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PATENTING THE HUMAN BODY: THE CONSTITUTIONALITY OF GENE PATENTS AND SUGGESTED REMEDIES FOR REFORM

Olga Bograd*

I. INTRODUCTION

LISBETH Ceriani wants to know her risk for ovarian cancer.1 Her physician told her that she could have a genetic predisposition to the disease, especially after being diagnosed with cancer in both of her breasts.2 The single mother, who is covered by a Medicaid insurance program for low-income citizens, sent her blood work to the only laboratory in the United States that is authorized to look at her genes and tell her if any mutations predispose her to the disease.3 The problem is that this laboratory will not accept her insurance, and she cannot afford the $3,000 test out-of-pocket.4

When faced with a similar problem, Rumi Limary switched insurance providers and finally obtained an analysis of her breast and ovarian genes from the exclusive laboratory, which informed her that she had a "genetic variant of uncertain significance."5 The laboratory does not look for all known mutations when analyzing breast and ovarian cancer genes, but at the same time, it is effectively blocking anyone else from looking.6 While Ms. Limary is willing to pay for more testing, no one can provide it because analyzing mutations in Ms. Limary's genes can bring liability for patent infringement.7

* J.D. Candidate, SMU Dedman School of Law, 2011. I thank my husband, Kyle, for introducing me to this intriguing topic and supporting me along the way.

1. Complaint at 10, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365 (S.D.N.Y. 2009) (No. 09 Civ. 4515), 2007 WL 1343027 (including a list of similarly situated plaintiffs); see also John Schwartz, Cancer Patients Sue Testing Company and Government Over Cancer Gene, N.Y. TIMES, May 13, 2009, at A16 (describing the predicament of another plaintiff). Genae Girard joined as a plaintiff when she was told she could not independently confirm her results from a Myriad laboratory, indicating she had a predisposition to ovarian cancer and thereby suggesting the need to get her ovaries taken out. Schwartz, supra.
2. Complaint, supra note 1, at 10.
3. Id.
4. Id.
5. Id.
6. Id.
7. Id.
Nearly twenty percent of human genes are patented under United States law. A large portion of these patents cover genes related to human health—almost half of human genes related to cancers, including the breast and ovarian cancer genes from the real-life examples above, are included in this list. Proponents of gene patenting point to statutes and case law to show an absence of any government restrictions—Congress has had opportunities to ban or limit gene patenting but currently has failed to do so. The patent protection for gene sequences is necessary, they say, to provide incentives for companies heavily investing in research. If these companies are not able to recoup their expenses through royalties and license fees, their investments are unlikely to ever pay off. But opponents of gene patenting point to the development of monopolies that can harm the most vulnerable members of society—the sick. The most obvious concerns voiced by critics of gene patenting include limited access to testing and diagnosis, no availability of confirmation or verification of test results, and no competition regarding the price of diagnostic testing. Finally, critics are concerned that patent holders of genetic material inappropriately interfere with the physician-patient relationship by marketing their diagnostic tests and analysis directly to the patients.

Part II of this Comment explains how gene patents developed under the U.S. patent law system, including the creation of the patent statutes and early case law addressing patentability of organic materials. Part III discusses the major recent developments and controversies in gene-patent law, including the most recent lawsuits and legislative actions. It also details the most recently suggested and most practicable solutions to the gene-patent dilemma in the United States. Finally, Part IV analyzes the

9. Id. at 240.
12. Id. at 487, 509.
15. Merz, supra note 13, at 326. A more recent example of such suggested interference is the BRACAnalysis diagnostic test, exclusively administered by Myriad Genetics, with more information about the test available at http://www.bracnow.com (last visited Aug. 11, 2010). The website provides a quiz to help potential patients determine if genetic testing is “right” for them, a link to the television commercial for the test, and a database of physicians who the patient can visit to have the physician order the BRACAnalysis test from the Myriad Genetics laboratory. Id.
possible changes meant to address the gene-patent debate, weighs the advantages and disadvantages, and analyzes the likelihood of these changes being successful in the immediate future.

II. THE DEVELOPMENT OF HUMAN GENES AND THE RIGHTS TO PATENT THEM

A. AN INTRODUCTION TO PATENT LAW IN THE UNITED STATES

The U.S. law governing patent protection has a history spanning centuries, enacted by the first Congress in 1790. Congress created such patent legislation based on constitutionally granted authority “to promote the progress of science and useful arts.” Under the subsequently passed legislation in 1793, anyone who applied was granted patent protection as long as they complied with the formal filing requirements. This simplistic process of obtaining patent protection continued until 1836, when Congress made its first major changes to the patent laws by introducing the Patent Office and granting it authority to not only consider patent applications but also refuse to grant patent protection if certain requirements were not met. Numerous amendments and more than a century later, Congress again revisited patent laws in a major way when it recodified Title 35 of the United States Code and created the patent laws in effect today.

