral. Justice Breyer has discussed the reason why it is important not to have patents on products of nature or laws of nature. He said:

The justification for the principle [that products of nature or laws of nature are not patentable] does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes too much patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection.

For twenty years from the date of the filing of the patent application, a patent holder controls any use of its invention and can prevent anyone else from using, making, selling, or importing the invention. The patent holder can keep an invention away from the public altogether. The inventor can decide that he will be the only one to sell the invention and charge as much as he wants for the invention. Or the inventor can, for royalty fees, grant exclusive rights to a single licensee to use the invention or make the invention available for royalty fees in a non-exclusive fashion to all comers.

Unlike in copyright law, there is no patent law exception for fair use. Unlike patent law in other countries, there is no general statutory research exception in the United States. Infringement is a strict liability concept and it is not necessary to prove intent to

38 Id.
infringe.\textsuperscript{44} In general, only infringers and potential infringers—and not third parties—have a right to challenge a patent in court.\textsuperscript{45} Under American patent law, an inventor can refuse to make the invention and forbid others from making it. In contrast, under American trademark law, a person can lose the mark if he does not use it for three years.\textsuperscript{46} And in Europe, patent holders are required to “work” the patent and make the invention available or else their rights are constricted.\textsuperscript{47}

The American patent system is a three-way give-and-take among the U.S. Patent and Trademark Office (“USPTO”), the courts, and Congress. All three have active roles in assuring that the goals of the patent system are met and that the monopoly granted is not too broad. Often this means that Congress and the courts winnow back patents erroneously granted by the USPTO.\textsuperscript{48} Between 25\% and 75\% of litigated patents are found invalid during litigation, sometimes because their scope is so broad that they cover unpatentable subject matter such as abstract ideas, laws of nature, or products of nature.\textsuperscript{49} Sometimes the director of the

\textsuperscript{44} Jurgens v. CBK, Ltd., 80 F.3d 1566, 1570 n.2 (Fed. Cir. 1996).
\textsuperscript{48} See, e.g., O’Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).
USPTO has had to review and invalidate provisions of improperly granted patents—\(^{50}\) this has happened, for example, with patents on certain computer programs.\(^{51}\) In other instances, Congress has stepped in—for example, by exempting doctors from patent infringement liability if they use a patented medical or surgical procedure.\(^{52}\)

One might think that the Constitution allows patents on certain products of nature, because Article I, Section 8, Clause 8 speaks of exclusive rights to “discoveries.”\(^{53}\) In the case of gene patents, the patent holder has discovered the gene sequence. However, the term “discoveries,” at the time Article I, Section 8, Clause 8 was written, meant the creation of something new, synonymous with our modern term “invention.”\(^{54}\) In the late eighteenth century, the terms “invention” and “discovery” both referred to the creation of something original.\(^{55}\) As Demaine and Fellmeth explain:

> An “invention,” in the parlance of the Constitution and early patent laws, is a new creation consciously sought and successfully reduced to practice by the inventor. A “discovery,” as used in the same parlance, was intended to denote a fortuitous creation of the inventor and not merely something found by him or her. Thus, an “invention” and a “discovery” share the requirement that the inventor create something original; the difference between the two is that an “invention” is consciously sought, while a “discovery” is created unexpectedly.

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\(^{50}\) Ex Parte Reexamination at the Initiative of the Director, 37 C.F.R. § 1.520 (2013).


\(^{52}\) 35 U.S.C. § 287(c) (2006) (exempting doctors from patent infringement liability if they use a patented medical or surgical procedure).

\(^{53}\) U.S. CONST. art. I, § 8, cl. 8.

\(^{54}\) Linda J. Demaine & Aaron Xavier Fellmeth, Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent, 55 STAN. L. REV. 303, 370 (2002). The authors further provide that the difference between a discovery and invention was that the first is the unexpected creation of something new, while the second is consciously sought. \textit{Id.}

\(^{55}\) \textit{Id.} (citing 5 OXFORD ENGLISH DICTIONARY 453 (James A.H. Murray ed. 1901)).
discovery in that era, as used in the intellectual property law, denoted something originating from the human intellect and not merely learned by that intellect.\textsuperscript{56}

Writing in 1889, another patent law scholar noted that someone “may invent a machine, and may discover an island or law of nature.\textsuperscript{57} For doing the first . . . , the patent laws may reward him, because he is an inventor . . . ; but those laws cannot reward him for doing either of the others, because he is not an inventor in doing either.”\textsuperscript{58} Mere “discovery” (as we use the term today) of a natural entity has never been patentable.

The observation that the drafters of the Constitution viewed discoveries as a type of invention is supported in the text of the first Patent Act. The Patent Act of 1793 specifically stated that “simply changing the form or the proportions of any machine, or composition of matter, in any degree, shall not be deemed a discovery.”\textsuperscript{59} Although the Patent Act of 1952\textsuperscript{60} does not specifically contain this language, it is considered by both Congress\textsuperscript{61} and the Supreme Court\textsuperscript{62} to merely codify all earlier patent acts.

\textsuperscript{56} Id. (citing 2 Ernest Bainbridge Lipscomb III, Lipscomb’s Walker on Patents § 6:2, at 6 (3d. ed. 1984)).


\textsuperscript{58} Demaine & Fellmeth, supra note 54, at 370 (citing Albert H. Walker, Text-Book of the Patent Laws of the United States of America § 2, at 2 (L.K. Strouse & Co.: New York, 2d ed. 1889)).


\textsuperscript{60} 35 U.S.C. § 101 (1952).


In *Graham v. John Deere Co. of Kansas City*, the Supreme Court, in dicta, addressed the need for a “discovery” to have a new and useful aspect be afforded patent protection as an “invention.”

The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly.

The patent laws of many other leading countries also distinguish “discoveries” from “inventions.” The British Patents Act of 1977 provides that “a discovery, scientific theory or mathematical

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Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’ S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).” *Id.* at 308–09.


64 *Id.* at 9.

65 The European Patent Convention (“EPC”) requires such an “inventive step,” excluding mere “discoveries” from patentable subject matter. European Patent Convention, art. 52, Nov. 29, 2000. The EPC offers that “discoveries, scientific theories and mathematical methods” are not regarded as patentable subject material. See *id.* Likewise, the European Directive on the Legal Protection of Biotechnological Inventions provides that “the simple discovery of one of [the] elements [of the human body] or one of its products, including the sequence or partial sequence of a human gene, cannot be patented” and that “a mere discovery cannot be patented” because inventions must involve an “inventive step.” Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art.16, 1998; see, e.g., European Patent Convention, art. 52 (Nov. 29, 2000); 1995. évi XXXIII. törvény a találmányok szabadalmi oltalmáról (Law on the Protection of Inventions by Patents), art. 1, § 2(a) (Hung.) (noting that “discoveries, scientific theories, and mathematical methods” are not patentable); see also Carlos M. Correa, *Internationalization of the Patent System and New Technologies*, 20 WISC. INT’L L.J. 523, 528 (2002); Ikechi Mgbeoji, *Patents and Traditional Knowledge of the Uses of Plants: Is A Communal Patent Regime Part of the Solution To the Scourge of Bio Piracy?*, 9 IND. J. GLOBAL LEGAL STUD. 163, 181 (2001).
“method” is not an invention. Furthermore, the “presentation of information” is not an invention under the British Act.

Recently, the Supreme Court, in rapid succession, granted certiorari in three cases that raised Section 101’s long-held three-part subject matter exception to patentability, considering in turn the patentability of abstract ideas, laws of nature, and products of nature. In 2010, in Bilski v. Kappos, the Court held that an abstract idea—hedging in trading energy futures—could not be patented. In 2012, in Mayo v. Prometheus, the Court held, 9-0, that a law of nature—how the body responded to the administration of a drug—was not patentable. To round out its consideration of the three-pronged exception, the Supreme Court decided Association for Molecular Pathology v. Myriad Genetics, Inc., holding that an isolated human gene is a product of nature and not patentable. The Court’s decision in Myriad was unanimous. The Court wrote:

We have long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable. Rather, they are the basic tools of scientific and technological work that lie beyond the domain of patent protection. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would tie up the use of such tools and thereby inhibit future innovation premised upon them. This would be at odds with the very point of patents, which exist to promote creation.

The Myriad decision rests on 150 years’ worth of legal precedents holding that mere discoveries are not patentable and that a gene is an unpatentable product of nature. The Court noted

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67 Id.
70 Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).
72 See, e.g., O’Reilly v. Morse, 56 U.S. 62, 112–21, 132 (1853); American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566, 594 (1874); Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 311 (1884); American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11–12 (1931); Funk Bros. Seed
that “groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”

The Court’s holding is in keeping with the understanding of the scientific and medical communities, which classify human genes as discoveries and products of nature, rather than inventions. The Human Genome Organization, the international organization of genomic scientists, wrote in 1992 that “the human genome is our common heritage and collective property; genetic information is . . . in the public domain . . . . [H]uman DNA is not patentable, but belongs to humankind.” The World Medical Association declared that “genetic information should be general property. Therefore no patents should be given for the human genome or parts of it.” The 2002 winner of the Nobel Prize in Medicine or Physiology, Dr. John Sulston, a genetics researcher, similarly pointed out that “[t]he genome sequence is a discovery, not an invention.”

The premise behind the subject matter limitation in patent law is that patents on products of nature will impede innovation in violation of the Progress Clause. But is that premise correct? An examination of the natural phenomenon that gene patents cover—and the potential and actual impact of gene patents on innovation—provide evidence that patents on products of nature do indeed impede innovation.


73 Myriad, 133 S. Ct. at 2110.


III. What Do Gene Patents Cover?

The science behind the discovery of a gene sequence was central to the Myriad court’s analysis and is also foundational to an assessment of whether patents on human genes spur or thwart innovation. A human gene consists of hundreds of thousands of combinations of the chemical bases, adenine (A), cytosine (C), guanine (G), and thymine (T). A gene is represented in scientific research, medical practice, and patent applications by a series of letters corresponding to the chemical bases. In all, there are approximately three billion chemical letters in a person’s genome.\(^77\) One segment of the hemoglobin gene looks like this: CCTGAGG.\(^78\) Various mutations in a gene can lead to disease. These can be likened to typos in the spelling of the gene. A single switch of the chemical letter A to T in the hemoglobin gene causes a serious disease, sickle cell anemia (CCTGAGG is switched to CCTGTGG).\(^79\) Sometimes, the typo is a repeat of the chemical letters. The devastating neurological disorder Huntington’s disease is caused by a stutter in the gene, where the chemicals represented by letters CAG are repeated numerous times.\(^80\) In other diseases, the problem is caused by the deletion of certain chemical letters.\(^81\)

Knowing the sequence of a gene is important in diagnostics and the development of treatment. Using a diagnostic test in which a small segment of DNA binds to its complementary strand from

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\(^77\) William Gregory Feero & Alan E. Guttmacher, Genomics, Personalized Medicine, and Pediatrics, 14 ACADEMIC PEDIATRICS 14, 14 (2013).


