

PATENTING EVERYTHING UNDER THE SUN: INVOKING  
THE FIRST AMENDMENT TO LIMIT THE USE OF  
GENE PATENTS

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*This Comment argues that the First Amendment should be used as a lens for determining whether something is a “natural phenomenon” for purposes of patent law. Patent law does not permit patents over natural phenomena; yet the U.S. Patent and Trademark Office (USPTO) has allowed patents over items that appear to be natural phenomena. Gene patents are one example. This Comment argues that genomic sequences should be considered natural phenomena. It also argues that because the current standards of the USPTO permit patents over these—and other—natural phenomena, there is a problem with the current patent standards. The problem is that the USPTO has upset the balance between preserving the rights of the patent holder and the public’s “right to know” about the information disclosed in patent applications. There currently exists no consistent standard for delineating which items are natural phenomena and which are not, and this permits many items that should be considered natural phenomena to obtain patents. This Comment argues that the First Amendment could offer a solution. Because First Amendment theory shares a focus on the public’s “right to know,” standards of First Amendment law can serve as a lens for determining whether an item is a natural phenomenon.*

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## INTRODUCTION

In 1955, Jonas Salk made headlines around the world when he developed the polio vaccine.<sup>1</sup> Journalist Edward Murrow invited Salk as a guest on his television show, "See It Now," to discuss the implications of the vaccine. In that interview, Murrow asked Salk who owned the patent to the vaccine. Salk responded, "Well, the people, I would say. There is no patent. Could you patent the sun?"<sup>2</sup> At the time, Salk recognized a need for a fundamental balance in intellectual property law between the rights of innovators and the rights of the public as a whole.

The landscape of patent law has changed dramatically since Salk's legendary interview. While the sun itself has not been patented, most everything under the sun has received some sort of a patent.<sup>3</sup> From bacteria to genomic sequences, scientists and medical researchers have raced one another to gain exclusive rights to study and develop new technologies.

Patent law has struggled to keep up with these scientific breakthroughs, especially in the field of biotechnology. The problem is that instead of encouraging innovation through the issuance of patents, the U.S. Patent and Trademark Office (USPTO) permits biotechnology companies to acquire patents that result in discouraging innovation by restricting access to information that was previously available to researchers.<sup>4</sup>

Gene sequences are one of the most controversial examples of materials that many think should be outside the scope of patent law. Some have questioned the USPTO's granting of gene patents<sup>5</sup> either because they see it as

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1. Bonnie A. Maybury Okonek & Linda Morganstein, *Development of Polio Vaccines*, ACCESS EXCELLENCE, <http://www.accessexcellence.org/AE/AEC/CC/polio.php> (last visited Nov. 3, 2010).

2. *Could You Patent the Sun?*, UNDER THE SAME SUN (Aug. 25, 2004), [http://www.underthesun.org/content/2004/08/could\\_you\\_patent.html](http://www.underthesun.org/content/2004/08/could_you_patent.html).

3. For example, the U.S. Patent and Trademark Office (USPTO) has awarded patents over a method of exercising a cat (encouraging it to follow a handheld laser), a method of swinging on a swing, a method of playing a bowling game, a tricycle lawnmower, and a motorized ice cream cone. See U.S. Patent Nos. 5,443,036 (filed Nov. 2, 1993), 6,368,227 (filed Nov. 17, 2000), 6,142,880 (filed Feb. 24, 1999), 4,455,816 (filed June 29, 1982), and 5,971,829 (filed Mar. 6, 1998), respectively.

4. In fact, the federal government recently recognized the flaws inherent in the USPTO's patent system when it filed an amicus brief in favor of Myriad Genetics, the plaintiffs in the case that inspired this Comment. Brief for the United States as Amicus Curiae Supporting Neither Party, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515), available at <http://graphics8.nytimes.com/packages/pdf/business/genepatents-USamicusbrief.pdf>.

5. For purposes of this Comment, "gene patents" are defined as any patents over genomic sequences that have been isolated and purified. An isolated and purified gene sequence is a gene sequence that has been separated from its other cellular components.

“playing God,” because they think gene patents do not meet the requirements of patent law, or because genetic information belongs to the public. Proponents of gene patents, however, assert that such patents are necessary tools for scientific innovation. So far, proponents of gene patents are winning the debate, and the USPTO has continued to grant gene patents at an accelerated rate.<sup>6</sup>

On May 12, 2009, however, the American Civil Liberties Union (ACLU) advanced a new argument as to why gene patents should not be allowed. In filing a case against the USPTO and medical researcher Myriad Genetics, the ACLU asserted that gene patents are unconstitutional on First Amendment grounds.<sup>7</sup> The ACLU claimed that gene patents implicated the First Amendment because they (1) limit the First Amendment right of scientists to have access to information to conduct their research; and (2) limit the First Amendment rights of the public because they prohibit information from entering the public domain.<sup>8</sup>

This Comment explores the theoretical underpinnings of the ACLU’s potential First Amendment claims. This Comment evaluates the ACLU’s arguments in light of the uniqueness of gene patents and delineates what the appropriate scope of the First Amendment protection against patents should be. While this Comment recognizes that there are some First Amendment arguments that the ACLU can make in opposition to gene patents, it suggests that the ACLU goes too far in claiming that all gene patents should be banned. The ACLU fails to address just how far this First Amendment protection should span. Indeed, taking the ACLU’s complaint at face value, it would seem that every patent could theoretically violate the First Amendment because it would limit the information present in the public domain.

Gene sequences are natural phenomena, like gold, hydrogen, and the *aurora borealis*. Patents are currently not granted for natural phenomena,<sup>9</sup> laws

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6. An estimated 47,000 patents discussing deoxyribonucleic acid (DNA) or ribonucleic acid have been granted in the United States. See Robert Cook-Deegan, *Gene Patents*, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 69, 70 (Mary Crowley ed., 2008). Debate over the merits of granting gene patents has raged for over a decade. Compare Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 121–29 (1999) (arguing that genes generally should not be patentable), with F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 699–700 (2001) (arguing that genes should be patentable).

7. See generally Complaint, *Ass’n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 09 Civ. 4515).

8. *Id.*

9. The USPTO defines a natural phenomenon as “a thing occurring in nature, which is substantially unaltered, is not a ‘manufacture.’” The USPTO further explains that “[a] shrimp with the head and digestive tract removed is an example.” U.S. PATENT & TRADEMARK OFFICE, *Rejections*

of nature,<sup>10</sup> or abstract ideas,<sup>11</sup> yet gene patents continue to be valid in the eyes of the USPTO because patents are technically only granted to “isolated and purified” genes. This Comment specifically addresses gene patents as natural phenomena instead of laws of nature. Natural phenomena are preexisting objects that people discover, like gold or oxygen. Laws of nature, on the other hand, are scientific relationships that people discover, like gravity or the theory of relativity. While one could argue that the comparing of a genotype to a phenotype is a law of nature, most gene patents are for specific genes that are not significantly manipulated from their natural state, making them natural phenomena. The USPTO’s granting of patents for these natural phenomena has upset the balance of patent law, tipping the scales too much in favor of the patent holder.

Items that are protected under patent law introduce something into the public domain that was not initially there. When an applicant submits a patent application to the USPTO, the applicant must disclose his or her invention to the public, in exchange for temporary economic protection. This is known as the patent bargain.<sup>12</sup> Thus, when an applicant submits his or her invention, he or she must be contributing something new to the public domain in exchange for the patent protection. Patents over natural phenomena, laws of nature, and abstract ideas, on the other hand, can remove something that initially existed in the public domain. An example of this distinction can be seen in Samuel Morse’s attempted patent over the telegraph and electromagnetic waves.<sup>13</sup> The Supreme Court, ruling on Morse’s application, determined

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*Under 35 U.S.C. 101 [R-5]—700 Examination of Applications*, [http://www.uspto.gov/web/offices/pac/mpep/documents/0700\\_706\\_03\\_a.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/0700_706_03_a.htm) (last visited Jan. 18, 2011) (citing *Ex parte* Grayson, 51 U.S.P.Q. (BNA) 413 (B.P.A.I. 1941)).

10. See *In re Meyer*, 688 F.2d 789, 795 (C.C.P.A. 1982) (“Scientific principles and laws of nature, even when for the first time discovered, have existed throughout time, define the relationship of man to his environment, and, as a consequence, ought not to be the subject of exclusive rights of any one person.”).

11. See 69 C.J.S. *Patents* § 26 (2010) (“Abstract idea or abstractions, i.e., concepts, are not patentable subject matter. While the means by which an idea may be made practically useful may be the subject of a patent, an idea, of itself, is not patentable, however new and useful, or even revolutionary and beneficial, to humanity it may be, or, as otherwise stated, regardless of its importance or the ingenuity with which it was conceived. The mere existence of an intellectual notion that a certain thing could be done, and, if done, might be of practical utility, does not furnish a basis for a patent. Mere mental theories are not comprehended within the subject matter described by Congress. A scientific explanation of a successful operation of a patented device is not patentable.” (internal citations omitted)).

12. See generally Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain After Eldred* (Aug. 9, 2004) (working paper), available at <http://ssrn.com/abstract=574141>.

13. See *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113, 120–21 (1853).

that while a patent over the telegraph was valid because it added something new to society, patenting electromagnetic following waves was improper, because electromagnetic waves existed in a state of nature.<sup>14</sup> Patenting such an object would remove something already present in the public sphere, limiting potential innovation and contradicting the core of the patent bargain—economic protection in exchange for adding to, not subtracting from, the public domain.

Despite the *Morse* Court's clarity in determining what is patentable, courts today lack a coherent, consistent way to determine whether an object is naturally occurring and therefore unpatentable. One possible solution lies in an unlikely place—the First Amendment. Because the idea of excluding natural phenomena, laws of nature, and abstract thoughts from patent protection can be linked to First Amendment values, these values may serve as a helpful lens for distinguishing laws of nature from patentable objects. Analyzing the importance of keeping information in the public domain through the lens of First Amendment theory can shed light on precisely where the boundaries of patent protection should be drawn. For example, where patent applicants merely stake a claim over something that already occurs in nature, like a genomic sequence, a patent should not be awarded. By contrast, where a patent applicant finds a genomic sequence in nature, identifies its function, and develops a diagnostic test or therapeutic treatment based on that function, such a test or treatment should receive patent protection.<sup>15</sup>

The USPTO's failure to define a strict boundary for what constitutes a natural phenomenon has wide-reaching impact. The ramifications of this problem are not limited to gene patents. For instance, the failure to define the boundaries of what constitutes a law of natural phenomena has led to similar controversies regarding whether primate embryonic stem cells and zinc finger proteins<sup>16</sup> should receive patent protection.<sup>17</sup> Thus, the lack of an adequate boundary defining the scope of patent law protection has broad implications. Pharmaceutical companies and other scientists should not be allowed to stake claims in natural phenomena solely to inflate their intellectual property portfolios at the

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14. *Id.* at 116, 120.

15. While the diagnostic test or therapeutic treatment should receive patent protection, as it is a product of human innovation, the actual genomic sequence, even in conjunction with such tests or treatments, would still belong in the public domain.

16. Zinc finger proteins are proteins that bind to DNA. They are frequently used for therapeutic gene modulation.

17. See *Found. for Taxpayer & Consumer Rights v. Patent of Wis. Alumni Research Found.*, 2010 WL 1734377 (B.P.A.I.); Subhashinin Chandrasekharan et al., *Proprietary Science, Open Science and the Role of Patent Disclosure: The Case of Zinc-Finger Proteins*, 27 NATURE BIOTECH. 140 (2009).

public's expense. To combat the problem of such frivolous gene patents and to limit needless and expensive litigation searching for the outer boundaries of patent law, the First Amendment can provide much needed guidance.

Part I of this Comment explores background information regarding gene patents and the ACLU's current case against Myriad Genetics. It then argues that gene patents should be analyzed separately from traditional patents because the underlying gene sequences are natural phenomena.

Part II evaluates some common First Amendment theories and advances three reasons why the ACLU may be correct that patents over genetic sequences violate the First Amendment. First, this Part draws from John Stuart Mill's theory of marketplace of ideas and argues that researchers have a right to access information. Because journalists and students similarly have a right to know information which is (or should be) in the public domain, it follows that scientists should some degree have a right to gather information about natural phenomena and laws of nature in order to conduct research. Second, Part II asserts that the public, too, has a right to know. Just as *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*<sup>18</sup> recognized consumers' right to access information about prescription drugs under the commercial speech doctrine, consumers have a right to receive information regarding their genetic makeup and susceptibility to disease.<sup>19</sup> Third, based on the notions of autonomy and individual freedom inherent in free speech law, this Part argues for the recognition of the public's right to make informed decisions about their own bodies.

Finally, Part III sets forth a standard by which courts and the USPTO can analyze gene patents and applies this standard to the ACLU's case against Myriad. This Part argues that because the idea of excluding naturally occurring substances from patent protection derives from First Amendment theory (namely, that certain information deserves protection to ensure that it remains in the public domain), the First Amendment can serve as a lens for classifying objects as natural phenomena. Specifically, this Part argues that because patents can be analogized to content-based restrictions on speech, strict scrutiny can serve as an appropriate tool for determining whether patents should be granted. Similarly, because the commercial speech doctrine incorporates First Amendment principles and pertains to speech regarding economic gain, one could also use the doctrine when making this determination. As no standard currently exists for determining whether something is a natural

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18. 425 U.S. 748 (1975).

19. *Id.*

phenomenon, courts can apply First Amendment tests as an additional heuristic for making that determination.

## I. BACKGROUND ON GENE PATENTS

### A. What Is a Gene?

Genes are the building blocks of life in all organisms. Each gene is a segment of deoxyribonucleic acid (DNA), which contains instructions for the development and functioning of living organisms.<sup>20</sup> For example, genes determine whether one's eyes will be green or brown, or whether one will be tall or short. Those genes then "serve as instruction books for making functional molecules such as ribonucleic acid (RNA) and proteins, which perform the chemical reactions"<sup>21</sup> that create our bodies.

A modern definition of a gene is "a locatable region of genomic sequence, corresponding to a unit of inheritance, which is associated with regulatory regions, transcribed regions, and/or other functional sequence regions."<sup>22</sup> While people often speak in terms of one's "good genes," everyone has the same genomic sequences.<sup>23</sup> Genomic sequences are the orders of the DNA bases in the sequence<sup>24</sup>—adenine, thymine, guanine, and cytosine. Thus, when scientists apply for a patent over an entire genomic sequence, they are patenting something that is present in every human body.<sup>25</sup> Only 1.4 percent of human DNA differs at the level of the single letters of the genetic code.<sup>26</sup> Variance in genetic inheritance among humans, therefore, is primarily determined by single

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20. *What Is a Gene?*, GENETICS HOME REFERENCE (Feb. 13, 2011), <http://ghr.nlm.nih.gov/handbook/basics/gene>; see also *BRCA: Genes and Patents*, ACLU.ORG (May 27, 2009), <http://www.aclu.org/free-speech/brca-genes-and-patents>.