Under the most recent codification of the U.S. patent laws in 35 U.S.C. § 101, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.” Those conditions and requirements indicate that the subject matter of the patent must have (1) utility, (2) novelty, (3) non-obviousness, (4) a written description, and (5) enablement. According to legislative history and later court interpretations, this language is meant to have a broad reach and cover “anything under the sun that is made by man” as long as specific requirements of Title 35 are satisfied. The subject matter satisfies the utility require-

16. S. REP. NO. 82-1979, at 2396 (1952) (“When the first Congress met, one of its very first items of business was the consideration of patents and copyright, and the first patent bill was H.R. 10 of the First Congress.”).
17. Id.; see also U.S. CONST. art. I, § 8 (“The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”).
18. S. REP. NO. 82-1979, at 2397.
19. Id.
21. § 101 (emphasis added).
22. Id.
23. Id. § 102 (2006).
24. Id. § 103 (2006).
25. Id. § 112 (2006).
26. Id.
ment if it is not only new but also "useful." The subject matter satisfies the novelty requirement only if it was not used in the United States prior to the patent applicant's invention of it, was not written about in United States or foreign publications prior to the invention, and was not patented in a foreign country within a year of the patent application in the United States. The subject matter does not satisfy the non-obviousness requirement when the difference between it and the subject from which it is being invented (what was known before) would be obvious to someone skilled in that subject. The written description and enablement requirements call for the patent applicant to describe the invented subject matter in detail and enable anyone skilled in the industry to which the invention pertains to be able to recreate it.

B. THE ROAD TO PATENTING LIVING THINGS

The basic concept of genetics has existed for centuries, originating from observing traits passed from parents to their children. Genetics as they are understood today, however, did not take shape until the twentieth century, which started with the discovery of the very first gene and concluded as the Human Genome Project was on the road to identifying every gene in the human DNA. The Human Genome Project was finally completed in 2003, with 23,688 genes identified. While most scientists struggle to define the term "gene" even today, a definition relied on by a basic medical textbook refers to it as a "physical and functional unit of heredity, which carries information from one generation to the next."

The surge to obtain patent protection for these newly discovered genes is a result of several major developments of the late twentieth century, including the economic hardship of the 1970s and 1980s. In response to this economic downturn, Congress sought to help domestic technology industries by making significant changes to the patent system.
cally, Congress passed legislation aiming to incentivize universities to financially gain from their government-sponsored scientific research. The Bayh–Dole Act, passed in 1980, was not created to benefit the government directly; however, the government indirectly profited through the increased taxes paid by the beneficiaries of the Act. The Act allowed universities to obtain patent protection on inventions that their researchers created using federal funding, and universities were also further encouraged to commercialize these inventions "for the public good." The Act, however, did not specifically restrict universities in their research and patenting practices, except for the limitation requiring them to prioritize partnerships with U.S. businesses, especially smaller companies. The Act did not require the universities that were receiving the government funding to make their subsequent inventions publically available. As a result of the Act, the government increased its contributions to scientific research at the university level, and patents acquired by universities increased from 264 in 1979 to 3,291 in 2002.

Another development that played a significant role in the gene-patent surge is twentieth century jurisprudence. In 1911, a New York district court first faced an organic substance patenting dilemma when it considered a patent on an extract from an animal gland. While the substance existed in nature, the court upheld the patentability of the substance because "no one had yet produced the free base." The court explained that this purified substance was patentable because:

[The patent holder] was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically.

"But, even if it were merely an extracted product without change, there is no rule that such products are not patentable."

This landmark decision led the way for other courts to also declare that organic matter may be patentable as long as it is in purified form and

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38. Id.; 35 U.S.C. § 200 (2006) ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . .")
39. Ledbetter, supra note 14, at 315.
40. Id.
41. Id.
42. Id.
43. Klein, supra note 36, at 989.
46. Id. at 103, 113–114.
47. Id. at 103.
48. Id.
other patent law requirements are also satisfied.\textsuperscript{49} Today, the United States Patent and Trademark Office uses the \textit{Parke-Davis & Co.} decision to justify granting patents on genes, explaining that patenting of genetic material "follows well-established principles, and is not a new practice."\textsuperscript{50}

One possible roadblock to granting patent protection on purified organic substances is the argument that these substances do not qualify as patentable under 35 U.S.C. § 102 because they are not novel.\textsuperscript{51} The Court of Customs and Patent Appeals was faced with this issue in 1970, when the lower patent courts both denied patent protection for compositions of matter that had been isolated and purified.\textsuperscript{52} The substances were derived from human and animal genital glands, but before they reached the state at which they were patented, they were treated with many substances including ether and phosphate, were allowed to evaporate and turn to powder, and finally were turned into crystals.\textsuperscript{53} In this purified form, the substances could lower rabbit blood pressure—a quality not present in the substances in a less purified form.\textsuperscript{54} The Court of Customs and Patent Appeals reversed the denial of patent protection in this case because it found the substances to be not naturally occurring—the pure form of the substances, as it was described in the patent, did not exist in nature.\textsuperscript{55} Because pure minerals are different from less pure minerals, the court concluded the pure minerals described in the patent application were novel, or "new" as compared to the less pure form.\textsuperscript{56} Therefore, the substances were patentable and the lower courts should not have denied the patent applications.\textsuperscript{57}