\(^79\) See Allyson Cole-Strauss et al., Correction of the Mutation Responsible for Sickle-Cell Anemia by an RNA-DNA Oligonucleotide, 273 SCIENCE 1386, 1386 (1996); see also Evelyn Santana et al., Different Frequency of Gene Targeting Events by the RNA-DNA Oligonucleotide Among Epithelial Cells, 111 J. INVESTIGATIVE DERMATOLOGY 1173, 1173 (1998).

\(^80\) F. O. Walker, Huntington’s Disease, 369 LANCET 218, 222 (2007).

the patient’s blood, a physician can compare a person’s genetic sequence to a reference sequence, such as a normal sequence or one with a mutation, to learn whether the patient is predisposed to a genetic disease.82

In *Myriad*, the challenged patents claim isolated BRCA1 and BRCA2 breast cancer genes identified in the patents by their sequences—the long string of the chemical bases: A, C, G, and T.83 The term “isolated” was defined in the patent as “substantially separated from other cellular components which naturally accompany a native human sequence or protein, e.g., ribosomes, polymerases, many other human genome sequences and proteins,” and the term “includes recombinant or cloned DNA isolates and chemically synthesized analogs or analogs biologically synthesized by heterologous systems.”84 Because the patents cover all BRCA1 and BRCA2 genes, their coverage extends to any person’s BRCA1 or 2 gene once it is removed (“isolated”) from his or her body.

The patents also cover any fragment of the BRCA1 gene sequence that is at least fifteen nucleotides in length.85 Nucleotides consist of a single chemical base (the A, C, G, or T) and its attached sugar/phosphate structure. The fifteen-nucleotide fragment claim is so broad that a sequence of fifteen nucleotides found in BRCA1 appears in all the other genes in the body.86 Thus, Myriad could exercise its patent not only with respect to testing for breast cancer, but also for any other gene.

Every person has a breast cancer gene, including men.87 In most cases, the gene sequence is normal and the person is not

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85 Patent ’282 at [5–6].
86 A 15 nucleotide sequence fragment from BRCA1 was found to appear 340,000 times on Chromosome 1 alone. See Thomas Kepler et al., *Metastasizing Patent Claims on BRCA1*, 95 GENOMICS 312, 313 (2010).
genetically predisposed to breast cancer. But in some cases there is a mutation in the breast cancer gene which increases the likelihood that a person will develop breast cancer.\textsuperscript{88} In order to find out whether the person was predisposed to breast cancer the person’s isolated gene sequence had to be analyzed, but the gene sequence was covered by Myriad’s patents. Similarly, in order for research to be done, the gene must be isolated and, thus, fell under Myriad’s patents.

IV. THE UNIQUE CHALLENGES GENE PATENTS POSE FOR INNOVATION

“As we have recognized before,” wrote the Supreme Court in \textit{Myriad}, “patent protection strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention.’”\textsuperscript{89} There are reasons to expect that patents on isolated human genes will hinder innovation. Gene patents do not cover tangible human-made inventions, but information from nature that has been discovered. Because many diseases are polygenic—the result of various genes acting in combination—it may be necessary for genetic researchers to have access to multiple genes, yet there is less incentive than in other fields to license patents non-exclusively.\textsuperscript{90} In fields where a single invention requires the licensing of many patents, such as in the car or cell phone industries, there is an incentive for patent holders in that field to deal fairly and create patent pools.\textsuperscript{91} If one car company needs another car company’s patent there is an incentive to cross-license, but for a small biotech company whose only intellectual

\textsuperscript{88} Id.
\textsuperscript{89} Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (brackets in original) (citing Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1305 (2012)).
\textsuperscript{90} See infra discussion at Part III.C.
\textsuperscript{91} A “patent pool” is an agreement between two or more patent owners to license one or more of their patents to one another or third parties. \textit{UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 4 (Jeanne Clark et al. eds., 2000) (citations omitted).}
property is a gene patent, there is less incentive to participate in patent pools as it would “undermine the gains from exclusivity.”

A. Genes as Information

Patent law is premised on the idea that the public will get free access to the information described in the patent in exchange for time-limited exclusivity. The right to make, use, or sell a claimed invention, in exchange for publishing in the patent the description of the invention for other inventors to build upon. However, the system breaks down when a patent is granted for information itself—such as the sequence of a gene. That patent gives the holder a right to prevent others from using the disclosed information entirely, not allowing others to build on it.

Thus, instead of incentivizing innovation gene patents can chill further discovery. Innovation is stifled and the basic patent bargain (exclusivity in exchange for information) is thwarted. As noted by University of Michigan law professor Rebecca Eisenberg, “DNA sequences are not simply molecules, they are also information.” She also notes that “patent claims to information—even useful information—represent a fundamental departure from the traditional patent bargain.”

Patents on genes have a broad preemptive effect because, unlike a drug, a gene cannot be “invented around”—its natural sequence is what is used in diagnosis or treatment and a man-made alternative with differing chemicals for the gene is useless for those purposes. With drugs and pharmaceuticals, however, the disclosure of a new drug in a patent may motivate other

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93 See Rebecca S. Eisenberg, Re-examining the Role of Patents in Appropriating the Value of DNA Sequences, 49 EMORY L.J. 783, 787 (2000).
95 Eisenberg, supra note 93, at 786.
96 Id. at 794.
researchers to find chemical analogs that may work better or in slightly different ways.\textsuperscript{97}

Genetic researchers routinely use patented inventions in their practices, such as automated gene sequencers or machines that amplify DNA.\textsuperscript{98} But patented genes are profoundly different from these inventions. When a researcher uses a patented machine he or she does not have to worry about patent infringement. The authorization and royalty are already built into the cost of the item the researcher is using. But when a researcher undertakes research involving a gene or compares one genetic sequence to another—even if comparison takes place only in the researcher’s mind—the researcher could be unwittingly infringing a gene patent. The researcher cannot readily determine before potentially incurring liability whether the comparison will infringe. Should researchers assume that all genes and biological facts are patented? Should they consult the USPTO database each time their research takes a turn that involves a new gene, biological fact, or other product or law of nature? Such a requirement puts a burden on the researcher to stop, mid-thought, and access a patent database or call a patent lawyer to determine if the use of a sequence or correlation infringes a gene patent, ultimately slowing down research.

B. Genes as Interactive Entities

Human characteristics, genetic predispositions, and diseases are generally the result of multiple genes acting in concert. Most common diseases with a genetic component are polygenic, with multiple genes having an influence. For example, eighty genetic


\textsuperscript{98} Francis S. Collins & Margaret A. Hamburg, \textit{First FDA Authorization of Next-Generation Sequencer}, 369 NEW ENG. J. MED. 2369, 2369 (2013). These include a patent on PCR, the means of amplifying DNA, \textit{see} Process for Amplifying, Detecting, and/or-Cloning Nucleic Acid Sequences, U.S. Patent No. 4,683,195 (filed Dec. 14, 1977), and patents on gene sequencers, \textit{see}, e.g., Detection of Specific Sequences in Nucleic Acids, U.S. Patent No. 5,521,065 (filed June 8, 1994).
loci are implicated in asthma, as many as forty-three genes in diabetes, and twenty-nine in spinocerebellar ataxia. Alzheimer’s disease, autism, bipolar depression, cancers, diabetes, hypertension, hypertriglyceridaemia, multiple sclerosis, spina bifida, and venous-thromboembolism are also polygenic.

Genetic research involving polygenic diseases is extremely vulnerable to the problem of patent thickets when more than one party controls patent rights to different genes that together contribute to a particular disease. In order to develop and provide a...


100 See U.S. Patents Nos. 7,635,559; 7,629,126; 7,585,630; 7,553,631; 7,521,193; 7,470,542; 7,374,930; 7,390,940; 7,255,988; 7,227,006; 7,173,119; 6,930,181; 6,902,888; 6,849,728; 6,783,942; 6,746,853; 6,620,583; 6,562,574; 6,544,745; 6,534,272; 6,365,727; 6,326,141; 6,319,671; 6,291,172; 6,248,527; 6,232,078; 6,187,533; 6,140,067; 6,074,822; 6,060,593; 5,840,493; 5,800,998; 5,766,851; 5,719,022; 5,589,374; 5,541,060.


102 Kaoru Okuzumi & Shoji Tsuji, Alzheimer’s Disease as a Polygenic Disease, 18 NEUROPATHOLOGY 111, 111 (1998); Yun Ju Sung et al., Genetic Investigation of Quantitative Traits Related to Autism: Use of Multivariate Polygenic Models with Ascertainment Adjustment, 76 AM. J. HUM. GENETICS 68 (2005); Malerba & Pignatti, supra note 99, at 95; Berthels et al., supra note 101, at 1114; M.L. Hamshere et al., Polygenic Dissection of the Bipolar Phenotype, 198 BRIT. J. PSYCHOL. 284, 286 (2011); Paul D.P. Pharoah et al., Polygenic Susceptibility to Breast Cancer andImplications for Prevention, 31 NATURE GENETICS 33, 35 (2002); David M. Lonard et al., The SRC Family of Coactivators: An Entree to Understanding a Subset of Polygenic Diseases?, 24 MOL. ENDOCRINOL. 279, 280 (2010); Alan Y. Deng, Genetic Basis of Polygenic Hypertension, 16 HUM. MOLECULAR GENETICS R195, R199 (2007); Robert A. Hegele et al., A Polygenic Basis for Four Classical Fredrickson Hyperlipoproteinemia Phenotypes that Are Characterized by Hypertriglyceridemia, 18 HUMAN MOLECULAR GENETICS 4189, 4190 (2009); Joanne H. Wang et al., Modeling the Cumulative Genetic Risk For Multiple Sclerosis From Genome-Wide Association Data, 3 GENOME MEDICINE 3, 4 (2011); Alexander G. Bassuk et al., Copy Number Variation Analysis Implicates the Cell Polarity Gene Glypican 5 as a Human Spina Bifida Candidate Gene, 22 HUM. MOLECULAR GENETICS 1097, 1103 (2012); Grahm F. Pineo, New Developments in the Prevention and Treatment of Venous Thromboembolism, 21 PHARMACOTHERAPY 51S, 54S (2001).
comprehensive and high-quality genetic test for predispositions to a polygenic disease, a scientist must license the patent rights for each contributing gene test.\textsuperscript{103} In some cases, this might involve one hundred different genes or more and, thus, could potentially involve one hundred different patent rights holders.