21. *The New Genetics: Chapter 1, How Genes Work*, NAT'L INST. OF GEN. MED. SCI. (2006), <http://publications.nigms.nih.gov/thenewgenetics/chapter1.html>.

22. See Helen Pearson, *What Is a Gene?*, 441 NATURE 398, 401 (2006); Elizabeth Pennisi, *DNA Study Forces Rethink of What It Means to Be a Gene*, 316 SCI. 1525, 1556–57 (2007).

23. See generally Int'l Human Genome Sequencing Consortium, *Finishing the Euchromatic Sequence of the Human Genome*, 431 NATURE 931 (2004).

24. See *Facts About Genome Sequencing, Human Genome Project Information*, GENOMICS.ENERGY.GOV, [http://www.ornl.gov/sci/techresources/Human\\_Genome/faq/seqfacts.shtml#whatis](http://www.ornl.gov/sci/techresources/Human_Genome/faq/seqfacts.shtml#whatis) (last modified Sept. 19, 2008).

25. See *id.* When scientists apply for a patent regarding a genomic sequence, typically they will merely identify the genomic sequence in question, spelling out the orders of the DNA bases as they appear for that genomic sequence (for example, adenine-thymine, guanine-cytosine, guanine-cytosine, adenine-thymine, etc.).

26. See GEORGE JOHNSON & JONATHAN LOSOS, *THE LIVING WORLD* 279 (6th ed. 2010).

nucleotide changes scattered among the human genome.<sup>27</sup> So when Myriad Genetics performs a diagnostic test to determine whether someone has an increased likelihood of having breast cancer, they are analyzing these nucleotide changes. Specifically, with the BRCA-1 and BRCA-2 genomic sequences, Myriad Genetics tests for mutations of the gene sequences to determine the likelihood that one will get breast cancer.

#### B. What Is a Patent?

A patent is a government-sponsored monopoly over an invention. These monopolies last twenty years, at which point the invention becomes a part of the public domain.<sup>28</sup> For the twenty-year duration of the patent, anyone who wants to use that patent must seek permission and/or pay royalties to the patent holder—meaning significant financial benefit for those who hold the “right” patents.<sup>29</sup>

The USPTO used to grant patents only to actual inventions (such as the light bulb), as opposed to discoveries (such as bacteria). While seeking financial gain by looking for profitable materials in nature is nothing new, the practice of granting rights in entire types of objects—as opposed to particular, finite instances of profitable objects, as in mining or oil drilling—has only occurred within the last fifty years.<sup>30</sup> The current practice of staking a claim in a product of nature is referred to as “bio-prospecting.”<sup>31</sup> As critics of bio-prospecting claim, “[i]t is the difference between making money by growing and harvesting apples, and making money by claiming rights to *all* apples and collecting royalties on all apples sold, whether you planted and harvested them or not.”<sup>32</sup>

As knowledge of genes and their functions progressed, researchers came to understand that gene mutations could be used to predict susceptibility to certain diseases.<sup>33</sup> In part because of this discovery and the accompanying desire to know more about the DNA of the human species, the world embarked

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27. *Id.*

28. See BRCA: *Genes and Patents*, *supra* note 20.

29. *Id.*

30. DAVID KOEPEL, WHO OWNS YOU?: THE CORPORATE GOLD-RUSH TO PATENT YOUR GENES 10 (2009) (“[H]umans have long exploited the natural world for profit . . . . Only within the last 50 years have profits begun to be made not solely by increased production . . . but rather by claiming rights over the ‘types’ of objects themselves—the universal *form* of the item . . .”).

31. *Id.*

32. *Id.*

33. *Can a Genetic Test Predict Parkinson’s, ALS?*, CNN.COM (Nov. 19, 2008), [http://articles.cnn.com/2008-11-19/health/als.parkinson.genetic.mutation\\_1\\_als-mutations-parkinson?\\_s=PM:HEALTH](http://articles.cnn.com/2008-11-19/health/als.parkinson.genetic.mutation_1_als-mutations-parkinson?_s=PM:HEALTH); see also JOHNSON & LOSOS, *supra* note 26, at 282–83.

on an attempt to map the human genome.<sup>34</sup> The map was published in 2001.<sup>35</sup> This caused many companies to race to develop the human genome, and one company in particular, Celera, developed a technique for rapidly encoding the structure of all genes.<sup>36</sup> With this tremendous discovery came a huge interest in genetic research, including a financial interest in gene patents.

### C. The History of Gene Patents

As Jonas Salk's comment about his polio vaccine implied,<sup>37</sup> it used to be extremely uncommon to allow a patent or any other sort of intellectual property right over part or all of a living organism. In 1980, however, the Supreme Court paved the way for future claims regarding living things in its decision in *Diamond v. Chakrabarty*,<sup>38</sup> holding that a bacterium (a living organism) used to clean up oil spills met the patenting requirements.<sup>39</sup> *Chakrabarty* stands for the proposition that so long as a living thing is modified by humans, it is patentable. Thus, even though the thing in question had been a natural phenomenon, it was no longer a natural phenomenon at the time of filing a patent application because scientists had manipulated the bacterium in a laboratory through cross-breeding.<sup>40</sup> This holding opened a new era in patent law.

In 1982, the USPTO recognized its first patent over a human gene sequence. This patent was granted to the University of California, which applied for a patent to the "isolated and purified" form of a gene that encodes the insulin protein."<sup>41</sup> To put something in an "isolated and purified" form means that it has been separated from other cellular components, with which it typically coexists in its native state.<sup>42</sup> Proponents of gene patents argue that "isolating and purifying" a gene constitutes an artificial modification, much like the cross-breeding

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34. See JOHNSON & LOSOS, *supra* note 26, at 282–83.

35. See *id.*

36. See Marcy Darnovsky & Jesse Reynolds, *The Battle to Patent Your Genes: The Meaning of the Myriad Case*, AM. INTEREST ONLINE (Sept.–Oct. 2009), <http://www.the-american-interest.com/article-bd.cfm?piece=653>. Although Celera had developed this technique, it still had to determine the *function* of each gene.

37. See *supra* note 2 and accompanying text.

38. 447 U.S. 303 (1980).

39. *Id.*

40. See *id.* at 309–10.

41. Darnovsky & Reynolds, *supra* note 36.

42. See Tony Dutra, *Genes Unpatentable Under § 101*, CTR. FOR GENETICS & SOC'Y (Mar. 31, 2010), <http://www.geneticsandsociety.org/article.php?id=5204>.

of bacteria upheld in *Chakrabarty*.<sup>43</sup> By separating the DNA from the proteins, proponents claim that scientists have manipulated the DNA.<sup>44</sup> However, critics assert that “isolation and purification” does nothing to the form and structure of the gene sequence.<sup>45</sup>

While there has been some concern from bioethicists and the medical community, the USPTO has continued to hand out gene patents “willy-nilly for very, very slight investments.”<sup>46</sup> While many assume that such patents are only granted over genetic tests or specific analytical methods of studying genes, that is not the case. The gene sequences themselves are being patented.<sup>47</sup> This means that a patent covers the particular fragment of DNA present in every human body.<sup>48</sup> When a gene or genetic sequence is patented, no other scientist can perform the act of comparing gene sequence information without paying royalties.<sup>49</sup> Given that many genes and their functions overlap, this has created a significant incentive for researchers to obtain as many patents as possible.<sup>50</sup> As of today, the USPTO has granted patents over genes associated

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43. See *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al. and Patenting DNA Sequences Under 35 U.S.C. § 101*, 2010 A.B.A. SPEC. COMM. ON BIOTECH., CHEMISTRY, MED. AND PHARMACOLOGY REP.

44. Deborah L. Lu, *The Uncertain Future of DNA Patents*, NAT'L L. REV. (Dec. 21, 2010), <http://www.natlawreview.com/article/uncertain-future-isolated-dna-patents> (“The isolation of a gene is not necessarily a standard and routine process of extracting and amplifying a desired gene. A gene is not merely the necessary sequence to express a protein. Rather, a gene may have several components, including, but not limited to, promoters, enhancers, exons, introns and untranslated regulatory sequences that are not ultimately translated into a protein. In other words, genes are not merely products of nature that can be routinely isolated. Furthermore, an isolated gene does differ from what is naturally occurring. For example, in a naturally occurring state, DNA is often coiled and bound to DNA binding proteins, such as histones. In contrast, isolated DNA is often relaxed and free of DNA binding proteins and exists in a buffered environment.”).

45. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (arguing that isolated and purified DNA is not patentable because it is not “markedly different” than what occurs in nature).

46. See Tom Reynolds, *Gene Patent Race Speeds Ahead Amid Controversy, Concern*, 92 JNCI J. NAT'L CANCER INST. 184 (2000).

47. *Id.*

48. See *supra* Part I.A.

49. Brief for American Medical Association et al. as Amici Curiae Supporting Plaintiffs at 9, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 09 Civ. 4515) (“Further, Myriad has obtained patents on the act of ‘comparing’ a person’s breast cancer gene sequence to the normal (‘wild-type’) BRCA2 gene sequence . . . . These patents prohibit others from performing the simple mental step of comparing gene sequence information.”).

50. John Schwartz, *Cancer Patients Challenge the Patenting of a Gene*, N.Y. TIMES, May 12, 2009, [http://www.nytimes.com/2009/05/13/health/13patent.html?\\_r=1](http://www.nytimes.com/2009/05/13/health/13patent.html?_r=1) (“In the future, genetic tests are likely to involve the analysis of many genes at once, or even of a person’s full set of genes . . . . [Researchers warn] that ‘it may be difficult for any one developer to obtain all the needed licenses’ to develop the next generations of tests.”).

with Alzheimer's disease, muscular dystrophy, colon cancer, asthma, and other illnesses, meaning that the study of genes as they interact with those illnesses is typically limited to one private firm.<sup>51</sup> Such patents are not limited solely to genetic sequences. There are a number of patents for things that were long considered beyond the reach of intellectual property law (such as Harvard University's OncoMouse, a mouse that has been genetically engineered to be prone to cancer).<sup>52</sup>

### 1. Requirements for Obtaining a Gene Patent

Per the Patent Act of 1952, genes in the abstract cannot be patented because they are naturally occurring objects.<sup>53</sup> However, the USPTO has permitted gene patents so long as the genes are purified and isolated. This means that "scientists who discover the beginning and end points of the string of base pairs constituting a particular gene, and delineate those points, weeding out extraneous bits that don't contribute to the functioning of that gene, have done enough in the eyes of the [US]PTO to warrant a monopoly right to that gene."<sup>54</sup> Because of the "gene patent gold rush" following the Human Genome Project, during which researchers continued to patent genes without proving their function, the USPTO amended its guidelines in 2001, to limit gene patents.<sup>55</sup> Specifically, the guidelines were revised to have a higher threshold for "utility," as critics asserted that simply identifying a gene without identifying its function was one of the main problems of the patent gold rush.<sup>56</sup> The new utility standards required two different tests: the "specific, substantial, and credible" utility test and the "well-established utility" test.<sup>57</sup> Under the new guidelines,

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51. Damovsky & Reynolds, *supra* note 36 ("The U.S. Patent and Trademark Office . . . has granted somewhere between 3,000 and 5,000 patents on human genes themselves, including those associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma and many other illnesses . . . 63 percent of them [have been patented] by private firms.").

52. *Id.*

53. See *A Brief History of the Patent Law of the United States*, LADAS & PARRY, LLP (July 17, 2009), <http://www.ladas.com/Patents/USPatentHistory.html>.

54. KOEPESELL, *supra* note 30, at 6.

55. *Final Guidelines for Determining Utility of Gene-Related Inventions*, USPTO (Jan. 4, 2001), <http://www.uspto.gov/news/pr/2001/01-01.jsp>.

56. See Anna E. Morrison, *The U.S. PTO's New Utility Guidelines: Will They Be Enough to Secure Gene Patents?*, 1 J. MARSHALL L. REV. INTELL. PROP. LAW 142, 153 (2001).

57. *The Fate of Gene Patents Under the New Utility Guidelines*, 2001 DUKE L. & TECH. REV. 0008, ¶ 10 (Feb. 28, 2001), <http://www.law.duke.edu/journals/dltr/articles/2001dltr0008.html>. See *Utility Examination Guidelines*, 66 Fed. Reg. 1092-02, 1105 (Jan. 5, 2001).

patent seekers must state a function of the gene before obtaining a patent.<sup>58</sup> Thus, although researchers need not develop a specific test or a specific analytical method of studying genes, they need to identify the presence of a gene and detail one of the gene's many potential functions in order to satisfy the patent office. For example, to prove that a gene meets the "specific, substantial, and credible" utility test, a patentee could not just claim that a gene had a diagnostic purpose but must explain a potential diagnostic purpose.<sup>59</sup> To meet the "well-established utility" test, "a person of ordinary skill in the art [must be able to] immediately appreciate why the invention is useful."<sup>60</sup>

The main problem with the revised guidelines is that they have had little, if any, effect. While the guidelines have changed, the examiners are still approving the same types of applications under the new standard.<sup>61</sup> Tanya Wei has thus suggested that it is imperative for courts to examine a test case concerning the guidelines, so that the modified guidelines can have legal significance.<sup>62</sup>

## 2. The Lack of a Consistent Standard

The rapid proliferation of gene patents has resulted in a lack of a consistent standard across the courts. Not only have the courts failed to address the seemingly outdated patent statute,<sup>63</sup> but they have also failed to address the distinction between property rights in one's body parts and intellectual property rights in one's genes.<sup>64</sup> Indeed, it seems that the USPTO simply began granting these patents before anyone was able to assess the practical, legal, and ethical

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58. Darnovsky & Reynolds, *supra* note 36 ("Celera used newly developed techniques to identify short sections of DNA that can be used to identify genes, though their function may be unknown. Its business model was to patent these DNA fragments quickly, and then to sort out their usefulness later. These patents . . . alarmed many scientists . . ."). The revised PTO guidelines were a response to the gene patent gold rush, in which Celera was the frontrunner. See John Carey, *The Genome Gold Rush*, BUS. WK., June 12, 2000, [http://www.businessweek.com/2000/00\\_24/b3685001.htm](http://www.businessweek.com/2000/00_24/b3685001.htm).

59. *The Fate of Gene Patents Under the New Utility Guidelines*, *supra* note 57, ¶¶ 12, 22.

60. *Id.* ¶ 37 (citing *Revised Utility Examination Guidelines; Request for Comments*, 64 Fed. Reg. 71440, 71441 (Dec. 21, 1999)).