Later decisions by the United States Supreme Court, however, made these earlier distinctions less clear.\textsuperscript{58} When faced with nature and patents in \textit{Parker v. Flook}, the Court stated that the laws of nature cannot be patented because those laws are not the type of discoveries contemplated by the writers of the patent statutes.\textsuperscript{59} The Court compared the laws of nature to Isaac Newton's discovery of gravity—even before Newton announced his discovery, the law of gravity already existed in nature.\textsuperscript{60} The Court explained that making the discovery did not give Newton the right to patent it and exclude others because the phenomenon of gravity had

\textsuperscript{52} \textit{In re Bergstrom}, 427 F.2d at 1396–98.
\textsuperscript{53} \textit{id}. at 1396.
\textsuperscript{54} \textit{id}. at 1397.
\textsuperscript{55} \textit{id}. at 1401.
\textsuperscript{56} \textit{id}. at 1401–02 (explaining that "pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a standard of reference, as seems to be the situation here, perforce the 'pure' materials are 'new' with respect to them").
\textsuperscript{57} \textit{id}. at 1402.
\textsuperscript{59} \textit{id}. at 596.
\textsuperscript{60} \textit{id}. at 593 n.15.
always existed. The only way a law of nature can be subject to a patent is when the patent applicant finds some way to use this law of nature to achieve a new and useful result.

Two years later, the Court had a chance to elaborate on its Parker dicta in a decision that set the stage for patenting of human genes. The Court once again delved into the patentability of the laws of nature, but this new decision allowing patenting of human-made microorganisms is what helped propel the gene-patent surge. In *Diamond v. Chakrabarty*, the Court considered whether a live bacterium that was genetically engineered qualified under the language of 35 U.S.C. § 101 as patentable subject matter. Chakrabarty was a microbiologist who made the bacterium that could break down crude oil, a quality not present in naturally occurring bacteria and therefore made this creation a potential asset when dealing with oil spills, and also extremely financially valuable. When Chakrabarty applied for a patent on the bacterium he was initially rejected—the patent examiner concluded that microorganisms are not patentable subject matter because they are products of nature, and generally, living things are not patentable under 35 U.S.C. § 101. The Supreme Court granted certiorari after patent appellate courts, analyzing Chakrabarty's application, split on the way living organisms are to be treated under 35 U.S.C. § 101.

The slim majority of the Court interpreted Congress as having intended § 101 to have a broad application, covering even what Congress could not contemplate at the time of the statute's creation. Instead of distinguishing the case on living organism grounds, the Court said the focus should be on whether the subject matter is naturally occurring. Something occurring naturally, such as a newly discovered mineral or a new plant found in the wild, could not be patented under the Court's interpretation of 35 U.S.C. § 101. In this case, however, no bacterium naturally occurring in nature had the same characteristics as the bacterium Chakrabarty engineered—that is why the bacterium was patentable subject matter, according to the Court. The Court concluded its analysis by emphasizing that it is up to Congress to clarify, if it sees fit, whether living things or genetically engineered organisms should be exempted from the patent

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61. *Id.* (quoting P. Rosenberg, *Patent Law Fundamentals* § 4, at 13 (1975)) (explaining that this reasoning is "founded upon the proposition that in granting patent rights, the public must not be deprived of any rights that it theretofore freely enjoyed.")
62. *Id.* at 591.
64. Klein, *supra* note 36, at 989; *see also Diamond*, 447 U.S. at 309, 318.
66. *Id.*
67. *Id.* at 305–06.
68. *Id.* at 306.
69. *Id.* at 315–16.
70. *Id.* at 309–10.
71. *Id.* at 309.
72. *Id.* at 310.
statute. Until Congress chooses to do so, the Court declined to make the tough judgment calls on matters of policy or competing values that it found would be involved in such an analysis.

III. CHAKRABARTY REPERCUSSIONS AND RECENT DEVELOPMENTS IN GENE PATENT LAW

A. THE BREWING BRCA GENE PATENT CONTROVERSY

Today, nearly twenty percent of human genes are patented under U.S. law. While the majority of genes still remain unclaimed, the ones to which rights have been asserted under patent law are primarily genes associated with human health. For example, patents are claimed on diabetes and obesity genes, as well as almost half of the genes related to cancers. As new diseases are discovered, patents are asserted on the viruses as well. In addition to these genes themselves being patented subject matter, patent holders also assert claims to numerous ways the genes may be used and ways in which they are manifested, including in diagnostic procedures. For example, one of the most patented genes is a tumor suppression gene, which is claimed in twenty separate patents.

Under U.S. patent law, owners of gene patents are not required to share their rights with anyone. However, many patent holders choose to grant licenses on their patents in order to make profits or continuing royalties from others’ use. Patent holders may limit such licenses by the scope of use—for example, allowing licensees only to research either diagnostic or therapeutic properties of the gene. The majority of gene patent holders do not have a problem issuing licenses to diagnostic laboratories.

For example, the patent holders for the cystic fibrosis gene, the Hospital for Sick Children and the University of Michigan, have chosen to grant nonexclusive licenses for laboratories diagnosing the dis-

73. Id. at 318.
74. Id. at 317. When the petitioner suggested multiple negative implications of granting a patent on a microorganism, the Court responded that it is up to Congress to make the more serious policy decisions it was being asked to make: “Whatever [the validity of negative consequences of the Court’s ruling], the contentions now pressed on us should be addressed to the political branches of the Government . . . .” Id.
75. Jensen & Murray, supra note 8, at 239.
76. Id. at 240.
77. Id.
79. Jensen & Murray, supra note 8, at 239.
80. Id.
81. Ledbetter, supra note 14, at 316.
82. Id.
83. Id.
As a result, the disease may now be diagnosed by a variety of tests and kits, allowing for potential price reductions and second opinions.