The genetics of hearing loss demonstrates this problem. At least sixty-five different genes have already been implicated in hearing loss, and two of these genes are patented and exclusively licensed to Athena Diagnostics.\textsuperscript{104} If Athena asserts its patent rights, then it is positioned to block the development of diagnostic tests or demand a high royalty from any party wishing to provide the most comprehensive and high-quality test to date. Alternatively, each gene contributing to the disease could be tested individually, meaning sixty-five different genetic tests might need to be done independently, which is inefficient and loses the economic benefit of consolidation of services.

This patent thicket can be especially problematic with respect to clinical care and research requiring biopsies. For the benefit of the patient, the surgeon takes a small amount of tissue in the biopsy.\textsuperscript{105} But when genetic diagnosis and research is fragmented because the tissue must be sent to dozens of different companies that have patents on genes related to the disease at issue or related to genetic sequences that indicate whether a certain form of chemotherapy will work or not, there simply is not enough tissue for all the necessary companies. This problem is a patent artifact, not a technological one. If a single lab were allowed to do all the

\textsuperscript{103} Heller & Eisenberg, supra note 92, at 698.


genetic sequencing required, only a small amount of tissue would be needed.

Our emerging understanding of genes and their interaction with the cellular environment indicates that the “old mechanistic view of genes ‘causing’ complex diseases such as cancer is simply wrong. Many human diseases are caused by complex dynamics between non-hereditary proteins, DNA, RNA, the cellular environment, and the external environment.”\(^{106}\) By allowing the patenting of one biological element in that process, namely the gene, research into this complex dynamic process is impeded. Billions of dollars of government research have shown that the gene is not “the C.E.O.” of heredity and that genes interact with other cellular elements.\(^ {107}\) Yet, because a gene patent holder can assert rights over all uses of the gene that patent holder can deny other researchers the rights to study how genes interact with other biological elements.\(^ {108}\)

C. Gene Patents and Exclusivity

The potential negative impact of gene patents on innovation will be further exacerbated if the patent is exclusively licensed. The holder of a patent can decide to license the invention to multiple entities or exclusively to just one entity. Alternatively, the patent holder can decide not to let any person or entity make, use or otherwise practice the invention. The problem of exclusivity seems pronounced with gene patents because of a preference of gene patent holders for exclusivity and because of the need to obtain permission to undertake research from multiple patent holders. Exclusive licensing occurred with genetic tests for breast and ovarian cancer, Alzheimer’s disease, spinocerebellar ataxia,


\(^{107}\) Kevan M.A. Gartland et al., *Progress Towards the “Golden Age” of Biotechnology*, 24S *CURRENT OPINION IN BIOTECHNOLOGY* S6, S6 (2013); Ray Greek et al., *Animal Models in an Age of Personalized Medicine*, 9 *PERSONALIZED MED.*, 47, 51 (2012).

hearing loss, hemachromatosis, and long QT syndrome. In addition, 52% of gene patent holders reported that they had only granted exclusive licenses. Another survey found that for-profit firms favor exclusive licenses of DNA sequence inventions.

Exclusive licensing of patents further hampers researchers’ ability to innovate because only one entity will then be allowed to conduct research. The ability to undertake research is also circumscribed when the researcher needs access to tools or information covered by multiple patents. Not only might the costs of research be increased by multiple patents, but if a single patent within the group is exclusively licensed to another entity, the research will be precluded altogether. In *Science*, Professors Michael A. Heller and Rebecca Eisenberg demonstrated how patents can deter innovation in biomedical research: “A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development.”

D. The Difficulties of Challenging Gene Patents

Gene patent cases are expensive and difficult to bring. The potential beneficiaries of the research do not have standing to sue. Nor can researchers bring a cause of action when their research is impeded, unless they have been threatened with a cease and desist letter or a patent infringement suit. Even if it were possible to sue when innovation was impeded, the median cost for suits reported for 2006 with under $1 million in damages at risk was $600,000; for those between $1 million and $25 million in


112 Heller & Eisenberg, *supra* note 92, at 698.

113 Ass’n for Molecular Pathology v. USPTO, 653 F.3d 1329, 1344 (Fed. Cir. 2011).

114 *Id.* at 1344.
damages at risk, the median cost was $2.5 million; and for suits with more than $25 million in damages at risk, the median cost was $5 million. The median cost only through the end of discovery was still $1.25 million for suits between $1 million and $25 million.

V. ANALYSES OF THE EFFECTS OF GENE PATENTS ON INNOVATION

There are several reasons to suspect that patents on genes will hinder innovation. But what actually happens in the lab and in the physician’s office? The question of whether gene sequence patents spur or impede innovation can be broken into two parts. First, do gene patents spur initial innovation—the location and identification of the gene sequence? Second, do gene sequence patents spur or impede subsequent innovation—the study of the prevalence of the related disorder, the development of diagnostic testing, the improvement of diagnostic testing, and the development of treatments? Some studies focus on one of these questions, while others look at systematic questions of whether gene patents discourage researchers from undertaking certain types of genetic research or discourage patients from participating in genetic research, either of which could have a devastating impact on innovation.

One should not underestimate the difficulty of studying whether gene patents are necessary for innovation. It is hard to analyze what innovation would have occurred, for example, if there were no gene patents. It is also hard to study whether a chill created by gene patents has led researchers to go into a different field of research entirely. Some studies exist, however, that attempt to assess whether researchers behave differently when they plan to patent genes than they would have if no such patents were available. Others address the extent to which researchers stop doing certain types of research because of gene patents. Still
other studies assess the extent to which the existence of gene patents may make people less willing to participate in research, thwarting the innovations of gene discovery and the development of diagnostics and treatments for genetic diseases.\textsuperscript{119}

A. Are Gene Sequence Patents Necessary for the Initial Innovation?

The scientific literature suggests that patents are not necessary to ensure the discovery of genetic sequences. Scientists were searching for and finding genes long before patents were available. They try to discover genes for many reasons—to help mankind, win Nobel Prizes, attain academic achievement, and create professional status.\textsuperscript{120} There is no evidence that the grant of gene patents, as opposed to the patent on the gene sequencing machine, facilitated faster gene discovery.\textsuperscript{121} A 2004 National Academy of Sciences report noted that scientists received the benefits of increased prestige and reputation as rewards for their discoveries.\textsuperscript{122}

Most geneticists are willing to undertake research to discover genes without patenting them. In fact, in a study of 1,229 American Society of Human Genetics members, 61% of those in industry, 78% of those in government, and 77% of academic scientists stated that they disapproved of patenting DNA.\textsuperscript{123} Forty-seven percent of respondents believed that patenting inhibits biomedical research while only 27% of respondents believed that gene patenting is necessary to encourage innovation.\textsuperscript{124} Thus, most

\textsuperscript{119} See infra Part V.C.3.

\textsuperscript{120} See John M. Golden, Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System, 50 EMORY L.J. 101, 152–61 (2001) (detailing empirical evidence that “public sector values,” such as intellectual curiosity and professional reputation, comprise the “dominant source of motivation for scientific and technological innovation”).

\textsuperscript{121} See, e.g., SEC’Y ADVISORY COMM., supra note 109, at 20–23 (describing the Committee’s findings that “scientists are motivated to conduct genetic research by reasons other than patents, suggesting that discoveries will be sought regardless of the availability of intellectual property rights”).


\textsuperscript{124} Id.
of the people whose professional lives are devoted to finding genes would do so without patenting them.

In fact, during the progress of the Human Genome Project (“HGP”) there was concern that gene patenting could be a significant hindrance. The HGP’s governing body, the National Human Genome Research Institute, required that all human genomic DNA sequence data resulting from projects under its funding be placed in the public domain. The concern was that patent applications on primary human genomic DNA sequences could have a “chilling effect on the development of future inventions of useful products.”

“[D]iscoveries will be sought regardless of the availability of intellectual property rights,” concluded the Secretary of Health and Human Services’ Advisory Committee on Genetics, Health, and Society. For example, the researchers involved in the race to find the Alzheimer’s gene “were driven by wanting priority of scientific discovery, prestige, scientific credit, and the ability to secure funding for additional research based on scientific achievement.”

Moreover, the patent incentive was not necessary for investment in gene discovery because the scientific work was generally funded by the U.S. Congress as part of the Human Genome Project through taxpayer money, rather than private funding. Over $1.8 billion of taxpayer money was spent by the U.S. government and non-profit institutions on genomics in the year 2000 alone. For example, Myriad used over $5,000,000 of

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127 Id.
128 SEC’Y ADVISORY COMM., supra note 109, at 23.
129 Id. at 21; Katie Skeehan et al., Impact of Patents and Licensing Practices on Access to Genetic Testing for Alzheimer’s Disease, 12 GENETICS IN MED. S71, S77 (2010).
taxpayer money, a grant from the National Institutes of Health, to fund the discovery of the BRCA1 gene sequence.\textsuperscript{131} Myriad also relied on the work of federal researchers from the National Institutes of Environmental Health Sciences (also paid with taxpayer money) and researchers from other institutions.\textsuperscript{132}

In \textit{Myriad}, amici curiae argued in favor of the patenting of genes, asserting that patents are needed to promote genetic innovations.\textsuperscript{133} However, none of these amici provided any actual evidence that gene patents were necessary for the initial discovery of gene sequences related to diseases or for subsequent innovation for new diagnostics or treatments for those diseases.\textsuperscript{134} Even the BRCA1 and BRCA2 sequences at issue in \textit{Myriad} would have been discovered without the patent incentive. The Breast Cancer Linkage Consortium, an international network of breast cancer researchers, was fully engaged in identifying the BRCA1 gene in a

\textsuperscript{131} Bryn Williams-Jones, \textit{History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing}, 10 \textit{Health L.J.} 123, 131 (2002) (“This research was supported in part by funding from the pharmaceutical company Eli Lilly, but also from government agencies such as the NIH which provided Skolnick with more than $5 million specifically to look for BRCA1.”).