61. This is because the standard for utility is based on the perception of a person of ordinary skill in the art. As long as those within the genetics industry find gene patents to be useful, the patent examiners will continue to approve applications.

62. Tanya Wei, *Patenting Genomic Technology—2001 Utility Examination Guidelines: An Incomplete Remedy in Need of Prompt Reform*, 44 SANTA CLARA L. REV. 307, 327 (2003).

63. After all, a twenty-year moratorium on inventions may have seemed appropriate two hundred years ago, but with rapid increases in biotechnology, it hardly seems workable.

64. KOESELL, *supra* note 30, at 14 ("In many ways, it seems like the Wild West. Claims are being staked out, and it's just a matter of time before a shoot-out ensues. What is clear is that our instincts about our self-ownership of our bodies and the information that makes them up is not in sync with the present patent law.").

complications.<sup>65</sup> “Currently, there is a large gap in the jurisprudence which leaves unanswered fundamental questions about [one’s] rights in [one’s] body, [one’s] genes, and means of challenging those who may have already staked claims on the products of both.”<sup>66</sup> The largest problem is that the line between what constitutes a mere scientific discovery and what constitutes a patentable invention has grown exceedingly muddled. The severity of this problem was especially clear in the district court’s decision in the ACLU’s case against the USPTO and Myriad—*Association for Molecular Pathology v. U.S. Patent & Trademark Office*.<sup>67</sup> In response to the lack of a consistent standard for what constitutes patentable subject matter, the court referred to the decision in *Chakrabarty*, instead of referring to the revised patent utility guidelines.<sup>68</sup> In *Chakrabarty*, the Court had drawn a distinction between products of nature and patentable objects by asking whether there was a “marked difference” between the product of nature and the patented object.<sup>69</sup> This distinction, which has been relatively absent from case law since *Chakrabarty*, gives no better guidance than the initial inquiry of whether something is, in fact, a law of nature. Indeed, the American Bar Association recently criticized the *Association for Molecular Pathology* decision for purporting to apply its “markedly different standard” but actually adopting a more stringent test.<sup>70</sup> Because there is a lack of consensus as to what the appropriate test should be for determining the patentability of a natural phenomenon, it is essential to develop such a test.<sup>71</sup>

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65. See *id.* at 21.

66. *Id.* at 85.

67. 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

68. *Id.* at 220 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

69. *Chakrabarty*, 447 U.S. at 309.

70. In an American Bar Association committee meeting regarding the *Association of Molecular Pathology* case, a resolution in favor of filing an amicus brief in the case was proposed. The authors of the resolution claimed that the following language was indicative of a more stringent standard than the “markedly different” standard that the court in this case claimed to apply. The § 101 standard discussed below analyzes whether an object is patentable under the patent statute:

There will almost inevitably be some identifiable differences between a claimed invention and a product of nature; the appropriate § 101 inquiry is whether, considering the claimed invention as a whole, it is sufficiently distinct in its fundamental characteristics from natural phenomena to possess the required “distinctive name, character, [and] use.”

Only two members of the Committee voted for the resolution. A.B.A. SPEC. COMM. ON BIOTECH., CHEMISTRY, MED. AND PHARMACOLOGY, *supra* note 43.

71. Christopher M. Holman, *Patent Border Wars: Defining the Boundary Between Scientific Discoveries and Patentable Inventions*, 25 TRENDS IN BIOTECH. 539 (2007).

#### D. The Current Gene Patent Controversy

##### 1. The Case Against Myriad Genetics

The current controversy in the patent community is the ACLU's lawsuit against the USPTO and Myriad Genetics<sup>72</sup>—a healthcare company that, in 1994 and 1995, patented the BRCA-1 and BRCA-2 genes, which are said to be predictors of breast cancer and ovarian cancer.<sup>73</sup> Specifically, women who have mutations of the genes have a 40 to 85 percent higher lifetime risk of developing breast cancer, and a 16 to 40 percent higher lifetime risk of developing ovarian cancer.<sup>74</sup> Additionally, the onset of cancer is more likely to occur early in life.<sup>75</sup> The ACLU asserts that it was unconstitutional for the USPTO to grant these patents, in part because patents over the BRCA-1 and BRCA-2 genes limit information that belongs in the public domain, in violation of the First Amendment.<sup>76</sup> The ACLU also alleges that gene patents are an unconstitutional violation of the First Amendment in two ways: (1) they limit scientific researchers' rights to gather information and have a chilling effect on research, as a thorough patent search is needed to even begin a simple research project, and frequently research must be cancelled because of patent controversies; and (2) the patents limit the general public's right to have access to information about their own bodies—be it through genetic testing or doctors' ability to examine genetic test results.<sup>77</sup>

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72. Complaint, *supra* note 7, at 3, 13.

73. BRCA: *Genes and Patents*, *supra* note 20 (“The BRCA genes—BRCA1 and BRCA2—are two genes that have been associated with hereditary forms of breast and ovarian cancer . . . . Women who have certain mutations along these genes have an elevated lifetime risk of developing breast and ovarian cancer because their ability to suppress cancerous growth has been reduced.”). See generally Caryn Lerman et al., *BRCA1 Testing in Families With Hereditary Breast-Ovarian Cancer*, 275 JAMA 1885–92 (1996); *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT'L CANCER INST. (reviewed May 29, 2009), <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA>.

74. Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 128 (2002).

75. *Id.*

76. Darnovsky & Reynolds, *supra* note 36 (“For 20 years (after which the protected inventions are supposed to enter the public domain), they give their holders the right to prevent anyone . . . from studying or testing ‘their’ genes . . . . They can determine who can do diagnostic tests involving those genes, and . . . how much the tests cost.”).

77. Turna Ray, *Myriad's BRCA Patents Not Only Illegal, but Also Unconstitutional*, ACLU Lawsuit Alleges, GENOMEWEB (May 13, 2009), <http://www.genomeweb.com/dxpgx/myriads-brca-patents-not-only-illegal-also-unconstitutional-aclu-lawsuit-alleges> (“According to ACLU's estimates, as much as 20 percent of all human genes are currently patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, and asthma.”).

The problems with the ACLU's argument are twofold. First, it seems that the ACLU seeks to ban any patent relating to genetics, including patents over diagnostic tests and other medical treatments. This would be far too expansive, as it would limit patents on anything dealing with genetics, including therapeutic tests, the creation of which required far more than the mere discovery of a gene. While an entire gene or gene sequence should not be patentable (as no further tests could be developed), there are some items pertaining to genes that deserve patent protection, such as diagnostic tests and therapeutic treatments, which require ingenuity beyond the discovery of a gene. Thus, while genes and genetic sequences should not be patentable, individual products that stem from the discovery of those genes should be patentable.

Second, the ACLU's argument fails to delineate why gene patents are different from traditional patents. It seems that under the ACLU's argument, any patent violates the First Amendment by limiting the information present in the public domain. The link between gene patents and their First Amendment protection must therefore be explored in greater detail.<sup>78</sup>

## 2. Prior Arguments Against Gene Patents

The ACLU is not the first organization to fight gene patents. Many others have claimed, on a variety of other grounds, that gene patents were illegal. To date, none of these arguments has been successful.

### a. Insufficiency of Gene Patents Under the U.S. Patent Law Statute

Since the inception of gene patents, many have argued that these patents do not meet the requirements of Section 101 of the U.S. Patent Act.<sup>79</sup> The Act requires that patentable objects be new,<sup>80</sup> useful, and non-obvious.<sup>81</sup>

The most controversial of these requirements has been that any gene that is patented actually be useful and have an identifiable use. In fact, in 2001, the USPTO raised the threshold for utility for gene patents. While formerly, scientists only needed to identify genes, the 2001 requirements demanded that scientists identify a genomic sequence *and* at least one function of the

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78. See *infra* Part II.B.

79. 35 U.S.C. § 101 (1996).

80. See, e.g., *Gen. Elec. Co. v. De Forest Radio Co.*, 44 F.2d 931 (3d Cir. 1930) (holding that when GE tried to patent the element tungsten without doing anything to that element, GE had not satisfied the novelty requirement).

81. 35 U.S.C. § 101.

gene.<sup>82</sup> But because it is so simple for researchers to name at least one function of a gene, this requirement is relatively easy for patent holders to satisfy. Of course, many other functions unknown at the time of the application of the patent may later be discovered, and the patent could inhibit research on these functions. Thus, even the newer standard may need to be amended.

Others have claimed that patents fail the novelty requirement. This requirement stipulates that the invention be something entirely new. After all, scientists use the same process each time a gene is isolated and purified. However, the patent office's standards apply the novelty requirement to individual genes, not to the processes used for isolation to analyze them.<sup>83</sup> Therefore, even though the isolation process may be the same, the USPTO considers it to be novel because a different gene is in question.

A similar argument applies to the non-obviousness standard. While some claim that patenting a gene has grown tremendously obvious because the practice is so widespread, the USPTO has taken the position that so long as a gene is different than those currently patented, the process of patenting that specific gene is not obvious.<sup>84</sup>

Thus, while critics of gene patents have made some strong arguments against the patent standards, the USPTO has so far not accepted them.

#### b. Gene Patents Fall Under the Research Exception

Scientists have also attempted to circumvent the problem of gene patents and continue genetic research by invoking the scientific research exception, which is analogous to the fair use doctrine in copyright law.<sup>85</sup> The problem,

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82. Andrew Yates, *The American Gene Patent Legal FAQ*, THINK GENE (Feb. 19, 2009), <http://www.thinkgene.com/the-american-gene-patent-legal-faq> ("Hypothetically, the 'use' of the patent could be how to read the gene sequence itself, but this use is not within the USPTO's stated guidelines. Disclosing only the nucleic acid molecular structure (the sequence) of a gene itself is not patentable. The gene plus a specific use is patentable."). See Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means?*, 7 COMPUTER L. REV. & TECH. J. 255, 258–60 (2003).

83. Chavez, *supra* note 82, at 259 ("When scientists clone sequences, they isolate only the protein-coding portions, thus isolating and purifying the gene sequence.' This isolation creates the requisite novelty necessary to satisfy patent law." (quoting Carrie F. Walter, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1037–38 (1998))).

84. *Id.* at 260 ("The Federal Circuit . . . [determined] that non-obviousness could be established for a specific gene despite the fact that the engineer isolated the gene through an already existing technique.").

85. The fair use doctrine is used to provide some access to copyrightable materials, typically when they are being used for educational rather than commercial purposes. It is the primary mechanism for balancing copyright law and the First Amendment to ensure that necessary information is present in the public sphere.

however, is that the scientific research exception is much narrower than the fair use defense. In fact, the research exception has been tremendously narrowed in recent years,<sup>86</sup> making it practically impossible for researchers to use it to study patented genes.

c. Gene Patents Have Failed to Qualify as Non–Naturally Occurring

A much stronger argument, in large part tied to the standards listed above, has been that gene patents should be disallowed because they are natural phenomena, and pursuant to the 1952 Patent Act, natural phenomena are not patentable.<sup>87</sup> The goal of the patent system was to encourage innovation.<sup>88</sup> This is why natural phenomena are not patentable. While one can patent a technology, patents are not permitted over elements like gold or aluminum. Simply put, there is a difference between an invention and a discovery. The problem is that today, with rapid innovations in science, distinguishing what is and is not a natural phenomenon has become exceedingly difficult.<sup>89</sup> This Comment takes the position that gene sequences and entire genes (as opposed to genetic tests and methods of studying genes) are naturally occurring and therefore should not be patentable. Parts II and III, which explore the relationship between the First Amendment and information that rightfully belongs in the public sphere, are intended to help clarify this argument.

d. Legislation: An Unsuccessful but Promising Solution

Finally, some members of Congress have recognized the threats of gene patents and have put forth the Genomic Research and Accessibility Act<sup>90</sup> to end the practice.<sup>91</sup> In reality, such legislation is the most workable solution to the gene patent problem,<sup>92</sup> as it would create a new framework by which to

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86. See, e.g., *Madey v. Duke Univ.*, 413 F. Supp. 2d 601 (M.D.N.C. 2006).

87. *A Brief History of the Patent Law of the United States*, *supra* note 53.

88. See Aaron Larson, *Patent Law*, EXPERT L. (Sept. 2003), [http://www.expertlaw.com/library/intellectual\\_property/patent\\_law.html](http://www.expertlaw.com/library/intellectual_property/patent_law.html).

89. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 48 U.S. 124, 134 (2006) (Breyer, J., dissenting) (“[T]he category of non-patentable ‘[p]henomena of nature’ . . . is not easy to define.”).

90. 153 CONG. REC. E315-16 (daily ed. Feb. 9, 2007).

91. *Reps. Becerra and Weldon Introduce Bill to Ban the Practice of Gene Patenting*, BECERRA.HOUSE.GOV (Feb. 9, 2007), [http://becerra.house.gov/index.php?option=com\\_content&view=article&id=218:reps-becerra-a-weldon-introduce-bill-to-ban-the-practice-of-gene-patenting&catid=24:2007-press-releases&Itemid=4](http://becerra.house.gov/index.php?option=com_content&view=article&id=218:reps-becerra-a-weldon-introduce-bill-to-ban-the-practice-of-gene-patenting&catid=24:2007-press-releases&Itemid=4).

92. Darnovsky & Reynolds, *supra* note 36 (“Writing for the four-justice minority, William Brennan agreed that ‘it is the role of Congress, not this court, to broaden or narrow the reach of patent laws,’ and said that Congressional guidance is crucial because ‘the composition sought to be patented

approach gene patents. Congressman Xavier Becerra, who authored the Genomic Research and Accessibility Act with Congressman Dave Weldon, has argued that gene patents significantly undermine scientists' ability to conduct research and that citizens of countries without gene patents have access to better genetic tests.<sup>93</sup> This legislation, however, has so far been unsuccessful.

### 3. What Makes Gene Patents Different?

The question left relatively unexplored in the ACLU's complaint is, what makes gene patents special? After all, any patent effectively limits information in the public domain by giving a scientist monopoly rights over his or her invention. However, gene patents are unique in terms of their impact on the public domain. There are three arguments as to why gene patents are different from other patents. Of these, the third argument—that genes are naturally occurring phenomena over which patents should be forbidden—is the strongest.

First, some argue that gene patents should be treated differently because of the unique role of DNA and the role it plays in understanding our common heritage.<sup>94</sup> This theory is often grounded in ethical and religious underpinnings.<sup>95</sup> However, the moral importance of gene patents seems unlikely to

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uniquely implicated matters of public concern.” (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 321–22 (1980))).

93. Xavier Becerra, *Gene Patenting Should Be Banned*, in *GENETIC ENGINEERING: OPPOSING VIEWPOINTS* 193, 195 (David M. Haugen & Susan Musser eds., 2009).