However, one major patent holder chose to exclude others from diagnosing mutations of a gene it held a patent on, thereby exacerbating the already brewing controversy over the issuance of gene patents. Myriad Genetics, Inc., a U.S.-based company, chose a path "unprecedented in the field of genetic testing," deciding to exercise its power to monopolize the diagnostic, as well as all other uses, of the breast and ovarian cancer genes (BRCA1 and BRCA2). Consequently, all non-Myriad-owned laboratories diagnosing a predisposition to these cancers by looking for mutations in the patient's genes were estopped from performing any more tests. The lawsuit that followed has been heralded by some as the "beginning of the end" to gene patenting.

Gene-patent litigation has mostly focused on patent infringement, exceeding license scope, and appealing the denial of patent applications by the patent office. According to a 2007 study, gene patent litigation peaked in 1997-1998 with a high of thirteen pending gene-patent lawsuits at one time. But that number has since dropped off to one or two law-

85. Ledbetter, supra note 14, at 317.
86. Id.
87. Id. at 315.
89. Michael Crichton, Patenting Life, N.Y. TIMES, Feb. 13, 2007, at A23 (noting that "[y]ou, or someone you love, may die because of a gene patent that should never have been granted in the first place"); Anna Salleh, Researchers in Patent Catch-22, ABC Sci. (Jan. 28, 2005), http://www.abc.net.au/science/news/stories/s1290889.htm ("Patenting of SARS genes renewed the debate over the ethics of gene patenting with opponents seeing patenting as a commercialization of life."); Jon F. Merz, Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine, 45 CLINICAL CHEMISTRY 324, 324 (1999). The author presents a fictitious scenario in which the Vatican purchases the exclusive license to the Down syndrome gene and announces its plan to enforce a monopoly, effectively eliminating early fetus tests of the disease in the United States. Id. The author explains his scenario as a cautionary tale:

The good news is that the Church will not prevent prenatal screening for devastating genetic anomalies that often lead to abortion of an affected fetus, a test that is the standard of care throughout the US. The bad news is that there is nothing in law that would prevent the license above from being negotiated, and little to prevent the licensee from preventing others from practicing the patented test.

Id.

90. On the company website, Myriad Genetics is described as "committed to improve patient healthcare through the commercialization of predictive medicine, personalized medicine, and prognostic medicine products." MYRIAD, http://www.myriad.com/ (last visited Jul. 23, 2010).
91. Matthijs, supra note 88, at 95.
95. Id.
suits per year. In May 2009, another gene-patent complaint was added to this list. But in an unprecedented move, the American Civil Liberties Union, physicians and physician groups, and patients joined in a lawsuit to challenge the constitutionality of Myriad’s BRCA1 and BRCA2 genes. Specifically, the plaintiffs alleged that the patenting of human genes and the process of comparing genes to look for a mutation is against the principle that laws of nature and products of nature cannot be patented. The second, and more unusual, claim was that the patents on human genes violate the plaintiffs’ First Amendment rights. And perhaps to emphasize the gravity of their allegations, the plaintiffs added the U.S. Patent and Trademark Office to the list of defendants in this action.

The complaint alleged an injury to the patients by way of restricted access to gene mutation testing to determine their predisposition to breast and ovarian cancers. This allegation is based not only on Myriad Genetics’s ownership of the patent but also on the fact that Myriad Genetics made the decision not to license the patents broadly to other physician facilities and laboratories. The patent prevents anyone other than Myriad Genetics from analyzing the patient’s BRCA1 and BRCA2 genes—either to determine a predisposition to the two cancers or to verify Myriad’s laboratory results independently. For example, the problems created by this limited access are evident in Myriad’s refusal to accept certain insurances to pay for the testing, leaving one of the plaintiffs who could not independently pay for the testing with no alternatives. Additionally, a plaintiff who received a test result stating “genetic variant of uncertain significance” is unable to obtain any additional analysis on her gene, even though Myriad Genetics does not test for all known mutations.

According to the complaint, researchers in the 1990s first began looking for a gene whose mutation would indicate a predisposition to breast and ovarian cancers. Collectively, the researchers concluded that this specific gene was located on human chromosome 17. A research team associated with Myriad Genetics “sequenced” this gene, named BRCA1,
and applied for the patent at issue in this litigation.\textsuperscript{110} Subsequently, Myriad’s research team sequenced another gene whose mutation also showed the predisposition—named BRCA2.\textsuperscript{111} The genes in their isolated form have the same qualities as the genes inside the human body. Nevertheless, the United States Patent and Trademark Office allows patenting of “isolated and purified” human genes.\textsuperscript{112} Because the patent office allows not only the patenting of the laws of nature but also the thought process of comparing one gene to another and noting its naturally occurring mutations, the plaintiffs allege in their complaint against Myriad Genetics and the patent office not only a violation of the patent statute, 35 U.S.C. § 101, but also the constitutional violation on the freedom of thought.\textsuperscript{113}