\textsuperscript{133} Brief for Biotech. Indus. Org. and Ass’n of Univ. Tech. Managers as Amici Curiae Supporting Reversal at 4, Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 2010-1406) [hereinafter Amici Curiae BIO]; see also Brief for Pharm. Research and Mfrs. of Am. as Amicus Curiae Supporting Defendant-Appellant Myriad Genetics, Inc. at 17, \textit{USPTO}, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 2010-1406) (“Without patent protection, the companies with the necessary expertise to develop those tests would lack a key incentive to undertake the research investment necessary to create and market these products and services.”).

\textsuperscript{134} “In fact, the examples cited by these Amici prove the harm that such patents have caused. For example, [Amici Curiae BIO] argues that the patenting of the hepatitis C genome was a success story. But it actually has been a disaster for public health because the patent holder blocked the deployment of an inexpensive effective test developed by a small biotechnology company and, as a result, many patients have not been tested or received timely treatment. Letter from Martin Munzer to Xavier Becerra, U.S. Congressman (May 25, 2007).” Brief for Am. Med. Ass’n et al. as Amici Curiae in Support of Petitioners at 16–17, Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 U.S. 2107 (2013) (No. 12-398) (citations omitted).
cooperative effort and planned to make the sequence publicly available and not to patent it. The publicly funded Consortium did most of the work to identify the BRCA1 gene, but shortly before it completed its work, Mark Skolnick, a member of the Consortium, founded Myriad Genetics and sought a patent on the BRCA1 gene, in violation of the goals of the Consortium. Skolnick utilized taxpayer money to sequence the BRCA1 gene, yet, once the gene was patented, the public paid over $400 million more in royalties each year because of those patents. If Skolnick had not sought the patent, the gene sequence would have been placed in the public domain.

A similar situation occurred with BRCA2. Myriad collaborated with Dr. Michael Stratton of London’s Institute for Cancer Research and other researchers. Stratton ended the collaboration upon learning of Myriad’s plans to patent the gene. The day after Myriad filed its patent for the BRCA2 gene, the Stratton group published its identification of the BRCA2 gene in Nature. As the district court in Myriad pointed out, “the consensus among the scientific community is that the Stratton group, rather than Myriad, was the first to sequence the BRCA2 gene.” Thus, patents were not necessary for the discovery of the BRCA1 and BRCA2 genes.

In fact, the patent incentive can impede the discovery of novel sequences. When Jonathan Shestack’s son was diagnosed with

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136 Paradise, supra note 135, at 143.
137 Williams-Jones, supra note 131, at 132; Nowak, supra note 132, at 209.
139 Williams-Jones, supra note 131, at 132.
140 Id.
autism in 1992, experts estimated that researchers would need DNA samples from at least 100 families with two or more autistic members in order to pinpoint a gene associated with autism.\textsuperscript{143} Shestack contacted the four groups of university scientists who were searching for autism genes and offered them funding.\textsuperscript{144} He discovered that no group had enough DNA samples to determine which genes are autism-related, but there were more than enough if the groups pooled their samples.\textsuperscript{145} Shestack asked the four groups to share their DNA samples with each other so that they all had a better shot at identifying autism-related genes.\textsuperscript{146} Every researcher with whom he spoke refused to share samples.\textsuperscript{147} Each wanted to be the one to find the autism gene and patent it.\textsuperscript{148} Rather than speed up the discovery of a gene sequence, the possibility of obtaining a patent slowed it down.\textsuperscript{149}

The possibility of patenting genes led colleagues and institutions to pressure scientists to seek such patents. As an article in Science pointed out, “Researchers and their institutions may resent restrictions on access to the patented discoveries of others, yet nobody wants to be the last one left dedicating findings to the public domain.”\textsuperscript{150}

The perceived need for gene patents fails to account for the incentives that already exist for innovation. In many other

\textsuperscript{143} Aaron Zitner, Whose DNA Is It, Anyway?, L.A. TIMES (July 18, 2003).
\textsuperscript{144} Id.
\textsuperscript{145} Id.
\textsuperscript{146} Id.
\textsuperscript{147} Id.
\textsuperscript{148} Id.
\textsuperscript{149} Id. Frustrated, Shestack started the Autism Genetic Resource Exchange to collect DNA samples from autistic patients and their families. Within a year, the Autistic Genetic Resource Exchange had DNA samples from 100 families. Id. Since then, its collection has grown to include samples from more than 2,000 families, which it makes available to autism researchers worldwide. AUTISM GENETIC RES. EXCH., AGRE for Families, http://agre.autismspeaks.org/site/c.lwLZKnN1LtH/b.5002167/k.93B4/AGRE_for_Families.htm (last visited Apr. 17, 2014). Over 400 research groups have used the AGRE database since 2001, publishing over 200 peer-reviewed scientific articles. AUTISM SPEAKS, Sharing our Genes for Research (June 25, 2013), http://www.autismspeaks.org/science/science-news/sharing-our-genes-research.
\textsuperscript{150} Heller & Eisenberg, supra note 92, at 698–99.
economic sectors, such as open-source software, fashion, and cooking, vigorous innovation exists wholly without patent rights.¹⁵¹ In fact, because of the potential for rapid and unrestricted copying, those sectors may develop innovations more quickly than in sectors protected by patent rights. Moreover, incentives to innovate already exist in the biotechnology and medical industries because the innovators are themselves users of the innovations.¹⁵² No one would seriously argue at this time that doctors need to patent surgical and diagnostic methods because without patents there is insufficient investment, invention, or discovery. And unlike in the pharmaceutical industry where massive costs of clinical trials require exclusive rights to protect investments, genetic discoveries and their application to testing, which largely do not entail such costs, may be more readily protected through traditional means such as lead-time advantage and complementary products and services.¹⁵³

B. Are Gene Sequence Patents Necessary for Subsequent Innovation?

Patenting DNA sequences can impede biomedical research by slowing progress at both the individual laboratory level and at a system-wide level, as well as by increasing the financial costs of undertaking research.¹⁵⁴ These impediments occur in at least four ways: (1) discouraging scientific researchers’ undertaking of


¹⁵² See, e.g., Katherine J. Strandberg, Users as Innovators: Implications for Patent Doctrine, 79 U. COLO. L. REV. 467, 483–90 (2008) (discussing conditions under which user innovations will be disseminated and patent rights will be counterproductive).


¹⁵⁴ See Heller & Eisenberg, supra note 92, at 698.
genetic research; (2) discouraging scientific researchers’ public disclosure of data; (3) discouraging scientific researchers’ cooperation with each other; and (4) discouraging volunteer participation in clinical studies.

1. Effects of Gene Patents on Researchers’ Undertaking of Genetic Research

Scientists are frequently inhibited from initiating or continuing genetic research because of the existence of gene patents.155 A scientific researcher who wants to conduct gene-related research might be required to pay a costly license fee for patent rights or else risk liability for patent infringement. In fact, the researcher might be required to obtain multiple licenses, each with its own

costly fee, if more than one patent covers the same gene. Furthermore, patent owners can withhold consent to licensing patent rights altogether for the life of the patent or grant exclusive rights to only one party and then threaten legal action against all other researchers, thereby inhibiting research conducted by universities, research institutions, and private groups.\footnote{156}

Forty percent of scientific researchers reported difficulties with being allowed to use a patented invention.\footnote{157} A substantial number of geneticists report that gene patents detrimentally impact subsequent discoveries: 49% of American Society of Human Genetics members reported being forced to limit their research in some way due to the existence of various gene patents.\footnote{158} Often, geneticists have been foreclosed from undertaking research on a substantial number of genes. Dr. Debra Leonard’s research at the University of Pennsylvania encountered roadblocks due to gene patents. She received numerous cease and desist letters demanding she stop research or pay licensing fees for the use of DNA molecules relating to the genes underlying Alzheimer’s disease, cystic fibrosis, hemochromatosis, Canavan disease, and spinocerebellar ataxia.\footnote{159}

Studies show the negative effects of patents on gene research into breast cancer,\footnote{160} ovarian cancer,\footnote{161} Charcot-Marie-Tooth

\footnote{156} Stifling or Stimulating—The Role of Gene Patents in Research and Genetic Testing Before the House Judiciary Subcommittee on Courts, the Internet, and Intellectual Property, Hearing before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary, 110th Cong. (2007) (statement of Dr. Wendy Chung, director of Clinical Genetics at Columbia University).

\footnote{157} Stephen Hansen et al., The Effects of Patenting in the AAAS Scientific Community 21 (2006).

\footnote{158} Rabino, supra note 123, at 15.

\footnote{159} Blanton, supra note 155, at 10.

disease, Alzheimer’s disease, Duchenne muscular dystrophy disease, MODY, hereditary hemochromatosis, Canavan disease, spinocerebellar ataxia, long QT syndrome, and hearing loss. The assertion of patent rights by gene patent holders have resulted in the reduction of genetic tests performed by laboratories for numerous diseases, such as Alzheimer’s disease, breast cancer, Canavan disease, hemochromatosis, long QT syndrome, ovarian cancer, and spinocerebellar ataxia. In other situations, the patent holder’s offer for a license was determined to be cost-prohibitive, often because the total volume

161 Cook-Deegan et al., supra note 160, at S16.
163 Skeehan et al., supra note 129, at S76 (discussing concerns about impact of gene patents on multiplex testing).
168 Berthels et al., supra note 101, at 1114.
169 Angrist et al., supra note 155, at S118.
170 Chandrasekharan & Fiffer, supra note 160, at S184.
171 Skeehan et al., supra note 129.
172 Cook-Deegan et al., supra note 160, at S28; Walsh et al., supra note 160, at 1379.
173 Colaianni et al., supra note 167, at S12.
174 Chandrasekharan et al., supra note 166, at S157; see Merz et al., supra note 155, at S79.
175 Angrist et al., supra note 155, at S118.
176 Cook-Deegan et al., supra note 160, at S28.
177 Powell et al., supra note 155, at S83; Berthels et al., supra note 101, at 1114.
of genetic tests performed at university laboratories is not large enough to justify the cost.\textsuperscript{178}

The impediments to research caused by patents might be even greater in genetics than in any other area of science because isolated DNA molecules are essential to the study of living systems. There are many types of research involving gene patents, such as basic science research into gene function or the contribution of gene sequences to diseases and more downstream research into implementing new genetic tests to diagnose diseases or improve the accuracy of diagnostic testing.\textsuperscript{179}

Myriad has blocked scientific research of the BRCA1 and BRCA2 genes\textsuperscript{180} at university laboratories, such as at Columbia University,\textsuperscript{181} Emory University,\textsuperscript{182} the University of Chicago,\textsuperscript{183} the University of Pennsylvania,\textsuperscript{184} and Yale University.\textsuperscript{185} In its defense, Myriad asserted that over 8000 papers can be found in the scientific literature on PubMed that make reference to BRCA1 and BRCA2. Myriad argued that the existence of these papers proves its patents do not prevent scientific research.\textsuperscript{186} However, this number is misleading because the search results include thousands of articles that do not involve any potentially infringing conduct: (1) review articles, which do not report new findings; (2) articles reporting research conducted in other countries; (3) studies that do not involve human genes but rather gene homologs from other

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\textsuperscript{178} See Colaianni et al., supra note 167, at S12; Chandrasekharan et al., supra note 166, at S157; Merz et al., supra note 155, at 577.