94. See Brief for International Center for Technology Assessment et al. as Amici Curiae Supporting Plaintiffs at 12, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515) (“Patents should not be granted for genes, which are *res communis*, the common heritage and inheritance of mankind. Under the common heritage theory, public resources are available for use by all without restriction for the benefit of humanity.”); Brief for National Women's Health Network et al. as Amici Curiae Supporting Plaintiffs at 17, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 09 Civ. 4515) (“Human genes help to determine who we are and how we function. Although individuals' genes differ in a few respects, the human genome that each of us inherits—the result of millions of years of natural evolution—links us closely to each other.”); Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 *UMKC L. REV.* 295, 297 (2007) (“Moral opponents of gene patents tend to be concerned with the implications of gene patents with respect to personal autonomy and human dignity. For many, the genome possesses a singularly important, perhaps even sacred status as the blueprint of life.”); Melissa L. Sturges, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 *AM. U. INT'L L. REV.* 219, 245 (1997) (arguing that the “Common Heritage of Mankind” is an important international legal concept).

95. Ricki Lewis, *Living Things*, *DOUBLE HELIX DEBATE*, <http://www.columbia.edu/cu/21stC/issue-3.1/lewis.html> (last visited Nov. 3, 2010) (“DNA is considered to be so intimately related to species identity that no parts of it should be controlled by corporate interests. In the case of human beings, human DNA is unique because it is human, and therefore possessing intrinsic value of a sacred kind. As one critic puts it, DNA bears the image of God.”).

influence the courts because the moral implications of gene patents are relatively divorced from the legal implications.<sup>96</sup>

Second, a corollary of the first argument is the idea grounded in individualism that one should not be allowed to patent DNA. Critics claim that by patenting any genes, researchers are cutting against individual rights because individuals have ownership in their specific genetic profile.<sup>97</sup> This argument is not particularly persuasive mainly because up to 99 percent of DNA is uniform among humans, meaning that only 1 percent of the genome may be genetically distinct for each human.<sup>98</sup>

The third argument, and the one that seems most legally sound, is the idea that genes are naturally occurring phenomena that belong in the public domain.<sup>99</sup> There is no question that patenting naturally occurring phenomena has been forbidden.<sup>100</sup> However, as analogous as gene patents are to natural phenomena for which the courts have forbidden patents, it appears that thus far the USPTO has not treated gene patents as natural phenomena undeserving of patent protection. The remainder of this Part explores the legal foundation for disallowing patenting of products of natural phenomena.

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96. Elizabeth Landau, *How Human Genes Become Patented*, CNN.COM (May 13, 2009), <http://www.cnn.com/2009/HEALTH/05/13/genes.patent.myriad/index.html> (“I think that legal arguments about why this kind of thing isn’t really something that should be patentable are really strong at a theoretical level . . . I wouldn’t be that confident that the American court system would agree.” (quoting Josephine Johnston, Bioethicist at the Hastings Institute)).

97. Debra Greenfield, *Freedom of Genes*, GENE WATCH, <http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=308> (last visited Mar. 3, 2011).

98. *Id.* (“[A]ny given form of any gene is present in many people and can be synthesized. The DNA molecule is defined at the atomic level by a genetic sequence. Scientists can make purified substances with the same characteristics as human genes, whereas they cannot exactly manufacture any person’s eyeball.” (quoting Lee Silver, Professor of Molecular Biology and Public Policy at Princeton University)).

99. See Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics’ BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 144 (2004) (explaining that Myriad’s actions were ethically questionable because it was taking “information [that] was largely in the public domain”); Lewis, *supra* note 95.

100. The public domain is explicitly recognized in patent law by judicial exclusion of the laws of nature, natural phenomena, and abstract ideas from patent protection. The U.S. Supreme Court has held that existing knowledge (such as the laws of nature) and materials (such as natural phenomena) that exist in the public domain are, by default presumption, not to be patented. See Brief for International Center for Technology Assessment, *supra* note 94, at 12 (“Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.” (internal quotation marks omitted)).

a. The Legal Foundation for Disallowing Patents of Natural Phenomena

The natural phenomenon argument is somewhat akin to the idea that genes are a part of our common heritage. The theory is that, like oceans, the sky, or the air we breathe, genes belong to everyone. Supporters of gene patents point out that they are not patenting the genes as they appear in nature. Rather, they are patenting “isolated and purified” forms of the gene, which makes these objects distinct.<sup>101</sup> However, these arguments seem unpersuasive because both the genes and the mutations patented by scientists are products that occur in nature.<sup>102</sup> When scientists forbid others from studying these genes or even from thinking about the correlation between mutated genes and diseases, it seems that they are really patenting natural phenomena.<sup>103</sup> Scientists would claim that even if such mutations occur in nature, it is the researchers who have to isolate that sequence. However, even though it took ingenuity for Isaac Newton to identify the law of gravity and for Albert Einstein to arrive at the equation  $E=mc^2$ , prior courts have recognized that it would be improper to patent these laws of nature, which are akin to natural

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101. Lewis, *supra* note 95 (“When you isolate something as it appears in its natural state you change it, even if the only change is the isolation. You have left behind the natural product and created something artificial. No isolated gene sequence occurs in nature,” [asserts Harold Edgar, Columbia Law Professor]). In 1990, the USPTO changed its regulations to include rules for filing claims on DNA sequences. See also Stephen Albainy-Jenei, *ACLU Mob Attacks Breast Cancer Test Patent*, PATENT BARISTAS (May 13, 2009), <http://www.patentbaristas.com/archives/2009/05/13/aclu-mob-attacks-breast-cancer-test-patent> (“While human genes are products of nature, the Myriad patents claim isolated forms of the genes not the genes in their [sic] natural state. That is, imagine pulling out a gene in its unrecognizable natural state hidden among a million other base pairs in the genetic code.”).

102. The presence of genes and even the presence of mutations “is dictated by nature, not any scientist.” Declaration of Sir John E. Sulston, Ph.D., at 7, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515). The patenting of genes requires only “placing [genes] in a form so that they can be sequenced and possibly used in other ways . . . . But isolating and purifying a gene is simply copying it into another format. It’s like taking a hardback book written by someone else, publishing it in paperback and then claiming authorship because the binding is different.” Brief for American Medical Association, *supra* note 49 (“Myriad has not . . . invented any chemical or mechanical methods of determining whether there is a mutation in a breast cancer gene. Rather, what the patentee claims to have discovered are pre-existing genetic sequences and a natural relationship (correlation) between certain mutations and breast cancer.”).

103. Myriad’s patents prevent others “from performing a simple mental process of comparing a mutant sequence . . . . The basic method claimed by Myriad—comparing the patient’s sequence to the non-mutated sequence, and thereby drawing a conclusion as to susceptibility to breast cancer—is nothing more than a law of nature.” Brief for March of Dimes Foundation et al. as Amici Curiae Supporting Plaintiffs, *Ass’n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 09 Civ. 4515).

phenomena.<sup>104</sup> The rationale has been that information that simply occurs in nature should be available in the public domain for future innovation and learning.

The courts have upheld the notion that patents should not be granted over items that are naturally occurring. Regarding isolated and purified materials, in *General Electric Co. v. De Forest Radio Co.*,<sup>105</sup> the court invalidated patent claims over tungsten, a naturally occurring metal, despite the researchers' claim that they had isolated and purified the metal. The court held that "[w]hat [the researcher] discovered were natural qualities of pure tungsten. Manifestly he did not create pure tungsten . . . . It existed in nature and doubtless has existed there for centuries. The fact that no one before [the patent applicant] found it there does not negative its origin or existence."<sup>106</sup>

The Supreme Court followed this line of reasoning in *Funk Bros. Seed Co.*,<sup>107</sup> where the Court invalidated a patent over mixtures of a certain root bacteria that were used to inoculate the seeds of plants. The Court held that such a patent was not allowable because the root bacteria occurred in nature, and simply repackaging them did not produce a new invention:

Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee . . . . [P]atents cannot issue for the discovery of the phenomena of nature . . . . [They] are not part of the storehouse of knowledge of all men.<sup>108</sup>

Much like purification of tungsten and repackaging bacteria, many gene patents could be ruled invalid because they seek to patent products of nature.<sup>109</sup> The patented objects "contain exactly the same genetic information as [their] natural counterpart[s], [do] the same work as naturally occurring gene-protein synthesis and [employ] the same processes to do it. The useful properties of a

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104. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) ("[A] new mineral discovered in the earth . . . is not patentable . . . . 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, . . . reserved exclusively to none.'" (quoting *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130 (1948))).

105. 28 F.2d 641 (3d Cir. 1928).

106. *Id.* at 643.

107. 333 U.S. 127 (1948).

108. *Id.* at 130-31.

109. A scientific principle "reveals a relationship that has always existed." *Parker v. Flook*, 437 U.S. 584, 593 n.15 (1978).

gene are not the ones the scientist has invented (or created through isolation or purification), but rather are natural, inherent properties of the genes themselves. . . . [T]hese patents improperly privatize the ‘storehouse of knowledge of all men.’”<sup>110</sup>

b. Why the First Amendment Lens Is Necessary

Given the strength of the argument that some gene patents are invalid attempts to patent natural phenomena, one might think further argument based on the First Amendment is unnecessary. However, it is apparent that the USPTO has not accepted the natural phenomenon argument, but has implicitly adopted the reasoning that isolating and purifying a gene is sufficient to avoid the prohibition on patenting a natural phenomenon. While the Supreme Court has not ruled on the issue in the context of gene patents, dicta in *American Wood-Paper Co. v. Fibre Disintegrating Co.*<sup>111</sup> suggested that the Court would find genetic material patentable if it had been isolated and purified.<sup>112</sup> Thus, the policy framework behind preventing the patents of natural phenomena, detailed below, which seems largely compatible with First Amendment theory, can provide ample additional reason why the USPTO should disallow gene patents.

The rationale for disallowing patents of natural phenomena is to protect the balance between the inventor’s rights and the public’s rights. “In crossing the line between patents on human invention and patents on nature itself, the Myriad patents upset the ‘careful balance’ inherent in patent laws that is ‘the very lifeblood of a competitive economy.’”<sup>113</sup> Recently, Justice Breyer further described the need for this balance, stating that “the reason for the exclusion [of laws of nature] is that sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts [sic],’ the constitutional objective of patent and copyright protection.”<sup>114</sup> The rationale

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110. See Brief for International Center for Technology Assessment, *supra* note 94.

111. 90 U.S. 566 (1874).

112. See *id.* at 594. The Court found that a patent for using bamboo pulp to make purified cellulose for the manufacture of paper was not valid because there was already a similar patent involving vegetable pulp. However, the Court seemed to indicate in dicta that if the patent had met the novelty requirement, it would be considered patentable.

113. See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

114. See *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126–27 (2006) (Breyer, J., dissenting).

for excluding natural phenomena from patent protection is that others must be able to access them to improve upon prior inventions.<sup>115</sup>

Unlike traditional inventions, like the bicycle or the television, “inventions” that are based on the natural phenomena cannot be improved upon. While patents over new inventions like bicycles and televisions add information to the public domain, gene patents take naturally occurring phenomena out of the public domain.<sup>116</sup> This was the rationale for the Supreme Court’s denying patent protection to Samuel Morse over electromagnetic waves. While the Court granted patent protection over the telegraph, with regard to electromagnetic waves, the Court feared that granting “broad rights to a law of nature (the use of electromagnetic waves at a distance) beyond its particular application in Morse’s concrete novel invention (the telegraph) would overcompensate the inventor by giving him rights to subsequent inventions by others that used the law of nature governing electromagnetic waves.”<sup>117</sup>

As with electromagnetic waves in *Morse*, it is not the case that all patents relating to genes should be disallowed. Indeed, patents over particular genetic tests or patents relating to a particular method of studying genes further the goals of the patent system because such patents leave room for innovation. When a company is permitted to patent a genomic sequence, other companies are no longer permitted to research that sequence in any way. So not only are they prohibited from creating new genetic tests and therapies, but companies are not permitted to research the genes without approval from the patent holder. Thus, researchers are not even allowed to analyze the correlation between mutated genes and breast cancer because they are not permitted to study the mutated genes. Furthermore, patenting the process of recognizing a correlation seems to patent abstract thought as well. The consequences of this patent are quite analogous to the consequences the Court feared in Morse’s time: Others are unable to develop new research technologies,

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115. Brief for March of Dimes Foundation, *supra* note 103, at 18 (“The key to this balance—which distinguishes human-made inventions from products of nature and laws of nature—is the recognition that there are interests in promoting innovation on *both* sides of any patent.”).

116. *Id.* at 19–20 (“Patents on products of nature, like gene sequence patents, take information out of the public domain rather than putting ideas into the public domain as is the intention of the Constitution and of the patent disclosure provisions.”); see also Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 41 U.C. DAVIS L. REV. 117, 220 (2007) (“[A]lthough the patent system currently grants gene discoveries the same broad claim scope as a traditional invention, patent law has left no room for competition. The first gene researcher to isolate and purify a gene blocks any second-arriving researcher from independently trying to purify and isolate the gene.”).

117. See *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 120–21 (1853).

new genetic testing strategies, and even new ideas regarding how best to treat breast and ovarian cancer.<sup>118</sup> This prohibition on thinking about information and excluding relevant laws of nature from the public domain does not seem tenable.<sup>119</sup>

#### 4. The Formidable Counterargument: Gene Patents Are Not So Different After All

Some legal scholars assert that genes are patentable. Courts, too, have recognized the patentability not only of isolated and purified microorganisms<sup>120</sup> but also of purified DNA sequences as well.<sup>121</sup> In reality, this is the greatest hurdle for those opposed to gene patents, including the ACLU.

The primary argument for the patentability of genes is that scientists work on gene sequences, just like any other inventor works on an invention. Scientists do not just pull a gene sequence out of thin air, send it in to the lab, and claim to have a patent. Any time a patentee applies for a patent for a gene sequence, that process requires: “isolating DNA, purifying DNA, removing a small segment of the DNA from its place in the genome and connecting it to bacterial DNA, chemically unwinding DNA, and constructing radioactive or florescent copies of the genomic DNA fragment.”<sup>122</sup> The process essentially involves making a copy of that genetic sequence.<sup>123</sup> To be clear, scientists are not receiving patents over, for example, a procedure in which they have discovered the method of isolating and purifying genetic sequences. However, some scientists have argued that this process should be granted patent protection because it is difficult and time consuming to isolate and purify genetic sequences.

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118. Brief for March of Dimes Foundation, *supra* note 103, at 16 (“Myriad’s claims are similar to a method of estimating the risk of heart attack on the basis of measurements of blood pressure. Such a claim, like Myriad’s methods claims here, preempts all uses of a particular law of nature.”).