The defendants filed a motion to dismiss based on multiple assertions, including lack of standing, sovereign immunity bar by the patent office, and failure to state a constitutional claim.\textsuperscript{114} Additionally, defendants asked to dismiss because there was no case or controversy—the plaintiffs had not taken any action, such as infringement, and there was no response by the defendants on which the plaintiffs could sue.\textsuperscript{115}

Underscoring the importance of the rights at stake, the district court denied the defendants’ motion to dismiss.\textsuperscript{116} The court focused on a constitutional grievance being at issue, and stated that “[t]he novel circumstances presented by this action against the USPTO, the absence of any remedy provided in the Patent Act, and the important constitutional rights the Plaintiffs seek to vindicate establish subject jurisdiction.”\textsuperscript{117} The court also concluded that the complaint was sufficient to allege a constitutional challenge because patenting laws of nature, which the complaint alleged to be the gene mutations and the genes themselves, violated the freedom of thought.\textsuperscript{118}

Even before the trial court denied the defendants’ motion to dismiss, the plaintiffs had already filed a motion for summary judgment.\textsuperscript{119} The motion reiterated the points raised in the initial complaint, emphasizing in particular the unconstitutionality of a patent that restricts comparing two genes (both products of nature) and thinking that one has an abnor-

\textsuperscript{111} Complaint, supra note 1, at 18.
\textsuperscript{112} Id. at 19.
\textsuperscript{113} Id.
\textsuperscript{115} Id. at 6–7.
\textsuperscript{116} Ass’n for Molecular Pathology, 669 F. Supp. 2d at 370.
\textsuperscript{117} Id. at 383.
\textsuperscript{118} Id. at 398.
\textsuperscript{119} Plaintiffs’ Memorandum of Law in Support for Motion for Summary Judgment at 1, Ass’n for Molecular Pathology, 669 F. Supp. 2d 365 (No. 09 Civ. 4515).
mality as compared to the other. Attorneys for the American Civil Liberties Union, one of the plaintiffs in this lawsuit, have indicated that by filing this complaint they aim to eradicate the patenting of human genes altogether, beyond just the BRCA1 and BRCA2. Specifically, one of the attorneys was quoted as saying "[w]e hope this [court] challenge is the beginning of the end to patents on genes, which limit scientific research, learning, and the free flow of information . . . . No one should be able to patent a part of the human body." The trial court granted the plaintiffs' motion for summary judgment, invalidating not only the processes of comparing genes but more importantly Myriad's patents on both the genes themselves. The court, however, dismissed the plaintiffs' First Amendment claims because of the constitutional avoidance doctrine—requiring courts not to reach unnecessary constitutional questions. The court noted that if the Federal Circuit or the Supreme Court upholds this decision, it would serve the plaintiffs' desired purpose of invalidating all current gene patents. However, Myriad Genetics promptly appealed the ruling to the Federal Circuit.

Although not directly pertaining to gene patents, Prometheus Laboratories, Inc. v. Mayo Collaborative Services is a timely case involving a patent claim that is very similar to Myriad's patent on comparing genes and finding mutations. Prometheus's patent at issue in the case covers a method for determining an effect of a drug on the human body, in order to treat gastrointestinal and nongastrointestinal autoimmune disorders. Specifically, the patent covers two steps: (1) administering a particular medication to a patient and (2) observing the drug's effects as it metabolizes in the patient's body, which allows the patent holder to change the medication dosage to better suit the patient. Mayo Collaborative Services used Prometheus's patented method for a period of time, after which it announced it was going to administer its own test. Prometheus responded with a lawsuit against Mayo for patent infringement, and in response Mayo filed its own lawsuit, claiming the method patented by Prometheus was not patentable subject matter under 35 U.S.C. § 101.

120. Id. at 19.
122. Id.
124. Id. at 237–38.
125. Id. at 238.
128. Id. at 1339.
129. Id.
130. Id. at 1340.
131. Id.
The district court agreed with Mayo and invalidated the patent, causing an appeal by Prometheus and a subsequent decision by the Federal Circuit.  \(^{132}\)

The court applied a new test, articulated in its earlier decision,\(^ {133}\) to determine that the process was indeed patent-eligible under 35 U.S.C. § 101.\(^ {134}\) Under this new test, a patent applicant can patent a process "either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article."\(^ {135}\) Additionally, the transformation "must impose meaningful limits on the claim’s scope to impart patent-eligibility" and the transformation must be significant.\(^ {136}\)

The court concluded that the patent in this case falls squarely "within the realm of patentable subject matter" because the human body undergoes a transformation when metabolizing the drug, therefore satisfying the first prong of the *Bilski* analysis.\(^ {137}\) More importantly, the court reasoned that despite metabolization being a natural process, the process could still be subject to a patent on the basis that administering the drug is *not* a natural process.\(^ {138}\) Moreover, determining whether the metabolized drug levels are too high also involves the unnatural process requiring the patent holder to "extract the metabolites from a bodily sample and determine their concentration."\(^ {139}\) Because administering the drug and determining its metabolized state are transformative and not natural processes, the court concluded that the patented process was valid under 35 U.S.C. § 101.\(^ {140}\) Finally, the court concluded that the final step of the patented process—the determination of whether too much or too little drug was administered—is patentable but only because it is part of the entire claim.\(^ {141}\) Significantly, the court stated in dicta that the mental determination—of whether enough of the drug was administered—by itself is not patentable subject matter.\(^ {142}\)