\textsuperscript{179} See Heller & Eisenberg, supra note 92, at 698.

\textsuperscript{180} Blanton, supra note 155, at 10.


\textsuperscript{182} Declaration of David Ledbetter, supra note 155, at ¶¶ 15–27.

\textsuperscript{183} Id. at ¶ 14.


\textsuperscript{185} Supplemental Declaration of Ellen Matloff, supra note 155, at ¶¶ 6–8.

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species; and (4) studies that do not involve the isolation of DNA.\textsuperscript{187} For example, the first page of results of a PubMed search for BRCA1 or BRCA2 includes numerous articles that do not involve isolating or analyzing either gene. Myriad’s count of articles include those that have nothing to do with patents, such as those with any mention of breast cancer, articles that address women’s sex life after mastectomy and reproductive decision-making by carriers of a mutation.\textsuperscript{188} The mere fact that scientific papers have been published about breast cancer in general does not prove that innovation based on research on the genetic sequence has not been thwarted.

Empirical research demonstrates that patents claiming human nucleotide sequences have a negative impact on follow-up research

\textsuperscript{187} Further restricting the search to articles in English and on Human BRCA1 shortens the total number of results to 2,896. However, this result still includes articles from authors performing research on BRCA1 in other countries, including China and France.

\textsuperscript{188} See Louise Donnelly et al., \textit{Reproductive Decision-Making in Young Female Carriers of a BRCA Mutation}, INT’L J. CANCER (2013) (discussing the effect of personal experience with cancer on reproductive decision-making in young women); Lesley King et al., \textit{Intentions for Bilateral Mastectomy Among Newly Diagnosed Breast Cancer Patients}, J. SURGERY ONCOLOGY (2012) (investigating the factors behind a rise in bilateral mastectomies among women diagnosed with unilateral breast cancer); see, e.g., Ellen Matloff et al., \textit{Unraveling the Next Chapter: Sexual Development, Body Image and Sexual Functioning in Female BRCA Carriers}, 15 CANCER J. 15 (2009) (discussing the unique set of emotional, physical, and sexual issues for female BRCA carriers); Supplemental Declaration of Ellen Matloff, supra note 155, at ¶¶ 6–7. Former Myriad adviser Phillip Reilly argues that “[t]he sheer volume of scientific publications on BRCA1/2 genes and their gene products belies the purported impediment in basic research. On December 10, 2009, I performed a search using the term ‘BRCA1’ in the PubMed database which retrieved almost 7,000 references. A similar PubMed search conducted using the term ‘BRCA2’ retrieved over 4,000 references.” Declaration of Philip R. Reilly, supra note 186, at ¶ 43. Reilly’s statement is ultimately unpersuasive. Although researchers may continue to research patented genes without licenses, thus infringing the patent unknowingly or with indifference to liability, the gene patent owner and any exclusive licensee has the power to enforce their patents. Moreover, Reilly’s search did not compare the number of publications before and after the patent on BRCA1 was granted. Instead, he looked at the total number of publications—which does not support his conclusion.
and the production of public genetic knowledge. One study compared gene patent paper citations prior to the issuance of a patent with citations in the post-patent issuance period as a means to evaluate the impact of gene patents on the flow of scientific knowledge. The study showed there was between a 5% and 17% reduction in the rate of citations after the issuance of a patent. The authors concluded that “[a] strict interpretation of [the] results suggests that follow-on genetic researchers forego about one in ten research projects . . . because of the causal impact of the gene patent grant.” Moreover, the effects were greatest with patents assigned to the private sector, with a 6% to 9% decrease in follow-on research citations. The authors interpret the decline in citations “as a net loss to long-run public knowledge production.”

2. Effects of Gene Patents on Epidemiological Research

Epidemiological research is important in public health to assist in the planning of nation-wide and community-wide initiatives on disease awareness and screening. The incidence of inherited diseases can help guide policy decisions by governments, physicians’ groups, and healthcare insurers about the cost-effectiveness of interventions such as preventive screening and the priorities between different genetic tests, physical examinations, and non-genetic lab tests.

If genes are patented, patent holders can block the collection of epidemiological data with regard to their patented DNA sequences. This would prevent the medical community and public at large from learning the actual incidence of genetic


\[191\] Id.

\[192\] Id.

\[193\] Id.

sequence variations in the population and those sequences’ relationship to particular diseases. This patent power might be used to prevent refinement in the estimates of the prevalence of genetic sequences in the population.

Simultaneously, the patent holder can distribute its own genetic incidence data and, in bad faith, report higher incidences than really exist or at least maintain outdated data for the life of the patent. This patent power might prevent the discovery of new data that could reveal mistakes in the data existing at the time of patenting and disclosed in the patent. There are already examples of patent owners refusing to share results from their own proprietary genetic tests with public medical databases.195 Asserting a patent over genes can freeze epidemiological evidence in time from the date of the patent until the patent expires 20 years later.

When a patent application is filed, the patent examiner has to take what the applicant says as correct, and there is no FDA review when a company offers a genetic test as a service.196 If a patent holder states that one in three people in the population have the gene related to its patent, patent rights allow the holder to prevent others from duplicating the patent holder’s research and evaluating it to see if the patent holder has exaggerated the prevalence of the mutation in order to sell more tests.197

195 See Declaration of Elizabeth Swisher, supra note 155, at ¶ 19 (noting that Myriad Genetics did not share data resulting from BRCA1/2 genetic testing with the public database Breast Cancer Information Core (“BIC”)).

196 See generally LORI ANDREWS, FUTURE PERFECT: CONFRONTING DECISIONS ABOUT GENETICS, 113, 169 (Columbia University Press: New York 2001) (discussing the FDA’s power to regulate genetic testing kits marketed for interstate commerce; however, academic, hospital, government, and commercial organizations create “home brews” that are made of their own genetic research). In a survey from 1995, out of forty-three biotech companies and 215 not-for-profit organizations that marketed their own testing kits, only around fifteen percent contacted the FDA. Id. Additionally, the FDA concedes that even though it does have the authority to regulate “home brew” kits, it is still not pursuing them in any manner. Id.

197 Id. at 125 (stating that when the genetic tests for breast cancer were first offered, one out of the four institutions studied greatly exaggerated the occurrence of the disease).
Even if the patent holder allows research by other scientists, the licensing costs may prevent other researchers from doing the necessary epidemiological studies to determine, for example, what proportion of people with the mutation in the general population will actually manifest the disease. The researchers discovering and patenting genes have a financial incentive to promote the use of those genes for diagnostics as rapidly as possible, and often before sufficient data is available to assess how well the tests predict future disease.

In one survey, 14 out of 27 gene patent holders said they would require a license for researchers to study the prevalence of mutations of the patented gene in the population. Myriad’s gene patents enabled it to specifically block epidemiological research at Columbia University and Yale University. A researcher at Yale could not do research to determine the percentage of patients with breast cancer who carry BRCA1 mutations without infringing Myriad’s BRCA1 patent. In addition, Myriad’s commercial position incentivizes its withholding of clinically useful data regarding BRCA1 and BRCA2 epidemiology. Other companies such as Athena have also blocked epidemiological research involving its patented genes.

In a survey of owners of patents claiming DNA, over 50% said they would insist on patent rights license agreements with any researchers desiring to study the prevalence of sequence mutations of the patented gene in human populations. This could halt epidemiological research, which is necessary to reveal the incidence of disease in the population, and seriously hamper public health efforts.

198 Caulfield et al., supra note 194, at 230.
199 Declaration of Wendy Chung, supra note 181, at ¶¶ 15–22.
200 Supplemental Declaration of Ellen Matloff, supra note 155, at ¶¶ 6–8.
201 Id.
203 See Cook-Deegan et al., supra note 160, at S28; Tom Walsh et al., supra note 160, at 1379; Powell et al., supra note 155, at S83; Berthels et al., supra note 101, at 1114.
204 Schissel et al., supra note 110.
By not even allowing research to verify that what the patent holder claims is true about the properties of the gene patented, gene patents interfere with the scientific method itself by preventing the replication of the gene patent holder’s hypothesis.\textsuperscript{205} Gene patents can prevent study replication to confirm study data, thereby blocking a core feature of the scientific community’s error checking mechanism.