119. *Id.* at 11 (“Similarly, laws of nature, such as bare correlations between a gene sequence and a disease, are not patentable. ‘[R]ecognition of a theretofore existing phenomenon or relationship carries with it no rights to exclude others from its enjoyment.’” (quoting *Parker v. Flook*, 437 U.S. 584, 593 n.15 (1978))).

120. See, e.g., *Parke-Davis & Co. v. H.K. Mulford & Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911) (upholding the validity of a patent over purified adrenaline).

121. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1218–19 (Fed. Cir. 1991).

122. Annabelle Lever, *Is It Ethical to Patent Human Genes?*, in *INTELLECTUAL PROPERTY AND THEORIES OF JUSTICE* 246, 247 (Axel Gosseries, Alain Marciano & Alain Strowel eds., 2008).

123. Liivak, *supra* note 116, at 192 (“Patent law has yet to contend with the fact that the resulting purified and isolated DNA molecules at the heart of these patents are the result of copying a naturally occurring molecule. The gene discoverer uses a naturally occurring DNA molecule as the template for making their patented purified and isolated gene sequence.”).

The Federal Circuit in *Amgen, Inc. v. Chugai Pharmaceutical Co.*,<sup>124</sup> agreed with those who favor gene patents. In *Amgen*, the court determined that isolated DNA encoding erythropoietin was patentable. The court stated that because genetic sequences do not appear in their natural state, as isolated and purified genetic sequences are modified from how gene sequences occur in nature, the sequences could receive patent protection.<sup>125</sup> Explicitly, the court held that “[a] gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it.”<sup>126</sup> The court recognized that a gene itself could not be patented, because it is a natural phenomenon.<sup>127</sup> However, the court determined that there was a clear distinction between gene sequences and gene sequences that had been isolated and purified.<sup>128</sup> Perhaps an even more persuasive argument is that, in addition to isolating and purifying a gene sequence, one must state the utility of that gene sequence to obtain a patent. Because the utility of a gene sequence is something that cannot be determined if a gene sequence is not isolated and purified, there is some merit to the argument that the scientific process of isolating and purifying gene sequences is relevant.

#### E. The Impact of Gene Patents

##### 1. The Alleged Negative Impact of Gene Patents

There are many arguments in opposition to gene patents, which is why they have been controversial since their inception. The primary arguments are that patenting genes can be seen as “playing God” and that gene patents hinder scientific research, limit the availability of genetic testing, result in a monopoly that keeps patients from receiving second opinions for test results from genetic testing, and discourage innovation.

First, perhaps one of the most popular arguments, albeit probably the least legally sound, is that patenting genes is playing God and that genes are sacred.<sup>129</sup> This argument becomes more persuasive when critics point to the slippery slope

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124. 927 F.2d 1200 (Fed. Cir. 1991).

125. Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 TEX. INTELL. PROP. L.J. 221, 230 (2003) (citing *Amgen*, 927 F.2d at 1218).

126. *Amgen*, 927 F.2d at 1206.

127. *Id.* at 1214.

128. *Id.* at 1206.

129. See Bryan J. Boyle, Comment, *Fishing for Utility With Expressed Sequence Tags After In re Fisher*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 589, 590 (2007).

surrounding gene patents: If the USPTO continues to permit the patenting of things that occur in nature, the USPTO might similarly permit many more patents over objects that should not be worthy of patent protection. If we allow something into the property system that seemingly does not belong, what is next? Shall we patent kidneys?<sup>130</sup>

Second, critics of gene patents claim that they limit scientific research and progress. Traditionally, patents were useful scientific tools because they encouraged people to assemble new products from the results of prior efforts. However, when scientists are barred from working with an entire genetic sequence, further research becomes impossible.<sup>131</sup> In the *Association for Molecular Pathology* case, for example, the only scientists who have the option of studying BRCA-1 and BRCA-2, which are most likely to lead us to information about a cure for breast cancer, are those who work for Myriad Genetics. Understandably, because of the threat of infringing on another entity's patent, a great deal of research has ceased, as scientists do not want to face the threat of paying damages for patent infringement by carrying on their study.<sup>132</sup> This keeps scientists from publishing even research articles that state a "direct correlation between a measurement and a natural phenomenon."<sup>133</sup> While some claim that this is not the norm, research has grown significantly more expensive because of gene patents and the need to conduct patent searches.<sup>134</sup>

Others claim that the limitations on research are even more severe, mainly because of the requirements of the USPTO. The USPTO requires that patent applications remain confidential for at least eighteen months after filing.<sup>135</sup> This has many implications for genetic researchers. For example, if a genetic researcher were studying the genes that contribute to Parkinson's disease, this research would take a great deal of time to conduct. By comparison, isolating and purifying a gene sequence takes very little time. If a biotechnology

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130. *Id.*

131. *See id.*

132. Gaia Bernstein, *In the Shadow of Innovation*, 31 CARDOZO L. REV. 2257, 2295 (2010).

133. Brief for Amici Curiae Affymetrix, Inc. & Professor John H. Barton in Support of Petitioner at 25, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006) (No. 04-607), 2005 WL 3597814.

134. *See* Bernstein, *supra* note 132; *see also* KOEPSSELL, *supra* note 30, at 18 ("Patents can have a chilling effect as each potential area for study must now be thoroughly researched not just within the scientific literature, but also through a patent search to see who owns what parts of the segment of the genome one wishes to study.")

135. Darnovsky & Reynolds, *supra* note 36 ("For example, the Human Genome Project website points out that because U.S. patent applications must remain confidential for 18 months after filing, researchers who use genetic sequences 'risk facing a future injunction if those sequences turn out to be patented by a private company.'").

company were to isolate and purify the genes related to Parkinson's disease, and apply for a patent, then the researcher's work would have been in vain. Not only would the researcher have to stop conducting research upon learning of the company's ownership of a patent over the genes, but the eighteen months of work the researcher conducted while the patent was under review by the USPTO—as well as the time spent before the patent was filed—would all have been wasted. In short, the implication is that scientists are less likely to research gene sequences because of the threat of an injunction.

There is also an example that applies to the instant case. When the European Patent Office granted Myriad Genetics its patents over the BRCA-1 and BRCA-2 genes, it received tremendous opposition from the Institut Curie and other European laboratories because those groups had developed genetic tests for the BRCA-1 and BRCA-2 genes that were more effective than the one Myriad Genetics offered.<sup>136</sup> After the patent, not only were the tests disallowed, but further research by those companies was also disallowed, meaning that their efforts had gone to waste. This is especially problematic because those groups were able to show that the Myriad test, in comparison to their more recent tests, missed 10 to 20 percent more of expected mutations.<sup>137</sup> Yet it is that less effective test that is offered today.

Furthermore, allowing gene patents limits scientific research because the structure of the patent system encourages patent holders to obtain exclusive rights over one gene by finding one particular function. But in reality, gene expression usually involves many complex interactions with other genes, so this approach makes little sense.<sup>138</sup> The nature of the system therefore inhibits scientists' ability to work cooperatively to obtain cures.

Third, one of the greatest problems with gene patents, at least from the general public's perspective, is that patents limit the availability and accessibility of genetic testing, which is often required to assess one's susceptibility to heritable diseases. Where one company, like Myriad Genetics, has a monopoly over an entire genomic sequence, the cost of genetic testing is extremely high, usually not covered by insurance, and is therefore not accessible to most of the

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136. Williams-Jones, *supra* note 74, at 138–39.

137. *Id.* at 139. While the Myriad test is effective and can often determine whether someone is likely to develop breast or ovarian cancer, it does have some instances of false negatives. Institut Curie's more recently developed test has fewer false negatives.

138. See GRAHAM DUTFIELD, INTELLECTUAL PROPERTY, BIOGENETIC RESOURCES AND TRADITIONAL KNOWLEDGE 22 (2004) ("Furthermore, as some critics point out, gene function is so complex that treating genes as patentable inventions on the basis of a single discovered function is more a reflection of ignorance than of insight.").

American public.<sup>139</sup> To be fair, insurance coverage is typically denied regardless of patent status, but because the economic incentive to obtain a patent drives the price of genetic tests, such tests are still expensive and not covered. With regard to Myriad's test offered, it is estimated that the test could easily be offered for \$1000, but Myriad's patent "has kept the cost of the test for BRCA1 and BRCA2 unreasonably high . . . priced at more than \$3000 [such that] some women who need it can't afford it."<sup>140</sup>

Fourth, critics assert that even when women can find a way to pay for the Myriad Genetics test, because of the monopoly, they cannot get a second opinion to assess the need for what are often life-saving procedures.<sup>141</sup> For example, when a woman learns from the Myriad test that she does not possess a genetic mutation under the BRCA-1 and BRCA-2 gene, she walks away from the possibility of treatment, even when she may actually possess the genetic mutation. Many women with a long family history of breast cancer may feel less than confident in the result, and yet there is no means of verifying the accuracy of the test.

Fifth, critics claim that gene patents cut against the purpose of patent law, which is to encourage innovation.<sup>142</sup> When the patent statute was first created, the founding fathers recognized that there needed to be some incentive for scientific creation but that such an incentive must be balanced with the ability to take new inventions, build on them, and make greater progress. Allowing patents over entire genetic sequences, however, alters that balance because innovation is no longer possible. If an entire sequence has been closed off from research for twenty years, the only person who can build on one's success is the patentee. These limitations on research undeniably affect the public interest. The public, indeed, has a strong interest in ensuring that patents are kept in their proper scope such that research can flourish.<sup>143</sup>

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139. Cynthia Ramnarace, *BRCA Genetic Testing: What You Need to Know*, EVERYDAY HEALTH, <http://www.everydayhealth.com/breast-cancer-awareness/brca-gene.aspx> (last visited Mar. 3, 2011).

140. Darnovsky & Reynolds, *supra* note 36.

141. Danny Townsend, *Myriad Genetics Can't Patent a Breast Cancer Gene*, SLATE, Apr. 7, 2010, <http://www.slate.com/id/2250082>.

142. See Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403, 405 (2005); see also Alan Devlin & Neel Sukhatme, *Self-Realizing Inventions and the Utilitarian Foundation of Patent Law*, 51 WM. & MARY L. REV. 897 (2009).

143. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 806 (1945) ("The far-reaching . . . consequences of a patent give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from . . . inequitable conduct and that such monopolies are kept within their legitimate scope.").

## 2. The Proponents' Response as to Why We Need Gene Patents

Despite opposition, the USPTO still allows gene patents. Proponents have offered several valid arguments as to why gene patents should continue. First, regarding limiting research, proponents of gene patents assert that gene patents further research. They provide an incentive for researchers to continue their work. Without patents, proponents claim, remarkable breakthroughs in medical technology would never have come.<sup>144</sup> Even if genetic research were stymied with expansive gene patents, research would not exist at all if there were no financial incentive. Because the very purpose of patent law is innovation,<sup>145</sup> they claim, we should encourage innovation in the sciences by permitting patents.

Furthermore, proponents point to the clear financial interests in gene patents. The financial incentive behind genetic research was demonstrated in March 2000, when President Bill Clinton and British Prime Minister Tony Blair issued a joint statement applauding the Human Genome Project's decision to "release raw information about the human DNA sequence and its variants rapidly into the public domain."<sup>146</sup> Immediately following the announcement, the stock prices of genetic research companies plunged.<sup>147</sup>

Second, proponents of gene patents argue that researchers who incidentally use patented genes in their research should have nothing to fear from the patent regime.<sup>148</sup> If one is simply performing research and will not interfere

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144. See Jim Greenwood, *Opposing View: Patents Promote Innovation*, USA TODAY, June 16, 2009, at 9A ("Even so, banning patents on gene-related breakthroughs would slow biomedical innovation to a halt—taking away the hope biotechnology offers to patients suffering from debilitating diseases such as cancer, Parkinson's and HIV/AIDS—while doing nothing to address what is really a much more complicated set of issues."); see also Geoffrey M. Karyn, *In Defense of Gene Patenting: The Principles of Our Patenting System Are Sound and Bring Immense Benefits*, GENETIC ENG'G & BIOTECH. NEWS, Apr. 1, 2007.

145. Mark Sagoff, *Some Patents on Genes Are Acceptable*, in GENETIC ENGINEERING: OPPOSING VIEWPOINTS 172, 174 (James D. Torr ed., 2001) ("[P]atents serve the utilitarian purpose of encouraging technological progress by offering incentives—temporary commercial monopolies—for useful innovations. One could argue, as the biotech industry does, that these temporary monopolies are not intended to recognize individual genius but to encourage investments that are beneficial to society as a whole.").

146. Darnovsky & Reynolds, *supra* note 36.

147. *Id.* (noting that Celera, Incyte, and Human Genome Sciences were among the research companies).

148. Karyn, *supra* note 144 ("As a practical matter, however, academic scientists who ignore patent rights have little to fear. The vast majority of patent owners simply do not want the adverse publicity of suing scientists and their universities, and the economic recovery is seldom worth the effort and money spent.").

with the financial incentives behind the patents, proponents claim, patent holders are highly unlikely to sue for infringement.<sup>149</sup>

Third, gene patent supporters assert that these patents prevent wasteful duplication of research, because there are not two groups of scientists working on the same project for many years.<sup>150</sup> Instead, the work can be shared.

Finally, from a free speech perspective, supporters of gene patents point out that one benefit of patent law is the disclosure of information to the rest of the country. That is, patent applicants must detail the patent and disclose it via the USPTO in order to obtain exclusive rights.<sup>151</sup> Thus, additional information is released into the public sphere and further discoveries can be made.

### 3. The Middle Ground

Both proponents and critics of gene patents make compelling arguments, but neither seems to be entirely correct. The problem with much of the scholarship surrounding gene patents is that the ability to patent genes is viewed as an either/or scenario. Proponents of gene patents insist that we should completely allow all patents relating to genes, even if it means patenting a gene itself. Opponents, on the other hand, demand that patents should be completely banned. A more reasonable approach would reach some sort of middle ground. It is almost certainly true that removing financial incentives entirely would hinder genetic research, which suggests that some form of patenting should be allowed. However, the current system goes too far in allowing patents over genomic sequences themselves. A balance would allow patenting some things that are useful to science (such as newly developed genetic tests), while preserving information that should be accessible to researchers (the ability to compare nucleotides as they naturally appear on a gene).

## II. THE EVALUATION OF THE ACLU'S ARGUMENT

### A. The ACLU's Novel Approach: Using the First Amendment

Because a legislative solution to the problem of gene patents has been unavailable, opponents of gene patents are advancing new arguments. The

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149. *See id.*

150. *Genetics and Patenting*, HUMAN GENOME PROJECT INFO. (Sept. 16, 2008), [http://www.ornl.gov/sci/techresources/Human\\_Genome/elsi/patents.shtml#4](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml#4) ("Wasteful duplication of effort is prevented.")