The court distinguished this part of the ruling from an earlier case, *In re Grams*, in which it found a somewhat similar process nonpatentable.\(^ {143}\)

In that case, the court invalidated a patent on:

(1) performing a clinical test on individuals and (2) based on the data from that test, determining if an abnormality existed and determin-

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132. *Id.* at 1341.
134. *Prometheus*, 581 F.3d at 1342.
135. *In re Bilski*, 545 F.3d at 961. The Supreme Court has since held that while this test is a valid analysis, it is not the sole test to determine whether a process is patentable. Instead, the Court suggested the lower courts should be more flexible with emerging technology. *Bilski*, 130 S. Ct. at 3221–23.
136. *In re Bilski*, at 961–62.
137. *Prometheus*, 581 F.3d at 1346–47.
138. *Id.* at 1346.
139. *Id.* at 1347.
140. *Id.*
141. *Id.* at 1348.
142. *Id.*
143. *Id.*
ing possible causes of any abnormality by using an algorithm. We found that this process was not drawn to patentable subject matter because the essence of the claimed process was the mathematical algorithm, rather than any transformation of the tested individuals. More specifically, the Grams process was unpatentable because "it was merely an algorithm combined with a data-gathering step," i.e., performing a clinical test.\textsuperscript{144}

This decision to validate the patented process of administering a drug and determining its level in the body after it has been metabolized is not settled law at this point. The Supreme Court granted certiorari and remanded the case back to the Federal Circuit to consider it again in light of the Bilski opinion, which affirmed the Federal Circuit decision but concluded that the machine and transformation test (which was also applied in Prometheus) is not the sole test to evaluate what is a patentable process.\textsuperscript{145} By remanding Prometheus, the Supreme Court declined an opportunity to elaborate on Bilski and thereby clarify what exactly it takes to patent a process. While not directly addressing gene patents, the Prometheus decision on remand, and on a potential appeal to the Supreme Court, may be the first concrete answer to how courts view process patenting within the biomedical field.

B. OTHER POTENTIAL AVENUES TO LIMIT OR STOP GENE PATENTING

While the Supreme Court has not directly addressed the patentability of genes, it might not have to if other branches of the government take decisive steps to address the current controversy. First, Congress can simply change the current laws to address gene patenting and either eliminate the practice altogether or limit it to prevent diagnostic monopolies and give patients more options.\textsuperscript{146} Also, the patent office can take steps to limit the future granting of patents by excluding patents on diagnostic and comparing methods,\textsuperscript{147} such as some of the Myriad patents. Other agencies have also expressed their desire for an overhaul, either through recommendations or even direct competition with the private community.\textsuperscript{148} And as a last resort, critics of gene patents have suggested offshoring of diagnostic tests to countries where gene-patent holders will not enforce a restriction—an option that upon further exploration is not likely to be successful.\textsuperscript{149}

1. Congress can amend current patent laws to ban all gene patents

The most obvious way to solve the gene-patent dilemma is to amend 35 U.S.C. § 101 in a way that would protect the rights of patients and doctors while still incentivizing research in the field. Not surprisingly, some mem-

\textsuperscript{144} Id.
\textsuperscript{145} Bilski, 130 S. Ct. at 3221.
\textsuperscript{146} See infra Part II.B.1–2.
\textsuperscript{147} See infra Part II.B.3.
\textsuperscript{148} See infra Part II.B.4–5.
\textsuperscript{149} See infra Part II.B.4.
bers of the 107th Congress attempted to do just that when they proposed the Genomic Research and Diagnostic Accessibility Act of 2002. The Act was introduced "[t]o amend title 35, United States Code, to provide for noninfringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing, and to require public disclosure of such information in certain patent applications." However, the proposed Act stalled in the early stages of the 107th Congress. Today, there is renewed talk of exempting patient care and research from gene patent infringement liability. But the opposition from the biotechnology sector is strong, and it appears any concrete steps toward relaxation of gene patenting are far off in the future.

2. Congress can pass legislation to amend patent laws and exclude gene diagnostic methods from patent protection

In Europe, critics have suggested that while patenting the isolated gene is allowed, patenting a diagnostic process such as comparing genes to find mutations is outside the scope of European patent law. The patent statute has an exception, stating that "European patents shall not be granted in respect of . . . methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practic[ed] on the human or animal body." This provision was first introduced to prevent patenting medical procedures, such as surgeries, and therefore not infringe on physicians' ability to aid their patients. While recent developments suggest that the European Patent Office has not extended this exception to block gene patenting entirely, it is perhaps an indication of what is to come in terms of gene-patenting exceptions. A commentator has suggested that "a broader interpretation of [this statutory exception] is a way to avoid monopolies on the use of a genetic sequence for diagnostic purposes in humans, without interfering with patent protection of other genetic applications, including the development of therapeutics." United States patent laws also have a limitation on patent infringement for medical procedures, added in 1999 at 35 U.S.C. § 287:

150. Genomic Research and Diagnostic Accessibility Act, supra note 10.
151. Id.
152. Id.
154. Id.
157. Matthijs, supra note 88, at 100.
159. Matthijs, supra note 88, at 100.
(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement . . . , the [infringement] provisions . . . of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

(2) For the purposes of this subsection:
(A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.\textsuperscript{160}

While this provision clearly excludes use of diagnostic testing, it has been suggested that the statute needs to be amended to include the use of gene patents for diagnostic purposes.\textsuperscript{161} By not allowing physicians to choose the method of diagnosis for their patients, physicians are prevented from looking out for the best interests of their patients.\textsuperscript{162}

3. \textit{While the patent office cannot act against current statute, it can take steps to limit granting of patents that have negative impact on patient care}

The United States Patent and Trademark Office is also unlikely to take any steps to limit the issuance or application of gene patents. When responding to public comments on the patentability of genes, the patent office made it very clear that it perceived gene patenting as ratified both by Congress in passage of 35 U.S.C. § 101 and by the jurisprudence interpreting the statute.\textsuperscript{163} In response to criticism that genes are found in nature, the patent office responded:

A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. Thus, the concern that a person whose body 'includes' a patented gene could infringe the patent is misfounded. The body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form.\textsuperscript{164}

The patent office also clarified that it would not take it upon itself to make any changes to patent laws in order to address the controversy surrounding gene patents.\textsuperscript{165} Responding to a recommendation that the patent office "should 'allow for others to learn from and improve the invention,'" the patent office clarified that the statute is very clear, and it authorizes a patent holder to exclude anyone else from utilizing the pat-

\textsuperscript{161} Merz, \textit{supra} note 13, at 328.
\textsuperscript{162} \textit{Id.}
\textsuperscript{164} \textit{Id.}
\textsuperscript{165} \textit{Id.} at 1096.
ent. Therefore, it is up to Congress to make exceptions, if any.

Commentators have also suggested that the patent office should more closely scrutinize the granting of patents on genes. They have identified several potential issues that may result in granting patents that are too broad, including financial incentives, expertise, and time management. The most troubling is the compensation system relied on by the patent examiners; they are rewarded with a bonus for granting or denying a patent and therefore are encouraged to move patent applications through rapidly. The potential for lack of scrutiny is exacerbated because denied applications are more often appealed, making it less problematic to grant the applications in order to avoid the long appeals process. Another suggested fix is making sure gene-patent applications are considered by examiners with at least some level of expertise in the biotechnology area because otherwise the patent applicants can get away with overly broad applications that an untrained eye will not scrutinize as closely. And finally, commentators suggest that patent examiners should spend more than the average eighteen hours on patent applications with more significant social value. This will require the patent office to make a judgment call as to which patent applications are of greater importance to society and how much more damaging a broad patent in one area will be than in another.

4. Other governmental agencies have taken steps that show their desire for an overhaul to the status quo

The Department of Health and Human Services has also weighed in on the gene-patent controversy by having the National Institutes of Health (NIH) issue recommendations to gene-patent holders. After soliciting public comments, NIH adopted a final version of the “Best Practices for the Licensing of Genomic Inventions: Final Notice.” After soliciting public comments on the recommendations, NIH was criticized for setting bad policy precedent by focusing on only one specialized sector of patent law. But NIH responded that this special treatment of gene patenting was justified because of the amount of controversy gene patenting had created and because of the government’s strong financial involvement

166. Id.
167. Id.
169. Id.
170. Id.
171. Id.
172. Id.
173. Id.
174. Id.
176. Id.
177. Id.
and contributions to genetic research through the Bayh–Dole Act.\textsuperscript{178} NIH first addressed the gene-patenting practice in general, suggesting that patents on genes should rarely be sought when the substance discovered requires little development and research to reach its full potential utility and commercial value.\textsuperscript{179} NIH also addressed licensing practices, suggesting that “[a] non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community.”\textsuperscript{180} When specifically addressing the licensing of gene patents, NIH suggested a particular licensing approach that would limit licenses within therapeutic research but would grant nonexclusive licensing for diagnostic tests and the discovery of still-unknown mutations of a gene.\textsuperscript{181}

NIH emphasized that government funding recipients and the biotechnology community as a whole should find these recommendations helpful in considering the consequences of their licensing practices on public health.\textsuperscript{182} However, these recommendations have no binding authority within the patent-holder community, and it is not clear how many patent holders abide by the recommendations (if any).\textsuperscript{183}