3. \textit{Effects of Gene Patents on Research on Diagnostics}

Studies have shown that gene patents are not necessary to encourage the development of diagnostic testing after the gene sequence is identified. Instead, gene patents have erected barriers to researchers who use genetics to develop innovative diagnostic tests. A comprehensive analysis by the Secretary of Health and Human Services’ Advisory Committee on Genetics, Health, and Society found that “patents were not needed to develop genetic tests for hearing loss, SCA [spinocerebellar ataxia], breast cancer, LQTS [long QT syndrome], Canavan disease, and HH [hereditary hemochromatosis]. Indeed, all of these tests were on the market before the test offered by the relevant patent-rights holder.”\textsuperscript{206}

The Secretary’s Advisory Committee found that patents “do not serve as powerful incentives for either genetics research in the diagnostic arena or the development of genetic tests” and that researchers “likely would continue” to pursue gene-disease association research without potential patent protection.\textsuperscript{207} In the case of the breast cancer gene, various researchers were willing to identify gene sequences and correlations without patenting them, and there was no shortage of researchers who were trying to sequence the breast cancer genes without the desire to patent those sequences.\textsuperscript{208}

\textsuperscript{206} SEC’Y ADVISORY COMM., \textit{supra} note 109, at 31.
\textsuperscript{208} Id.
Not only were gene patents not necessary for the development of genetic tests, according to studies, but they actually impeded the development, deployment, and improvement of genetic tests. A study that surveyed genetics lab directors revealed that at least 25% of labs had abandoned one or more genetic tests that they themselves had developed, due to notification from the patent holder or licensee.\textsuperscript{209} In addition, 53% of genetics labs had stopped developing new clinical genetic tests due to concerns about gene patents and licensing patent rights.\textsuperscript{210} These included diagnostic genetic tests for Apolipoprotein E, BRCA1 and BRCA2, Duchenne/Becker muscular dystrophy, myotonic dystrophy, Canavan disease, spinocerebellar ataxia, adenomatous polyposis of the colon, Charcot-Marie-Tooth disease, fragile X syndrome, Huntington disease, and Factor V Leiden.\textsuperscript{211} This observation suggests that gene patents are restricting the development of new and improved diagnostic tools.\textsuperscript{212} These inhibitory effects occur in direct response to gene patenting. For example, 30% of clinical labs report not developing or abandoning testing for mutations in a gene causing hereditary hemochromatosis in response to the issuance of a patent to DNA sequences related to that gene.\textsuperscript{213}

Gene patents also impede the improvement of genetic tests. When a single entity controls all testing of a gene sequence, it might not provide the highest quality test or it may decide, for commercial reasons, not to offer testing for all the known mutations in the gene sequence. Yet the gene patent impedes others from undertaking research to develop a better test. For example, there have been problems with quality and interpretation of results in long QT syndrome testing where research in diagnostics might have been useful.\textsuperscript{214} When more information about genetic sequences linked to long QT syndrome was

\textsuperscript{210} Id.
\textsuperscript{211} Id.
\textsuperscript{212} See Angrist, supra note 155 ("[F]or the patents of concern here? [T]he costs to innovation, competition, and medical care are truly serious.").
\textsuperscript{213} Merz et al., supra note 155, at 577.
\textsuperscript{214} Angrist et al., supra note 155, at S118 (2010).
discovered, the lab with the exclusive license for testing for long QT syndrome did not offer the tests for these new markers.\footnote{Id.}

According to a study published in 2006, the test Myriad employed to detect breast cancer risk missed mutations that caused the disease.\footnote{Tom Walsh et al., supra note 160, at 1379.} In the study, researchers sampled DNA from 300 members of high-risk families in which four or more members had been diagnosed with either breast or ovarian cancer.\footnote{Id. at 1379.} All 300 patients had received negative test results from Myriad.\footnote{Id. at 1380.} The research team used six methods to search DNA for breast cancer gene mutations.\footnote{Id. at 1380–81.} The researchers found that 12% of the patients studied carried rearrangements of BRCA1 or BRCA2 that were not included in Myriad’s array.\footnote{Id. at 1386.}

In France, Dr. Stoppa-Lyonnet and her colleagues found a significant mutation in an American family’s BRCA1 gene that was correlated with breast and ovarian cancer but missed by the Myriad test.\footnote{See Sophie Gad et al., Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied By Direct Sequencing, 38 J. MED. GENETICS 388 (2001).} The family was missing one-third of the gene, but the Myriad test did not look for deletions.\footnote{Id. at 390.} Yet, by undertaking that test, the French doctors were risking a patent infringement suit based on Myriad’s European patent.\footnote{Id.; see also Steve Benowitz, French Challenge to BRCA1 Patent Underlies European Discontent, 94 J. NAT’L CANCER INST. 80, 80–81 (2002).}

When numerous laboratories can study DNA sequences (rather than just one lab, as in the case of Myriad), previously unknown mutations will be discovered. Consequently, in countries where the Alzheimer’s and hemochromatosis genes were not patented,
researchers found previously unknown mutations and were able to offer patients better tests than are available in the United States.\textsuperscript{224}

Even when patent owners are willing to license patent rights non-exclusively to multiple laboratories, the cost, complexity, and time delays have served as major impediments to researchers. A study that surveyed American scientists of various disciplines reported how patents directly affected their research decisions: 58\% had delayed research, 50\% had changed research, and 28\% had abandoned research.\textsuperscript{225} The study reported that 58\% of scientists believed that complex licensing negotiations for patent rights was the main factor preventing their participation in certain areas of research.\textsuperscript{226} For example, GeneDX is a company focused on developing tests for rare genetic disorders, but the president of GeneDX has stated that expenses resulting from gene patents, like negotiating licenses, paying upfront, and ongoing royalty costs, have caused GeneDX to lose interest in developing a test for rare disorders covered by gene patents.\textsuperscript{227} In another example, a global public health crisis emerged with the quick spread of a pathogenic coronavirus that caused severe acute respiratory syndrome ("SARS"). SARS vaccine research was likely inhibited and delayed because of concerns about the patent rights regarding the DNA sequences in the SARS-causing virus.\textsuperscript{228}

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\item[$\textsuperscript{225}$] HANSEN ET AL., supra note 157, at 7.
\item[$\textsuperscript{226}$] Id.
\item[$\textsuperscript{227}$] SEC’Y ADVISORY COMM., supra note 109, at 29–30.
\item[$\textsuperscript{228}$] James H.M. Simon et al., Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role Of Patent Pooling, 83 BULL. OF THE WORLD HEALTH ORG. 707, 708 (2005). “These firms face the unenviable task of deciding whether to invest potentially many years’ [sic] of effort and hundreds of millions of dollars into developing a vaccine without knowing whether there will be a market for it,” researchers wrote in the World Health Organization Bulletin. “The uncertainty over patent rights makes this decision even more difficult, because it is neither possible to determine the future cost of licensing the patent rights, nor whether all necessary patents will be available for licensing . . . .” Id.
\end{enumerate}
Gene patent holders might have little incentive to undertake research to create their own gene-based products. Instead, by not initially asserting their patent rights, they may allow others to develop genetic tests, vaccines, or medical therapies. When a commercial application is finally developed, the patent owner may step in and sue the true innovator to collect royalties for past infringement, block the improved technology from reaching the public for the life of the patent, or just take the other party’s innovative technology away from them and sell it for their own profit. These potential scenarios can ultimately deter researchers who are aware of patents from trying to develop better tests and treatments.

The potential for gene patent holders to assert claims to other scientists’ later work discourages innovation. According to SARS researchers, “The net result is a scenario in which patent owners, putative licensees and consumers may lose out by incurring increased costs, risks and potential delays to product development, which in turn will have an impact on public health.” The potential for gene patent holders to assert claims to other scientists’ later work discourages innovation. According to SARS researchers, “The net result is a scenario in which patent owners, putative licensees and consumers may lose out by incurring increased costs, risks and potential delays to product development, which in turn will have an impact on public health.” Yet, time is of the essence in mitigating public health crises, such as reducing the spread of infectious diseases by developing and deploying effective vaccines. Gene patents also hamper pharmacogenomics research, the development of genetic tests to determine if a particular drug will be effective for a particular patient. Such tests look for a particular genetic variation (such as a T rather than an A at a certain point in the genome). But if the patent holder is also the maker of the drug, the patent holder might prohibit anyone from using that test. For example, a pharmaceutical company has filed for a patent on a genetic test to determine the effectiveness of its asthma drug. But the company says it will not develop the test—or let anyone else develop it. A test would help doctors determine that certain people would not benefit from the inhaler, thus diminishing the market for the inhaler.

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229 Id.
231 Id.
In *Myriad*, the company relied on a 2002 survey of twenty-five German pharmaceutical companies, biotech startups, and clinical institutions to argue that gene patents have not slowed research.\(^{232}\) The authors of the survey concluded that there was no reluctance of those interviewed to enter research fields where “gene related patents” had been granted and that patents on research tools, including isolated DNA molecules, had no effect on the cost or pace of research in Germany.\(^ {233}\) But the findings of the German study are not applicable to research and gene patent practices in the United States. In contrast to the law in the United States, German patent law contains a general research exemption which states that the “effect of a patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.”\(^ {234}\) The United States, however, has only an extremely limited research exemption.\(^ {235}\) The German Patent Act allows for the application and grant of a compulsory license for reasons of public interest.\(^ {236}\) U.S. patent law does not have such a compulsory licensing provision.

In summary, patents on genes have slowed the development and improvement of genetic tests, have prevented the integration of new knowledge into tests currently being offered, and have deterred the development of tests for some diseases altogether.

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\(^ {233}\) Joseph Straus et al., *supra* note 232.


\(^ {235}\) See Paradise & Janson, *supra* note 42, at 150. (35 U.S.C. § 271 (e)(1) exempts “uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”).

\(^ {236}\) PatG § 11.24 (1998). Section 11.24 of the German Patent Act allows the grant of a compulsory license, if such a license would be in public interest.
C. What Are The Effects of Gene Patents on Researchers’ and Research Subjects’ Willingness to Participate in Research?

Gene patents can hinder innovation in a less direct manner as well. They can discourage researchers and research subjects from participating in research where genes are likely to be patented.

1. Effects of Gene Patents on Researchers’ Withholding or Delaying Public Disclosure of Data

Traditionally, scientists conducting publicly-funded research tended to favor disseminating discoveries and data to each other and to the public at large.237 Recently, however, there appears to be a trend toward less disclosure of information from university researchers, especially in biomedical research.238 In particular, there is evidence that gene patents might be causing delays in publishing or the withholding of key discoveries and data from the public, who might have funded the research in the first place.239

Before the 1980s, university researchers using federal funds were prohibited from patenting their work. But with the passage of the Bayh-Dole Act, the universities and researchers could seek

239 Prevalences and Predictors, supra note 238, at 142; National Survey of Faculty, supra note 238, at 1224; Campbell et al., supra note 155, at 473–80; Huang & Murray, supra note 190, at 1214; Vogeli et al., supra note 238, at 128–36; Murray & Stern, supra note 238, at 683; WALSH ET AL., supra note 238, at 10.
The commercial possibilities provided by patenting DNA are causing (1) less sharing of information between scientists and (2) less cooperation among scientific groups. The reduction in sharing information has a direct impact on collaborative efforts among researchers, impeding innovation. According to a study of academic researchers in the life sciences, one in five professors had delayed publication of research results for at least half a year in order to protect financial interests such as patent rights. The study found that scientists who directly engaged in the commercialization of their research were three times more likely to delay publication than those doing basic work.