151. *Id.* ("Secrecy is reduced and all researchers are ensured access to the new invention.")

ACLU has fashioned a novel approach in its suit against Myriad, claiming that gene patents are unconstitutional on First Amendment grounds. Admittedly, the ACLU has included some of the previously attempted arguments in its complaint as well, such as the idea that gene patents do not meet the patent statute requirements, but this is the first attempt at invoking the First Amendment.<sup>152</sup> While some have been skeptical of the approach, this is “the first challenge supported by a large number of prestigious scientists who explicitly counter the argument that gene patents are needed for scientific progress.”<sup>153</sup> Moreover, although it seems that the ACLU seeks to ban gene patents altogether, a court decision on First Amendment grounds would likely provide the kind of balancing test necessary to differentiate between those gene patents that should be allowed and those that should be prohibited.

The ACLU’s argument is that “[t]he First Amendment protects the freedom of thought, academic inquiry, and the exchange of knowledge and ideas. Gene patents implicate the First Amendment because the very thought that there is a relationship between specific genetic mutations and diseases has been patented and because scientific inquiry is limited.”<sup>154</sup> Essentially, the ACLU makes the argument that patenting a basic research tool is a violation of the First Amendment because it restricts the free flow of information.<sup>155</sup>

## B. Making Sense of the First Amendment and Patent Law

Many seem understandably skeptical of invoking the First Amendment argument in discussions of patent law. While the two areas of law are typically not discussed in tandem, there is no doubt that the doctrines overlap. Indeed, scientific research has been described as a form of speech,<sup>156</sup> which is the first hurdle to invoking the First Amendment.

Patent law and the First Amendment intersect because patents are essentially a limitation on the marketplace of ideas. “Patents are not free market devices. They are government-sponsored monopolies. They are created

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152. Complaint, *supra* note 7, at 3.

153. Darnovsky & Reynolds, *supra* note 36.

154. *BRCA: Genes and Patents*, *supra* note 20.

155. See Schwartz, *supra* note 50 (“[T]he restrictions on competition that . . . Myriad . . . put in place—blocking alternatives to the patented tests, and even the practice of interpreting or comparing gene sequences that involved those genes— . . . started to look like . . . [a violation of the First Amendment].”).

156. Michael Davidson, *First Amendment Protection for Biomedical Research*, 19 ARIZ. L. REV. 893, 918 (1977) (stating that “most biomedical research is speech”).

to control the free marketplace of ideas and hand investors a unique, legal monopoly over every expressive token of their idea.”<sup>157</sup>

Until now, the relationship between patent law and the First Amendment has not been controversial because the two seem unrelated. Still, scholars have explained that “[i]n order to provide an incentive to innovate . . . the invention must be disclosed to the public. Freedom of speech and the right of the public to receive information is therefore specifically furthered by patent law.”<sup>158</sup> Indeed, as patents have traditionally been used, they have posed no problems to First Amendment rights. In fact, patents can be seen as furthering those rights because patents over new inventions force new information into the public domain through disclosure.

However, this symbiotic relationship between patent law and the First Amendment only exists when a patent is introducing something new into the public sphere. When a natural phenomenon is involved, patenting it takes information that previously existed in the public sphere and removes it. It is this removal of a natural phenomenon from the public domain that can constitute a violation of the First Amendment.

The courts have, at least on some level, recognized this conflict by holding that where information belongs in the public domain, it is not patentable.<sup>159</sup> The “[p]ublic domain is the universe of inventions and creative works that are not protected by intellectual property rights and therefore available for anyone without danger or whose patent or copyright has expired.” Thus, whenever an abstract idea is at issue, the courts have recognized that such information is not patentable because it violates the First Amendment.<sup>160</sup>

Additionally, there is some initial support for the notion that genetic material belongs in the public domain. The United Nations, for example, has adopted the position that “the human genome is the property of humanity

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157. KOEPEL, *supra* note 30, at 146.

158. Estelle Derclaye, *Intellectual Property Rights and Human Rights: Coinciding and Cooperating*, in *INTELLECTUAL PROPERTY AND HUMAN RIGHTS: ENHANCED EDITION OF COPYRIGHT AND HUMAN RIGHTS* 133, 158 (Paul L.C. Torremans ed., 2008).

159. See *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 6 (1966) (“Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.”); 1 JAY DRATLER, JR. & STEPHEN M. MCJOHN, *INTELLECTUAL PROPERTY LAW: COMMERCIAL CREATIVE AND INDUSTRIAL PROPERTY* § 2.03 (2010) (“From the founding of our nation, the . . . structure of intellectual property law has reflected this basic rule, consistent with the First Amendment’s guarantee of free speech: abstract ideas are nobody’s property. Rather, they inure to everybody’s benefit; they are the building blocks . . . with which future advances may be made.”).

160. *Id.*

[and] in its natural state can not give rise to any financial gains.”<sup>161</sup> The support of former President Bill Clinton and former Prime Minister Tony Blair for the Human Genome Project and their assertion that the human genome should belong to the public further support the notion that genetic information belong in the public domain.<sup>162</sup> Others argue that genetic information belongs in the public domain because the Human Genome Project. The Human Genome Project, a public project with the goal of sequencing the entire human genome, was funded by taxes.<sup>163</sup> None of the genes identified in the project were patented, and during the project, more than five million dollars of public funding went into locating the BRCA-1 gene.<sup>164</sup> If the taxpayers funded genetic research, surely they should also reap the benefits.

Thus, while some are skeptical of the ACLU’s argument, there is no doubt that courts, scholars, and political leaders have recognized the potential conflict between patent law and First Amendment law. Even if this conflict rarely comes to fruition, gene patents are clearly a case in which the public’s access to natural phenomena is limited by patenting information that belongs in the public domain.

### C. Applicable Strands of First Amendment Theory

Various theories of the First Amendment shed additional light on what information should be preserved in the public domain and therefore excluded from patent protection. The principal theoretical justifications for the First Amendment can be summarized as follows: (1) John Stuart Mill’s argument regarding the marketplace of ideas, which recognizes that in order for citizens of a democracy to weigh competing ideas and come to rational conclusions, they must have as much information as possible at their disposal; (2) the role of public discourse in a democracy, which is to encourage debate and deliberation and encompasses a speaker’s right to speak as well as the public’s right to listen; and (3) individual liberty and autonomy—that First Amendment

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161. Emilie Bouliong & Sandrine de Montgolfier, *Patentability and the Human Genome: Issues, Debates, and Controversies* (June 2000), <http://infodoc.inserm.fr/ethique/etheng.nsf/7adab9aba4615f8dc12569c9005670ca/9c2efd02ef7d19b580256b0b005f7731?OpenDocument> (quoting UNESCO, *Universal Declaration on the Human Genome and Human Rights* (Nov. 11, 1997)).

162. Brian Gargano, *The Quagmire of DNA Patents: Are DNA Sequences More Than Chemical Compositions of Matter?*, 2005 SYRACUSE SCI. & TECH. L. REP. 3, 16 (citing U.K. Prime Minister Tony Blair & U.S. President Bill Clinton, *Joint Statement to Ensure That Discoveries From the Human Genome Are Used to Advance Human Health*, Mar. 14, 2000, available at <http://www.genome.gov/10001356>).

163. BRCA: *Genes and Patents*, *supra* note 20.

164. *Id.*

freedom is not just a means to an end, but an end in itself for purposes of individual fulfillment. The argument that scientific researchers have First Amendment rights to conduct their experiments is largely supported by Mill's theory, whereas the argument that the public has a right to information regarding their own bodies is widely supported by the second theory relating to public discourse. Finally, though the argument for autonomy with regard this Comment argues that the value placed on autonomy by First Amendment to the First Amendment has been largely linked to the right of the speaker, theory also dictates encouraging speech that enables others to exercise autonomy and attain individual fulfillment.

1. Mill's Marketplace of Ideas Supports the Notion That Scientists Have a Right to Gather Information

Mill theorized that so long as there was a robust marketplace where information was free-flowing, citizens would be able to delineate between the good arguments and the bad.<sup>165</sup> The archetypal analogy to explain Mill's ideas compares ideas in society to apples on an applecart. Just as consumers are better able to recognize a pristine apple by comparing it to a bruised apple, citizens are better able to recognize good ideas by comparing them to bad ideas. The more ideas present in society, the better the results. Mill's approach is centered on the idea that, in order for democracy to function, citizens must be able to compare and contrast ideas in order to make informed decisions.<sup>166</sup> While some have suggested that Mill's idea of the marketplace of ideas applies only to political discourse, it is appropriate for scientific discourse as well. The idea of a free marketplace of ideas applies not only to public discourse generally but also more specifically to science and technology. For example, one reason why the United States has such a "dynamic research establishment" is that discourse regarding scientific research is vibrant in this country. "It does not behoove the courts to upset this singularly productive applecart without good reason."<sup>167</sup>

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165. See generally JOHN STUART MILL, ON LIBERTY (1859).

166. Phillip J. Cooper, *The Supreme Court, the First Amendment, and Freedom of Information*, 46 PUB. ADMIN. REV. 622, 623 (1986).

167. DRATLER & MCJOHN, *supra* note 159, § 2.03.

a. The Right to Know

Mill's argument for a robust marketplace of ideas rests on a presumption that knowledge is good for the public. It suggests a right to access knowledge in order to foster the marketplace.<sup>168</sup> Indeed, the courts have recognized that there is some right to knowledge.<sup>169</sup> More broadly, if the First Amendment protects a marketplace of ideas, it should also protect the generation of information to be included in the marketplace.

b. The Right to Gather Information

Because the public needs ample information in order to weigh competing ideas, First Amendment theory has traditionally supported a right of access to information necessary to further research.<sup>170</sup> The right to gather information has been recognized in other areas of First Amendment jurisprudence. Most notable has been the Court's recognition of a First Amendment right of the press to gather information. "The press has continually asserted its rights under the Press Clause as embodying the public's right to know . . . . [T]he public's right to know is the philosophical basis of many statutes that force government entities to provide documents on request or allow the public into meetings" so that the press can have unfettered access to such information and disseminate it to the public.<sup>171</sup> Thus, an underlying right to access this information, but when the public does not have the resources, "the press is the necessary representative of the public's interest."<sup>172</sup>

This argument is equally valid, if not more so, as applied to the scientific community. The general public has neither the educational background nor the resources necessary to compile and analyze complex scientific information.

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168. See Gary E. Marchant & Lynda L. Pope, *The Problems With Forbidding Science*, 15 SCI. & ENG'G ETHICS 376 (2009).

169. See *Griswold v. Connecticut*, 381 U.S. 479, 482–83 (1965) ("The right of freedom of speech . . . includes not only the right to utter or to print, but the right to distribute, the right to receive, the right to read and freedom of inquiry . . . . Without those peripheral rights the specific rights would be less secure.").

170. John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1217–18 (1977) (concluding that "[i]f the First Amendment serves to protect free trade in the dissemination of ideas and information, it must also protect the necessary preconditions of speech, such as the production of ideas and information through research").

171. Malla Pollack, *The Right to Know?: Delimiting Database Protection at the Juncture of the Commerce Clause, the Intellectual Property Clause, and the First Amendment*, 17 CARDOZO ARTS & ENT. L.J., 47, 69–70 (1999).

172. *Saxbe v. Wash. Post Co.*, 417 U.S. 843, 864 (1974) (Powell, J., dissenting).

It thus becomes scientists' role to gather this information and inform the public about new research and techniques that can improve its health and quality of life. Indeed, others have recognized the analogy between gathering information for scientific research and gathering news.<sup>173</sup>

c. Discouraging Censorship

The right to gather information is also apparent in the academic context, where many believe that the First Amendment serves as a vehicle to protect against censorship.<sup>174</sup> Just as we recognize that the public has a right to access information about the government via the press, we recognize that the public has a right to access more general forms of knowledge through free access to other reading materials. The right to access information is similarly tied to notions of autonomy and individual fulfillment, discussed in greater detail below.

d. The Right to Gather Scientific Information

Much as limitations on the press's ability to gather information can violate the First Amendment, expansive gene patents violate the First Amendment by limiting information that belongs in the public domain. It seems that the framers recognized the particular importance of scientific knowledge and inquiry, which suggests that they would have highly valued the right to gather scientific information.<sup>175</sup> Similarly, the American Bar Association has

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173. See Richard Delgado & David R. Millen, *God, Galileo, and Government: Toward Constitutional Protection for Scientific Inquiry*, 53 WASH. L. REV. 349, 378 (1978) (analogizing scientific research to newsgathering and arguing that scientists should receive at least as much free speech protection as journalists).

174. See W. Bernard Lukenbill & James F. Lukenbill, *Censorship: What Do School Library Specialists Really Know? A Consideration of Students' Rights, the Law and Implications for a New Education Paradigm*, 10 SCH. LIBR. MEDIA RES. (2007), [http://www.ala.org/ala/mgrps/divs/aasl/aaslpubsandjournals/slmrb/slmrcontents/volume10/lukenbill\\_censorship.cfm](http://www.ala.org/ala/mgrps/divs/aasl/aaslpubsandjournals/slmrb/slmrcontents/volume10/lukenbill_censorship.cfm); see also Marc Jonathan Blitz, *Constitutional Safeguards for Silent Experiments in Living: Libraries, the Right to Read, and a First Amendment Theory for an Unaccompanied Right to Receive Information*, 74 UMKCL. REV. 799 (2006).

175. The framers of the U.S. Constitution discussed the sacred nature of scientific inquiry. Gary L. Francione, *Experimentation and the Marketplace Theory of the First Amendment*, 136 U. PA. L. REV. 417, 428 (1987); see also Roy G. Spece, Jr. & Jennifer Weinzierl, *First Amendment Protection of Experimentation: A Critical Review and Tentative Synthesis/Reconstruction of the Literature*, 8 S. CAL. INTERDISC. L.J. 185, 213, 218 (1998) (arguing that scientific experimentation should enjoy First Amendment protection because the scientific method fits uniquely within the marketplace of ideas or, alternatively, because that experimentation is "uniquely and powerfully facilitative of highly valued thought").

recognized that scientific research is worthy of First Amendment protection.<sup>176</sup> Some have even gone so far as to say that scientific research does not just deserve First Amendment protection; it deserves even greater protection than other forms of speech.<sup>177</sup>

When a natural phenomenon is taken out of the public domain, the search for truth is severely limited. Mill would surely support traditional patents, which add information to the public domain through mandated disclosure. With these patents, information that did not previously exist, such as a concept or design for a new computer part, must be released into the public domain with the hope that future engineers will develop an even better product. Patents over laws of nature, on the other hand, essentially take apples from Mill's applecart, keeping the public from seeing their bruises or comparing them with other apples. The ability to study and think further about a gene is simply precluded. Mill would likely find this troubling and antithetical to the search for truth.