The trend of secrecy and delay in publishing data while seeking a patent has a particularly negative impact on genetic research. Among life science researchers, geneticists were the most likely to report withholding data. A study that surveyed mostly geneticists reported that 24% felt there were frequent delays in publication caused by the withholding of data.

A survey of life scientists at the 100 most research-intensive universities in the United States reported that 44% of geneticists and 32% of other life scientists had withheld data, either in verbal exchanges or as part of the publishing process. While the most common reason for withholding information was to “protect their lead,” about 6% of scientists reported withholding information to allow time for patents. For example, the discovery of a gene causing hemochromatosis was submitted for publication over a

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241 Surveys of academic researchers suggest there is a trend toward less and less sharing of information. See infra Part V.C.1.
242 National Survey of Faculty, supra note 235, at 1226.
243 Id. at 1227.
244 Id.
245 Campbell et al., supra note 155, at 478.
246 Prevalences and Predictors, supra note 238, at 140–42 (2006). The incidence of data-withholding might be higher than reported in the study because of selection biases resulting from nonresponses and underreporting of negative behaviors.
247 Id.
year after the gene patent was filed, most likely for the purpose of assuring patent rights were secured first.\textsuperscript{248}

There is evidence suggesting that the increase in secrecy in the university laboratories is also damaging the training of new scientists. A survey of doctoral students and postdoctoral fellows in the life sciences revealed profound effects of data withholding on the next generation of scientists. Of the trainees surveyed, 49\% said withholding of information had a negative effect on progress in their laboratory and 33\% felt it interfered with their education.\textsuperscript{249} Approximately 25\% of trainees reported that they had asked and been denied access to information, data, materials, or programming associated with published or unpublished research during their training.\textsuperscript{250} Nearly 33\% of postdoctoral fellows reported exposure to withholding of both published and unpublished information, data or materials, while only about 20\% of doctoral students reported similar withholding experiences.\textsuperscript{251} In another study, 56\% of geneticists reported that they felt data withholding was harming the education of students and postdoctoral fellows.\textsuperscript{252}

There is additional evidence linking the patenting of academic research to a diminution in sharing knowledge. An analysis of patent-paper pairs showed a reduction in scientific literature citations once a corresponding patent is granted.\textsuperscript{253} Another study of patenting activity and publication activity among academics reported a modest anti-commons effect in the field of biotechnology.\textsuperscript{254} An anti-commons problem occurs when a large number of patent holders exist in a single field, making it difficult

\textsuperscript{248} Merz et al., supra note 155, at 578.
\textsuperscript{249} Vogeli et al., supra note 238, at 131–32.
\textsuperscript{250} Id. at 131.
\textsuperscript{251} Id.
\textsuperscript{252} Campbell et al., supra note 155, at 478.
\textsuperscript{254} Huang & Murray, supra note 190, at 1214 (2009).
to negotiate and obtain all the necessary rights for follow-on research. 255

As noted by Timothy Caulfield, a law professor at the University of Alberta, there is “substantial empirical evidence that university researchers are becoming more secretive and less willing to share research results or materials.” 256 One study that surveyed biomedical researchers reported that 19% of recent requests were not fulfilled, that failures to supply materials are increasing, and that one out of six respondents had a project delayed owing to a lack of timely access to research materials. 257 Another study shows that secrecy is rampant in universities and the withholding of information is harmful. 258

Among life scientists, geneticists appear to be withholding data, information, and materials the most. Nearly half of all geneticists who requested information, data, or materials related to published research from another academic were denied access. 259 The consequences of this withholding of data, information, and material reported by geneticists included: detracted somewhat or greatly from the level of communication in science (77%), slowed rate of research progress (73%), harmed the quality of peer relationship (63%), termination of collaborations (28%), abandoned promising line of research (21%), delayed reciprocal requests, (18%) and refusal to respond to reciprocal requests (13%). 260 Thirty-five percent of the geneticists believed sharing of research materials had decreased over the 1990s. 261

255 Heller & Eisenberg, supra note 92, at 698.
258 Vogeli et al., supra note 238, at 133.
259 Campbell et al., supra note 155, at 478.
260 Id.
261 Id.
While this increasing secrecy could be due to many reasons, evidence shows a correlation between proprietary interests and secrecy. One study showed that scientists who directly engaged in the commercialization of their research were twice as likely to refuse to share information as those doing basic work.\textsuperscript{262}

Most important to the accuracy and credibility of scientific research, the refusal to share prevents replication and verification of experimental data. A study that surveyed geneticists reported that 28\% were unable to duplicate published research because other academic scientists refused to share data, information, or materials.\textsuperscript{263}

2. \textit{Effects of Academic Researchers’ Lack of Awareness of the Potential Impact of Patents}

If researchers correctly realized that these patents could be applied against them, the negative effect of gene patents on research would be even greater. There is considerable evidence that researchers underestimate the reach of gene patents and mistakenly think that the United States has a general research exemption.\textsuperscript{264} Only 5\% of academic researchers bother to regularly check for patents and others routinely infringe patents.\textsuperscript{265} Many academic researchers ignore patents.\textsuperscript{266} It has been suggested that there is a “general lack of awareness or concern among investigators about existing intellectual property.”\textsuperscript{267} However, this cultural view is not grounded in the law\textsuperscript{268} and such a false sense of

\begin{footnotesize}
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\item Prevalences and Predictors, supra note 238, at 140–42.
\item Campbell et al., supra note 155, at 478.
\item Gaisser et al., supra note 104, at 408.
\item Walsh et al., supra note 257.
\item Gaisser et al., supra note 104, at 407–08.
\item In \textit{Madey v. Duke University}, the Federal Circuit restricted the common law research exemption to activities that are “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002), \textit{cert. denied}, 539 U.S. 958 (2003). This exemption does not cover research that is conducted “in furtherance of the alleged infringer’s legitimate business,” including the business of education at a university. \textit{Id}. at 1362–63. Thus, a researcher will be liable for infringement
\end{enumerate}
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confidence could be leading many researchers to ignore patents simply because they currently fear no repercussions. If a highly-publicized suit were brought against a researcher, then researchers might change their behavior dramatically. But when some gene patent holders threaten researchers and force them to stop their research, they often obtain a confidentiality agreement from the researchers and their universities as a condition for not pursuing damage actions for uses the researcher already made of the gene sequence. Thus, other scientific researchers may not adequately be assessing the implications of patents for their own research.

There is a persistent belief among many academic researchers that they are shielded from liability for patent infringement, perhaps because their work is largely funded by the government and generally produces no immediate commercial revenue.\(^{269}\) This might explain the contradictory results of some studies. Some studies report that 49% of geneticists have limited research due to gene patents,\(^{270}\) but others suggest that only 1% felt that a patent had caused them to delay a project, and none reported abandoning a project because of a patent.\(^{271}\) The majority of researchers surveyed in the latter study were doing basic science research, primarily in the fields of genomics or proteomics, whereas about 10% of those surveyed worked on drug discovery, diagnostic test development, or clinical testing.\(^{272}\) Only 5% (18 of 379) of the academic researchers in the study regularly checked for patents related to their research and only 5% were made aware of

\(^{269}\) See, e.g., Misha Angrist & Robert M. Cook-Deegan, *Who Owns the Genome?*, 11 NEW ATLANTIS 87, 94 (2006) (stating that purportedly “contradictory” statements in the law have led “academic genome researchers [to] feel more protected from litigation” than they actually are); Caulfield et al., *supra* note 256, at 1092 (noting that researchers continue to “operate in a patent-dense environment, without the benefit of a clear research exemption”).

\(^{270}\) Rabino, *supra* note 123, at 15.

\(^{271}\) Caulfield et al., *supra* note 256, at 1092 (citing Walsh et al., *supra* note 257).

\(^{272}\) WALSH ET AL., *supra* note 238, at 10.
intellectual property related to their research through a notification.\textsuperscript{273} The remaining respondents reported doing research to develop research tools or were engaged in other research activities.\textsuperscript{274}

Just because patent litigation against basic science researchers has been infrequent in the past does not mean it will remain so in the future because patent holders have the legal right to sue anyone for infringing conduct. Already, “[s]uch routine forbearance [by patent holders] does not apply to the genetics and diagnostics industries, and thus for the patents of concern here the costs to innovation, competition, and medical care are truly serious.”\textsuperscript{275}

In 2002, the Federal Circuit Court of Appeals in \textit{Madey v. Duke University}\textsuperscript{276} clarified the common law research exemption. The court held that the research exemption was limited to activities that are “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”\textsuperscript{277} It might be reasonable to expect that academic researchers’ awareness of patents would have increased after the \textit{Madey} case, but a study found only a small increase to 5% of academic respondents looking for patents related to their field since that decision.\textsuperscript{278} However, their employers—the academic research institutions—were paying increased attention to patent concerns.\textsuperscript{279} Twenty-two percent of academic researchers were notified by their institutions to be careful with respect to patents on research inputs.\textsuperscript{280} This was an increase from 15% of academic researchers that had received notifications from their institutions five years previously.\textsuperscript{281} The notifications by the institutions seemed to have little effect upon the academic researchers, however, with only 5.9% of those notified by their

\textsuperscript{273} Walsh et al., \textit{supra} note 257.
\textsuperscript{274} WA\textsc{L}SH ET AL., \textit{supra} note 238, at 10.
\textsuperscript{275} Angrist & Cook-Deegan, \textit{supra} note 269.
\textsuperscript{277} \textit{Id.} at 1362.
\textsuperscript{278} WA\textsc{L}SH ET AL., \textit{supra} note 238, at 8. Prior to the decision, 3% of researchers looked for such patents. \textit{Id.}
\textsuperscript{279} \textit{Id.}
\textsuperscript{280} \textit{Id.} at 16.
\textsuperscript{281} \textit{Id.}
institutions “regularly checking patents” compared to 4.5% of those not notified by their institution regularly checking patents.\footnote{282} It seems even direct warnings do little to increase researchers’ sensitivity to potential patent infringement liability.

To the extent that some university professors are undertaking research on genes without the consent of the patent holder, they may unwittingly be exposing themselves to costly patent infringement liability. If the unapproved researcher does discover, say, a gene therapy, the holder of the gene patent can prevent the researcher from marketing it or can demand a huge royalty.\footnote{283} If the subsequent researchers actually understood this possibility, there would be less incentive for them to develop innovative cures—the sort of invention that is legitimately protected by patent law.

3. Effects of Gene Patents on People’s Willingness to Participate in Genetic Research and Donate Biological Samples For Research

Gene patents deter volunteers from participating in medical research. Potential research subjects are less likely to participate in research if they are aware that their participation in research might lead to patents that ultimately increase the cost of their health care and negatively affect their quality of healthcare. In a study of potential research subjects, 32% of those surveyed said they would be offended if research conducted with their own tissue was used for patenting of products.\footnote{284}

\footnote{282}Id.

\footnote{283}As attorney Barbara A. Caulfield of Affymetrix, Inc., a gene chip company, has stated, DNA-based science has not yet spawned widely-marketable products. Once that occurs, patent owners will not hesitate to block infringing research. When Caulfield spoke at a July 2007 seminar of the Genetics & Public Policy Center, she noted that patent owners become litigious “very, very quickly when there’s money involved.” GENETICS & PUB. POL’Y CENTER, WHO OWNS YOUR GENES? INTELLECTUAL PROPERTY AND THE HUMAN GENOME 17 (2007), available at http://www.dnapolicy.org/resources/PatentingGenePOPStranscript.pdf; see also Gary Stix, Owning the Stuff of Life, 294 SCI. AM. 76, 82 (2006).

Human genes are different than other patentable inventions. They are parts of people, raising individual rights issues about granting companies monopolies over their use. A person’s genetic information can be a key source of self-understanding and a powerful tool for diagnosing or treating diseases of that person or his or her children. However, issuing a patent to the researcher who first identifies a version of the gene can impede medical diagnostics and the search for further mutations and treatments and can prevent a person from learning genetic information about himself or herself.

Refusal by a gene patent holder to allow another laboratory to perform a test can have dire consequences. Long QT syndrome is a disorder of the heart’s electrical system that is characterized by irregular heart rhythms and a risk of sudden death. The University of Utah obtained multiple patents on the genes associated with the disease and granted an exclusive license to DNA Sciences. GeneDx had also developed testing for the disorder. GeneDx was sued for infringement and prohibited from offering its tests even though the exclusive license holder was not ready to offer a test. Meanwhile, the exclusive license changed hands twice as DNA Sciences’ assets were acquired by the company Genaissance, which was in turn acquired by the company Clinical Data, Inc. For two years, diagnostic testing was not offered for long QT syndrome despite GeneDx’s capability and

286 Id.
287 Id.
288 Stifling or Stimulating, supra note 285 (statement of Dr. Marc Grodman, CEO of Bio-Reference Laboratories, Inc.).
willingness to offer the test. During this period at least one patient, age ten, died from her undiagnosed long QT syndrome, which could have been prevented had testing been available.\textsuperscript{290}

Numerous studies show that the public willingness to donate tissue samples depends on how or by whom their sample will be used.\textsuperscript{291} The public generally has a positive attitude toward participating in research, but this attitude is based on trust.\textsuperscript{292} Many studies show how trust is an important factor affecting a person’s willingness to participate in research.\textsuperscript{293} Potential research participants consider the commercial interest affecting a person’s trust in research and uses of tissue an important issue when deciding whether to participate in research.\textsuperscript{294} These studies also show that willingness to provide specimens for genetic research hinges on trust between the donor and the researcher.\textsuperscript{295}

\textsuperscript{290} Stifling or Stimulating, supra note 285.
\textsuperscript{291} See Briana Mezuk et al., Participant Characteristics That Influence Consent for Genetic Research in a Population-Based Survey: The Baltimore Epidemiologic Catchment Area Follow-up, 11 CMTY. GENETICS 171, 173 (2008); see also Conrad V. Fernandez et al., Knowledge and Attitudes of Pregnant Women with Regard to Collection, Testing and Banking of Cord Blood Stem Cells, 168 CAN. MED. ASS’N J. 695, 695 (2003); Paul R. Helft et al., Cancer Patients’ Attitudes Toward Future Research Uses of Stored Human Biological Materials, 2 J. OF EMPIRICAL RES. ON HUM. RES. ETHICS 15, 18 (2007).
\textsuperscript{293} WilcoxF & Schroer, supra note 292; Hull et al., supra note 292; Kettis-Lindblad, supra note 292; Malone et al., supra note 292.
\textsuperscript{294} See Klaus Hoeyer et al., The Ethics of Research Using Biobanks: Reason to Question the Importance Attributed to Informed Consent, 165 ARCHIVES OF INTERNAL MED. 97, 98 (2005).
\textsuperscript{295} See Malone et al., supra note 292; see also Kettis-Lindblad et al., supra note 292, at 435.
According to another study, a significant number of participants would not like their samples used in research funded by entities with commercial interests. For example, a significant minority of people (29.3%) surveyed were against their stored tissue being used by drug or pharmaceutical companies. In another study, 18.7% said that their decision to participate would be affected by whether funding was provided by a private company versus a public or independent source. A third study reported that 54.9% of respondents considered corporate interests in the research an important issue in the decision whether to participate in a study, while 14.1% ranked this as the most important issue.

In addition to the negative impact that gene patents have on innovation, the possibility of patenting genes has caused some physicians and university researchers to view patients as treasure troves. Doctors, health care institutions, researchers, and hospitals have gone to court to gain ownership of patients’ cell lines, tissue, and genes in order to commercialize them, even over the patients’ objections. Genetic research is being undertaken on people without their consent as researchers prospect for genes.

VI. CONCLUSION

What if each generation of scientists was forbidden to use—or even think about—the theorems, principles, and natural phenomena that had been discovered or proven by the previous generation of scientists? In order to assure that does not happen, a patentability analysis under the Progress Clause requires courts to weigh “how much future innovation is foreclosed relative to the contribution of the inventor.” Indeed, “the reason for the exclusion is that sometimes too much patent protection can impede

296 However, approximately two-thirds or 62.6% believed it was “all right” for their tissue samples to be used in profit-motivated research. Helft et al., supra note 291, at 18.
297 Kettis-Lindblad et al., supra note 292, at 435.
298 Hoefer et al., supra note 294.
299 Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007).
rather than ‘promote the Progress of Science and useful Arts.’”\(^{301}\) In *O’Reilly v. Morse*, the Court held that by patenting all uses of electromagnetism to produce characters at a distance, “while he shuts the door against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light.”\(^{302}\) In the case of a gene patent, the patent holder can improperly avail himself or herself of all later discoveries related to genetic diagnosis and treatments, disproportionate to its efforts.

Recently, the Supreme Court decided a trio of cases that re-invigorate the Constitutional foundation for the patent system. The Justices have taken to heart the Constitutional mandate that the patent system “promote the Progress of Science and the useful Arts.”\(^{303}\) In *Bilski v. Kappos*,\(^ {304}\) the Court harkened back to Thomas Jefferson’s idea that “[t]he underlying policy of the patent system [is] that ‘the things which are worth to the public the embarrassment of an exclusive patent,’ . . . must outweigh the restrictive effect of the limited patent monopoly.”\(^{305}\) The *Bilski* decision emphasized that, under the U.S. Constitution and Section 101, the Court is “careful in interpreting the Patent Act to ‘determine not only what is protected, but also what is free for all to use.’ In particular, the Court has long held that ‘[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable’ under § 101,” because such patents “would ‘wholly pre-empt’ the public’s access to the ‘basic tools of scientific and technological work.’”\(^ {306}\) In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Court similarly noted that “the grant of a patent might tend to impede innovation more than it would tend to promote it.”\(^ {307}\)


\(^{302}\) O’Reilly v. Morse, 56 U.S. 62, 113 (1853).

\(^{303}\) U.S. CONST. art. I, § 8, cl. 8.

\(^{304}\) 130 S. Ct. 3218 (2010).

\(^{305}\) Id. at 3258 (Breyer, J., concurring) (indicating where the Justices were in agreement) (citation omitted).

\(^{306}\) Id.

Association for Molecular Pathology v. Myriad Genetics, Inc., the Court acknowledged that patents might “imped[e] the flow of information that might permit, indeed spur, invention.”

The Supreme Court is concerned with drawing the boundaries of subject matter eligibility, holding that laws of nature and products of nature are not patentable, in order to eliminate “the enormous potential for rent seeking that would be created if property rights could be obtained in them and . . . the enormous transaction costs that would be imposed on would-be users.’” Patents on human genes overcompensate the patent owner for merely discovering natural information, such as gene mutations’ correlation with disease, while allowing them to tax any user of the natural information. While all patents have the power to create short term costs, such as excluding others from using the invention, increasing the cost of using the invention or blocking improvements/creation of new technologies based on the invention and systemic patent thicket/anticommons effects, there is evidence that gene patents have already created inefficiencies in healthcare delivery, increased research costs and prevented research projects altogether.

310 SEC’Y ADVISORY COMM., supra note 109, at 33 (2010); Powell et al., supra note 152, at S90, S91; Berthels et al., supra note 101, at 1114; Chandrasekharan & Fiffer, supra note 104, at S184; Angrist et al., supra note 155, at S118; Blanton, supra note 155, at 10; Supplemental Declaration of Ellen Matloff, supra note 155, at ¶¶ 6–8; Declaration of Haig H. Kazazian, supra note 155, at ¶¶ 7–11; Declaration of Arupa Ganguly, supra note 155, at ¶¶ 3–14; Declaration of Debra Leonard, supra note 155, at ¶ 19; Declaration of Elizabeth Swisher, supra note 155, at ¶¶ 2, 9–16, 24; Declaration of Madhuri Hegde, supra note 155, at ¶¶ 6–12; Declaration of Harry Ostrer supra note 155, at ¶¶ 10, 12–14; Declaration of David Ledbetter, supra note 155, at ¶¶ 13–24; Mildred Cho et al., supra note 155, at 5, 7; Merz et al., supra note 155, at 577; see also Rabino, supra note 123, at 15; Campbell et al., supra note 155, at 478; Schissel et al., supra note 110, at 118.
The analyses of studies related to gene patents demonstrate how patents on products of nature, laws of nature, and abstract ideas can impede innovation. Consequently, the underlying goals of the Progress Clause are served by the *Myriad* decision which continued to exempt these items from patentability.