## 2. The Role of Public Discourse in a Democracy

As discussed above, just as there is a right on part of scientists to conduct their research, there is a right on part of the public to have access to that information. *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*<sup>178</sup> recognized that consumers need access to information to make informed decisions when it comes to prescription drugs.<sup>179</sup> Similarly, consumers need access to information regarding their genes.

### a. The Public's Right to Listen

While typical First Amendment theory recognizes the speaker's rights to speak, scholars have, although somewhat less frequently, recognized the

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176. Zona F. Hostetler, *Report and Recommendation to the House of Delegates*, 2002 A.B.A. SEC. INDIVIDUAL RIGHTS & RESPONSIBILITIES, available at <http://www.abanet.org/irr/policies/committees/health/0802scientificknowledge.pdf> (claiming that First Amendment protection is warranted for scientific inquiry because such inquiry is "essential to the advancement of knowledge and the discovery of truth").

177. Steven Goldberg suggests that scientific research does not just require First Amendment protection but actually requires even higher protection than other forms of speech typically protected under the First Amendment. See Steven Goldberg, *The Constitutional Status of American Science*, 1979 U. ILL. L.F. 1, 1-7.

178. 425 U.S. 748 (1976).

179. *Id.* at 756-57.

hearer's right of hearers to listen.<sup>180</sup> The notion that scientists (speakers) have a right to gather information in order to contribute it to the public domain essentially recognizes the right of the speaker. However, free speech also confers rights on listeners, that is, the recipients and the public.<sup>181</sup> Indeed, the courts have recognized the importance of the free flow of information so that the general public can make informed decisions.<sup>182</sup>

b. The Public's Access to Information for Informed Decisionmaking

It makes sense that the courts would recognize a right of the general public to access information regarding their own bodies. It is only by having access to genetic tests, new treatments for diseases, second opinions, and the like, that people can make informed decisions regarding their medical care and other life choices. Without such information, the function of deliberation in democratic society is lost.<sup>183</sup> While the concepts of public deliberation and personal autonomy are distinct, gene patents show the interrelatedness of the two theories. Not only do people need access to information to participate in a democracy, but they also need access to information to make personal choices. However, the benefits of receiving information are distinct from the personal autonomy and individual fulfillment that are achieved by having a *right to listen*.

This argument finds further support in the commercial speech doctrine. The commercial speech doctrine is a strand of First Amendment theory that recognizes businesses' free speech rights. While businesses typically have fewer

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180. Pollack, *supra* note 171, at 70–71 (discussing scholarship detailing “multiple entitlements in the First Amendment, including the rights ‘to hear the views of others and to listen to their version of the facts,’ ‘the right to inquire,’ and ‘to a degree, the right of access to information’”).

181. See discussion, *supra* note 180. Alexander Meikeljohn similarly asserted that the First Amendment does not just extend to an individual's right to speak but also to a community's right to hear. See Frederick Schauer, *Must Speech Be Special?*, in *THE FIRST AMENDMENT: A READER* (John H. Garvey & Frederick Schauer eds., 1992); see also Cass Sunstein, *Beyond the Republican Revival*, 97 *YALE L.J.* 1539, 1549 (1988) (explaining the public's constitutional right to be informed so as to promote effective dialogue).

182. See Anthony Lewis, *A Public Right to Know About Public Institutions: The First Amendment as a Sword*, 1980 *SUP. CT. REV.* 1, 6 (“After *Lamont* it was clear, as the Court later explained, that where there is ‘a willing speaker,’ the First Amendment gives protection ‘to the communication, to its source and to its recipients both.’” (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756 (1976))); Cooper, *supra* note 166, at 623 (“In *Garrison v. Louisiana*, the Court underscored the need to protect ‘the paramount public interest in a free flow of information to the people.’”).

183. Pollack, *supra* note 171, at 67 (explaining that the United States was “founded [on] the resounding rhetoric of a public *need to know* [and] James Madison penned the famous matching bromides that ‘[k]nowledge will forever govern ignorance’ and ‘[a] popular government without popular information [ ] for the means of acquiring it is but a prologue to a farce or a tragedy or perhaps both’”).

speech rights than individuals or the press, the courts have recognized that even businesses have a right to disseminate information.<sup>184</sup> Importantly, however, a company's right to disseminate information was tied to the public's need to receive such commercial information.

In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, the seminal case involving the commercial speech doctrine, the Supreme Court analyzed the validity of a statute that limited pharmaceutical companies' First Amendment rights of pharmaceutical companies to advertise.<sup>185</sup> The Court determined that such a statute was unconstitutional on First Amendment grounds because it failed to allow accurate information about prescription drugs to be disseminated to the public.<sup>186</sup> Thus, although corporations possess free speech rights under the commercial speech doctrine, the Court premised these rights on the public's right to receive information. Indeed, unlike most individual speech, for commercial speech to be protected, it must be neither false nor misleading. Thus, the primary interest motivating the commercial speech doctrine is not the speaker's right, but the right of the listener—which is advanced only insofar as the information conveyed is accurate.

Thus, just as the courts would recognize a preference for the dissemination of more (accurate) information about prescription drugs, the courts should also recognize a preference for more information on bodies and genetic makeup, which would lead to individuals taking greater initiative in seeking treatment and preventative healthcare.<sup>187</sup> While there are undoubtedly some limits to how patent protection should be relaxed in favor of the public interest, there is definitely a need to improve access to information. The problem inherent in the current Myriad Genetics controversy highlights the imbalance in the status quo. While it may be true that no one has the right to any and all information and patents relating to healthcare, the notion that one company could have a monopoly over a particular gene relating to a specific disease is troubling. The current monopoly both limits the functioning of Mill's marketplace of ideas and stifles the discourse pertaining to healthcare and scientific research. Thus, balance needs to be restored. While companies should be

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184. Bruce E.H. Johnson, *Advertising and First Amendment in Speech*, FIRST AMENDMENT CTR., <http://www.firstamendmentcenter.org/speech/advertising/overview.aspx> (last visited Mar. 3, 2011).

185. 425 U.S. 748 (1976).

186. See *id.* at 748.

187. See *BRCA: Genes and Patents*, *supra* note 20 (calling gene patenting "a civil liberties issue because gene patents undermine the free exchange of information and scientific freedom, bodily integrity, and women's health[, and i]n granting exclusive rights to gene patent holders, the U.S. government in essence gives those patent holders complete control over those genes and the information contained within them").

able to make new genetic tests and other lucrative medical discoveries, they should not be able to patent genes in ways that make medical care inaccessible to most Americans.

#### D. Autonomy and Individual Fulfillment

The final strand of First Amendment theory to be explored is that of autonomy and individual fulfillment. The traditional First Amendment argument with regard to autonomy has been that promoting the right of the speaker to speak contributes to autonomy and individual fulfillment.<sup>188</sup> Similarly, if research is a form of expression, scientific researchers may have the right to the individual fulfillment obtained by conducting their research.

Furthermore, the First Amendment may be valuable by promoting the individual fulfillment that comes from being able to listen. Applied to the case of gene patents, a right to attain autonomy and individual fulfillment by listening would correspond to a right to receive information about one's own body.<sup>189</sup> Julie Wallbank, for example, has proposed that children have a First Amendment right to access their genetic histories to further self-fulfillment and autonomy. Wallbank argues that a child's right to know his or her biological origins should take precedence over a parent's right to anonymity.<sup>190</sup> Similarly, Carolyn Burke has written of the adoptee's right to know his or her genetic origins based on adoptees' compelling psychological need to know their natural heritage.<sup>191</sup> While the argument based on the autonomy of the listener is the least established of the three First Amendment arguments advanced by the ACLU, and while it may be the least likely to be adopted by the Court, it seems the most logical and intuitively true, as it seems central to

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188. Thomas I. Emerson, *Colonial Intentions and Current Realities of the First Amendment*, 125 U. PA. L. REV. 737, 744 (1977) ("Not only was freedom of speech, press, assembly, and petition considered as a social good, essential for the progress of society, but it was also viewed as an important means for personal fulfillment.").

189. In a May press statement, ACLU Executive Director Anthony Romero stated: "Knowledge about our own bodies and the ability to make decisions about our health care are some of our most personal and fundamental rights. The government should not be granting private entities control over something as personal and basic to who we are as our genes." *OBOS Joins ACLU Lawsuit Challenging Breast and Ovarian Cancer Gene Patents*, OUR BODIES OURSELVES (June 4, 2009), <http://www.ourbodiesourblog.org/blog/2009/06/obos-joins-aclu-lawsuit-challenging-breast-and-ovarian-cancer-gene-patents>.

190. See generally Julie Wallbank, *The Role of Rights and Utility in Instituting a Child's Right to Know Her Genetic History*, 13 SOC. & LEGAL STUD. 245 (2004).

191. See generally Carolyn Burke, Note, *The Adult Adoptee's Constitutional Right to Know His Origins*, 48 S. CAL. L. REV. 1196 (1975).

the idea that people should have individual freedom and control over the protection and care of their own bodies.

### III. THE FIRST AMENDMENT STANDARD AND ITS APPLICATION

#### A. The Standard

While this Comment argues that the granting of gene patents should be restricted on First Amendment grounds, the argument is different from that advanced by the ACLU in *Association for Molecular Pathology*.<sup>192</sup> Rather than argue, as the ACLU does, that all gene patents are prima facie unconstitutional, this Comment suggests that patenting natural phenomena is unconstitutional.<sup>193</sup> Patents over natural phenomena violate the First Amendment by removing something from public discourse that was already there. Thus, the USPTO's current categorization of natural phenomena is incorrect to the extent that the USPTO regards isolated and purified gene sequences as inventions rather than natural phenomena. Therefore, the courts and the USPTO need additional guidance as to how to delineate what objects are patentable and what objects are out of bounds because they are natural phenomena.<sup>194</sup> Because the rationale for disallowing patents over natural phenomena is largely based on First Amendment grounds, First Amendment analysis can serve as a helpful lens for distinguishing when an object is a natural phenomenon and when it is not.

Thus, the USPTO infringes on First Amendment freedoms of scientists and the general public when it allows a patent over a law of nature. To combat this infringement, there are several tests the courts could use, depending on which interpretation of the First Amendment they find most applicable to gene patents. This Part explores two possibilities, strict scrutiny and the commercial speech doctrine.

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192. 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

193. See *First Nat'l Bank of Bos. v. Bellotti*, 435 U.S. 765, 783 (1978) (“[T]he First Amendment goes beyond protection of the press and the self-expression of individuals to prohibit government from limiting the stock of information from which members of the public may draw.”).

194. See Eileen M. Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN'S L. REV. 519, 541 (2006) (explaining that “a discussion and analysis of the subject matter that [the public domain] contains is essential”).

## 1. Strict Scrutiny

The USPTO and the courts could define natural phenomena based on strict scrutiny. Under this approach, gene patents would be regarded as content-based restrictions on speech.<sup>195</sup> When the government grants a monopoly on all speech with particular content (the content being the expression of the abstract idea in question), this constitutes a content-based restriction on everyone other than the patent holder. Content-based restrictions on speech warrant the use of strict scrutiny to determine if they are unacceptable limitations on the marketplace of ideas and thus prohibited under the Constitution.

For example, if the government were to have granted a patent over electromagnetic waves to Samuel Morse, the government would have restricted all other inventors and scientists from writing about the use of electromagnetic waves in the future. Because patents concern “every possible expression of an abstract idea” and are not content-neutral restrictions (that is, patents do not restrict particular media through which inventors’ ideas are shared, but restrict the sharing of ideas in general), patents are content-based restrictions on speech.<sup>196</sup> Accepting the idea that a patent is a content-based restriction on speech would require the government to prove that such a patent serves a compelling state interest, and that the patent is narrowly tailored to achieve that interest.<sup>197</sup>

## 2. Commercial Speech Doctrine

Alternatively, the courts and the USPTO could use a test and reasoning derived from the commercial speech doctrine. Under this approach, it would be unconstitutional to keep genetic information from the public because such information is beneficial to the public in making decisions about healthcare. The standard applied in commercial speech cases requires that (1) the interest in the restriction of speech is substantial; (2) the restriction directly advances the state interest; and (3) the restriction is narrowly tailored to

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195. See generally Brief for the ACLU as Amicus Curiae for Affirmance in Support of Appellee, *In re Bilski*, 546 F.3d 943 (Fed. Cir. 2008) (No. 2007-1130).

196. Violations of constitutional freedoms like the freedom of speech may be overcome only by a governmental objective of the highest order attainable in the least intrusive way. See *Press-Enterprise Co. v. Super. Ct. of Cal.*, 478 U.S. 1, 13–14 (1986).

197. Brief for the ACLU, *supra* note 195, at 13 (“Under strict scrutiny, [a restriction] may be saved only if it is narrowly tailored to promote a compelling government interest.” (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 582 (2001))).

meet that interest.<sup>198</sup> This test differs from strict scrutiny because it poses a much lower threshold for the government. While strict scrutiny requires the government to put forth a compelling government interest, the commercial speech doctrine requires only a substantial government interest.<sup>199</sup> For example, to meet the burden of showing that it has a compelling interest in enacting a regulation, the government must usually show that its interest is tied to the health, safety, and welfare of the people.<sup>200</sup> By contrast, substantial interests require a much lower showing, allowing lesser interests like aesthetics<sup>201</sup> and residential noise<sup>202</sup> to meet this test.

## B. Application of the Standard

### 1. Strict Scrutiny Applied

To test the viability of this standard, we examine two objects that should be classified as natural phenomena: the BRCA genes and electromagnetic waves. Then, we will look at three objects that should meet the requirements of patent law: a test for determining the likelihood of developing breast cancer, the telegraph, and Google's mathematical algorithms.

#### a. Strict Scrutiny Applied to Natural Phenomena

Applying the strict scrutiny standard to patents of natural phenomena, the first question is whether the state can advance a compelling interest for awarding the patents. In almost any patent case, the state will likely advance the interest in recognizing personal property rights and promoting innovation, which scholars Jason Schultz and Corynne McSherry have hypothesized would qualify

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198. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 748 (1975).

199. *Va. State Bd. of Pharmacy*, 425 U.S. at 771, 774, 776 (referring interchangeably to a substantial government interest and a significant government interest in describing the test for the commercial speech doctrine).

200. The archetypal compelling government interest is national security. See *Korematsu v. United States*, 323 U.S. 214 (1944) (justifying the internment of Japanese Americans during World War II by identifying national security as a compelling governmental interest).

201. See *City of Ladue v. Gilleo*, 512 U.S. 43, 48 (1994) (recognizing a substantial government interest in maintaining the aesthetics of a neighborhood).

202. See *Ward v. Rock Against Racism*, 491 U.S. 781, 800 (1989) (recognizing that there was a substantial government interest in regulating loud music played near a residential area).

as compelling.<sup>203</sup> However, any patent over a natural phenomenon should fail the narrowly tailored test. When someone tries to patent a nonpatentable object, his or her claim cannot be narrowly tailored because by patenting things that are understood as outside the scope of patent law, a patentee's claim is too broad. For example, ideas are nonpatentable objects akin to natural phenomena (one cannot patent the idea of comparing a genotype and a phenotype). Some have recognized that when a patent attempts to claim ownership of an idea, this does not meet the narrowly tailored prong of the strict scrutiny test.<sup>204</sup> Thus, where a patent is awarded over a natural phenomenon, it is overly broad and fails the narrowly tailored prong.

With the BRCA gene, for example, the claim is overly broad because it restricts speech by failing to allow others to study correlations between naturally occurring genes and diseases, and by limiting scientists' ability to search for other potential functions of the BRCA genes.

Similarly, with electromagnetic waves, the claim is overly broad, as the Supreme Court explained, because it would either overcompensate Samuel Morse for his invention by giving him rights to others' potential future inventions or would restrict others from inventing additional uses for electromagnetic waves. The second scenario seems to be of greater concern. The problem is that if patent holders *know* that their inventions are crucial to further others' research, they can set the licensing prices exorbitantly high, hindering future innovation. In effect, awarding Morse a patent over electromagnetic waves could have stalled any innovation based on the telegraph for twenty years, possibly delaying the invention of the telephone, cellular telephone, text messaging and so on—unless Morse altruistically granted other scientists the ability to research electromagnetic waves. As *Association for Molecular Pathology* shows, companies like Myriad Genetics are not typically so generous in licensing to allow further research—nor even in pricing their own products to make them available to the public at a reasonable price.

#### b. Strict Scrutiny Applied to Patentable Objects

Applying strict scrutiny standards to items that are not natural phenomena, however, would produce different results. The compelling interest, for

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203. Brief for the ACLU, *supra* note 195, at 12; Jason Schultz & Corynne McSherry, *Patent Injunctions and Speech Technologies* 11 (unpublished working paper), available at [https://www.law.berkeley.edu/files/Schultz\\_McSherry2.doc](https://www.law.berkeley.edu/files/Schultz_McSherry2.doc) (explaining that the Intellectual Property Clause supports upholding a compelling government interest in encouraging innovation).

204. Brief for the ACLU, *supra* note 195, at 13.

the most part, would be the same. Patent holders would still suggest, correctly, that there is a compelling government interest in promoting innovation and thus in allowing patent holders to reap financial rewards for their efforts. With regard to the narrowly tailored prong, however, courts would likely find that patents over true inventions are not as overbroad as patents over natural phenomena would be.

Take, for example, a test for determining the likelihood of breast cancer. A patent over such an object would not be overly broad because it would simply be introducing a test into the public sphere. Researchers could still study the breast cancer gene. They could search for other potential functions of the gene. They could even formulate newer and more effective tests (such as the test created by the Institut Curie) in order to improve on the invention.

A similar analysis would apply to the telegraph. Morse would be able to put forth his invention and yield a significant profit, but others would still be able to study electromagnetic waves, learning more about their presence and potential applicability to other forms of communication like the telephone or television.

Finally, to take another, more modern example, it is clear that Google's mathematical search algorithms could also constitutionally be patented.<sup>205</sup> Allowing Google to patent its algorithms has encouraged innovation by providing Google with substantial profits in reward for putting a substantial amount of information at people's fingertips. Notably, Google was not able to patent, for example, the ability to conduct searches. Other companies, such as Yahoo and Microsoft's new Bing, have introduced their own search engine technologies. Their presence has spurred Google's continued innovation and improvements in its original product. Awarding the initial patent over Google's algorithms meets the narrowly tailored prong because it was limited enough in scope that it allowed these other developments to occur.

Evaluating all of these claims through the lens of strict scrutiny shows that when a patent is not overly broad but is sufficiently narrowly tailored to achieve the compelling interest in innovation, an opportunity arises for future innovators.

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205. Technically, the patent is owned by Stanford University, though Google owns all licensing rights to the patent. See Lisa M. Krieger, *Stanford Earns \$336 Million Off Google Stock*, SAN JOSE MERCURY NEWS, Dec. 1, 2005; see also U.S. Patent No. 6285999 (filed Jan. 9, 1998).

## 2. The Commercial Speech Doctrine Applied

### a. The Commercial Speech Doctrine Applied to Natural Phenomena

A second approach would be to examine patents through the lens of the commercial speech doctrine.<sup>206</sup> This would first require that the interest in restricting speech is substantial. Because a substantial interest is a lower standard than a compelling interest, it would undoubtedly be met with regard to nearly every patent applicant. The next prong requires that the restriction directly advances the state interest. Here, those objecting to patents over natural phenomena could rightfully claim that no one can invent around a natural phenomenon. That is, inventors cannot “create” a new gene. Any subsequent invention based on a gene would be a patentable object (such as diagnostic test, therapeutic treatment). Such inventions would use the understanding of genes to encourage innovation but would not actually improve upon genes. Therefore, patents over natural phenomena can never further the government interest in innovation. Of course, patent holders could argue that patents promote innovation in general, but this argument would likely not prevail, just as in *Morse*.<sup>207</sup> Moreover, the patents would be more extensive than necessary because they would restrict so much information and science from purposeful use in the future.<sup>208</sup> Thus, the commercial speech doctrine would almost certainly limit the use of patents over laws of nature.

### b. The Commercial Speech Doctrine Applied to Patentable Objects

Unlike natural phenomena, true inventions—like a test for determining the likelihood of developing breast cancer, the telegraph, and Google’s mathematical algorithms—would pass the commercial speech doctrine test. All three examples demonstrate the significant interest in promoting innovation. The test for breast cancer would encourage additional, more accurate tests and would

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206. While many conceive of the commercial speech doctrine as applying only to corporations, the commercial speech doctrine can apply both to individuals and corporations. See *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 764 (1976) (“[S]ociety also may have a strong interest in the free flow of commercial information. Even an individual advertisement, though entirely ‘commercial,’ may be of general public interest.”). The commercial speech doctrine requires that the speech in question have the motive of obtaining a profit. It is irrelevant who is attempting to earn such a profit, whether an individual or a corporation.

207. 56 U.S. (15 How.) 62 (1853).

208. See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 580 (1979).

potentially encourage treatments to fight breast cancer. The telegraph would advance future inventions (as it did), such as the telephone, and Google's mathematical algorithms have encouraged additional innovation for search engines. Moreover, the restrictions are not more extensive than necessary because they only limit a monopoly over that particular invention for twenty years. In those twenty years, however, inventors are not prohibited from "inventing around" the particular invention. In other words, once something has been patented, an inventor can improve upon the patented object without infringing a patent.

The same is not the case with natural phenomena, as one would not be able to "invent around" the BRCA genes by creating a new gene. If an inventor were to create an object such as a diagnostic test based on his or her knowledge of the BRCA gene, however, then this would be a patentable object. Thus, while patents over natural phenomena will fail the commercial speech doctrine test, patents over traditional inventions will not.

The application of the strict scrutiny and commercial speech tests to these five objects suggests that in either case, because of the presence of a narrowly tailored prong, a law of nature should always fail First Amendment scrutiny, and a patentable object should always pass the test. Thus, First Amendment analysis can serve as an effective lens for determining whether an item is, in fact, a law of nature.

### C. Arguments Against the Use of the First Amendment

Critics may argue against the usefulness of the First Amendment as a lens for determining whether an object is a natural phenomenon. Three arguments that could be advanced are: (1) it is difficult to determine from the onset which inventions will serve a government interest; (2) the patent office does not need an additional mechanism for determining whether something is patentable; and (3) the First Amendment sets too high a threshold.

The primary counterargument advanced against the use of the First Amendment for determining when patents should be granted is that it may be difficult from the outset to determine whether something will further a significant or compelling governmental interest. While "encouraging innovation" is not the only potential interest the government could advance, it is highly likely that this would be the interest in question. How is one to know, before patenting, whether his or her project will lead to more innovation?

While this is a worthy argument, this is a problem that pervades all law. For example, if the government passes a restriction that forbids handing out flyers in a park in the hope of limiting clutter, it is impossible to know from the

outset whether this regulation will actually achieve the government's goal. Perhaps frequenters of the park will instead start handing out posters or some other material that causes clutter, and the interest would not be achieved. However, the government does not refrain from passing regulations simply because it is unsure of whether the interest will ultimately be achieved. Rather, by looking to prior examples, the government can at least gauge the likelihood of whether the interest will be achieved. This is, of course, imperfect, but history can provide some guidance. Similarly, by looking to prior inventions, the patent office can gauge whether a potentially patented object is likely to encourage innovation. While this is not a perfect solution, it provides more guidance than is available under the current test.

Another argument that could be advanced is that it makes no sense to force upon the courts a new method for determining natural phenomena, as the courts can look to case law and existing patents to decide whether something should be classified as a natural phenomenon. Theoretically, the First Amendment could become an unnecessary additional step in the courts' analysis and could just muddle the patent classification system.

However, this argument is flawed. The argument that the USPTO and the courts need no special mechanism for determining natural phenomena fails because the USPTO is currently not adequately categorizing patent applications. It is understandable that categorization would be difficult for the USPTO because gene patents, and patents over naturally occurring objects in general, are relatively new to the patent scene. The USPTO has not had a significant amount of time to revise its practices. However, there is something wrong when the USPTO allows patents over entire genes and genomic sequences. Thus, because the rationale for excluding laws of nature from patent protection is based on the argument that patents should not remove information from the public sphere, the First Amendment can serve as a helpful guideline. Moreover, the First Amendment forces the USPTO to focus its attention on why something is to be classified as a law of nature, rather than just blindly extending patent protection.

Additionally, some could argue that the First Amendment simply imposes too high a bar for patents, as the threshold for passing strict scrutiny is extremely high. It might thus be argued that the First Amendment would restrict the USPTO from granting patents that should be granted. However, the idea that applying the First Amendment might exclude many items from patent protection that should, in fact, be protected is a false one. Perhaps the largest difficulty with the First Amendment analysis is meeting the compelling interest (or substantial interest) standard. However, because scholars have agreed that

encouraging innovation is a compelling governmental interest—precisely because of the Intellectual Property Clause of the Constitution<sup>209</sup>—this is not an issue. The only real hurdle to be overcome is the narrowly tailored prong (or the idea that restrictions cannot be more extensive than necessary), and this is not likely to cause difficulty for items that are not natural phenomena.

In the end, any patent that can be invented around is narrowly tailored, and the real problem with natural phenomena is that they encompass so much information that they cannot be invented around. This problem is not present with patents that do not constitute natural phenomena. Therefore, anything that should receive patent protection but is related to a natural phenomenon, such as genetic tests, methods of evaluating genes, and medical treatments, will still receive patent protection.

Indeed, the real benefit of using the First Amendment to evaluate and limit gene patents is that it invokes a balancing approach instead of simply banning gene patents altogether. The approach that the ACLU favors seeks the elimination of gene patents, but this approach would be fundamentally undesirable. After all, as supporters of gene patents point out, patents are an important incentive to scientific research. Without a financial incentive, research would likely not be conducted. Just as genetics research is chilled under the status quo of broad gene patenting, it is foreseeable that there would also be significantly less—probably very little in the end—genetic research if all patents even tangentially related to naturally occurring genes were banned.

Nevertheless, the status quo has tipped the balance too far in favor of patent holders.<sup>210</sup> To a large extent, this has harmed the rights of scientists and the public. Thus, a system needs to be devised that could actually give patent credit where credit is due, while limiting the presence of gene patents in general. In this regard, a balancing approach seems particularly helpful because it could reward those inventions that seem deserving of patents, such as particular genetic tests and methods of analyzing genetic data, while limiting the use of gene patents that cover an entire genomic sequence and thereby prohibit the free flow of information.<sup>211</sup>

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209. See Schultz & McSherry, *supra* note 203.

210. See KOEPEL, *supra* note 30, at 18 (“But all bargains require balance, and at some point it is possible we went too far in favoring the rights of innovators over the necessity for public good. Intellectual property laws have changed over the past hundred years, shifting their focus away from moving innovations into the public domain . . .”).

211. Adejoke Oyewunmi, *The Right to Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma*, in PATENTING LIVES: LIFE PATENTS, CULTURE, AND DEVELOPMENT 53, 67 (Johanna Gibson ed., 2008) (“Ultimately, what is needed is a framework which strikes the right balance between the regulation of access and utilisation of biological resources and

In fact, it is precisely because the First Amendment does not require a ban on gene patents that it provides a workable standard. Prior attempts at fighting gene patents—such as claiming that all gene patents do not meet the requirements of the patent statute or that all gene patents cover natural phenomena—are problematic. Although they eliminate all of the problems of gene patents, these prior attempts failed to recognize some of the benefits of less expansive gene patents and discouraged scientific innovation.

### CONCLUSION

Because patents are currently allowed over naturally occurring genetic sequences, despite the prohibition against patents covering natural phenomena, something needs to be done. Using the First Amendment as a lens is one way to determine whether an object identified in a patent application should be classified as a natural phenomenon. This approach differs from the one advocated by the ACLU in a recent lawsuit against Myriad Genetics, which argues that gene patents should be disallowed in general because they are abstract thought not patentable according to the First Amendment. Instead, this Comment argues that the reason some gene patents should be disallowed is that they constitute laws of nature. Although natural phenomena are not patentable, gene patents seem to have slipped through the cracks at the USPTO. Examining the rationale for prohibiting patenting natural phenomena—that patents should not remove anything from the public domain—demonstrates that there is an underlying First Amendment protection against patenting natural phenomena. This argument is buttressed by evidence that overbroad gene patenting is already inhibiting potentially life-saving research by making it practically impossible for multiple researchers to pursue tests and remedies based on promising genes.

Thus, instead of allowing all patents under the sun or disallowing gene patents completely, courts and the USPTO can use the First Amendment as a lens for analyzing potential patents. By using the narrowly tailored prong, the courts and the USPTO will be less apt to grant patents over objects that remove information from the public domain. In this regard, the First Amendment can prevent future patents over laws of nature.

While there are other potential ways to address the gene patent problem, it seems that the First Amendment is an effective tool for allowing patents

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the protection of innovations and knowledge systems . . . without discrimination, while at the same time, taking care to put in public interest safeguards.”).

where they should be allowed and prohibiting patents that encompass natural phenomena. Using the First Amendment as a lens for determining laws of nature instead of banning gene patents altogether can restore balance to patent law.