5. The government is joining the race to patent genes and thereby prevent more private monopolies

The world outbreak of the SARS virus revealed another way the government could act to protect the public against potential monopolizing of gene patents.\textsuperscript{184} Once the genetic sequence of the virus was decoded by multitudes of scientists around the world, everyone joined the race to patent every part of the virus.\textsuperscript{185} The United States government, via the Centers of Disease Control and Prevention (CDC), joined the race to patent the SARS gene along with pharmaceutical companies and private researchers.\textsuperscript{186} In what some referred to as a “pre-emptive strike,”\textsuperscript{187} the government decided to join the race to patent the virus with “[t]he whole purpose of the patent [being] to prevent folks from controlling the technology . . . . This is being done to give the industry and other researchers reasonable access to the samples.”\textsuperscript{188} This action by the government, whether an act of desperation or innovation, could set a new trend in patent law, and create a solution for the future victims of yet-undiscov-

\begin{footnotes}
\footnotetext{178} Id.
\footnotetext{179} Id. at 18415.
\footnotetext{180} Id.
\footnotetext{181} Id.
\footnotetext{182} Id.
\footnotetext{183} Id.
\footnotetext{185} Scientists Race to Patent SARS Virus, supra note 78.
\footnotetext{186} Id.
\footnotetext{187} Gene Patents, supra note 184.
\footnotetext{188} Scientists Race to Patent SARS Virus, supra note 78.
\end{footnotes}
6. Offshoring diagnostic testing to countries where gene patent holders do not enforce their rights

At first glance, another path to avoid gene-patent infringement is to go outside the United States to conduct any potentially infringing research. While the European Patent Office first granted Myriad Genetics a complete patent on diagnosing mutations in the BRCA1 gene, this patent has since undergone major scrutiny and has been revoked but later reinstated in modified form. Specifically, after Myriad Genetics first received patent protection for the BRCA1 gene in Europe, critics, including governments, organizations, and other professionals, were initially successful in getting the entire patent revoked. But Myriad Genetics appealed this decision, and eight years later the patent was partially reinstated—allowing about sixty percent of possible BRCA mutations to be covered by the gene patent while excluding the rest. Consequently, European diagnostic laboratories are now unsure on how to proceed without running into infringement liability. But with some mutation-diagnosing not off limits, the laboratories appear in a better position to bargain for licenses than laboratories in the United States—where all diagnostic procedures infringe on the patent.

Despite this setback by the European Patent Office, companies that hold gene patents in the United States, such as Myriad, cannot enforce their patents unless they are consistently paying maintenance fees to the governments of the other countries where they want the patents enforced. Therefore, offshoring diagnostic tests, where infringement claims cannot reach, is still a possibility, especially in Europe with so many countries sharing borders.

192. Matthijs, supra note 88, at 95.
194. Id.
195. Id.
196. Id.
IV. WHICH OF THE POSSIBLE SOLUTIONS OFFER THE BEST PROTECTION FOR PUBLIC HEALTH WHILE RETAINING THE INTEGRITY OF THE PATENT SYSTEM?

A. THE POSSIBLE ROLE OF THE JUDICIAL SYSTEM, AT LEAST IN THE IMMEDIATE FUTURE, APPEARS TO BE LIMITED

The patent litigation pending in lower courts today does not appear to present a clear opportunity for the Supreme Court to weigh in on the gene-patenting debate in the immediate future. When weighing in on the *Bilski* decision, the Court affirmed the Federal Circuit and declined to "define further what constitutes a patentable 'process.'"197 It does not appear that this decision will affect the nearly twenty percent of gene patents already granted.198

A closer look at the Supreme Court's stance on the issue may be obtained when the Federal Circuit decides *Prometheus* on remand, and the potential appeal to the Supreme Court.199 While the *Prometheus* claims also do not directly address the patentability of genes, the case does present issues resembling Myriad Genetics's patent claims on the BRCA1 and BRCA2 genes. Specifically, the patents in both cases lay claim to a process that involves analyzing an extract of the human body and making a mental determination based on this observation.200 In *Prometheus*, the mental process patented concerns the mental determination of an effect a medication has on the human body once it is metabolized.201 Similarly, Myriad Genetics's patented method concerns the mental process of looking at two genes, mentally noting any differences, and the mental thought that a difference indicates a mutation and therefore a predisposition to cancer.202 However, as the Federal Circuit explained in *Prometheus*, the major distinction between the patent in *Prometheus* and patents similar to Myriad Genetics's is that the process in *Prometheus* is only one part of a larger patent process claim.203 In the comparable Myriad Genetics claim, the granted patent solely concerns the mental analysis.204

The earliest that the Supreme Court can weigh in directly on the gene-patent controversy is if the Myriad Genetics litigation moves all the way up on appeal. However, even if the case moves up, it is still unlikely that the court will choose to hear this potential appeal not only because of the small number of appeals it accepts annually, but more importantly because of the position it took in *Chakrabarty*, where it declared that similar decisions of policy are better left for the legislature.205 However, the

200. *Id.; Complaint, supra* note 1, at 23.
201. *Prometheus*, 581 F.3d at 1348.
202. *Complaint, supra* note 1, at 23.
203. *Prometheus*, 581 F.3d at 1348.
204. *Complaint, supra* note 1, at 23.
Court may be interested in the Myriad litigation because of the years of controversy surrounding genes patents and the lack of any action by the other branches of the government. Also, the Court might be interested in the freedom of thought challenge in the novel First Amendment claim the plaintiffs presented—a way to challenge a gene patent that the courts had not yet seen. If the Supreme Court chooses to adopt the In re Grams reasoning, at least a portion of Myriad Genetics's patents may be invalidated.

The more complex issue, and one the Court is less likely to address directly, is whether the genes themselves are subject to patenting. While the Myriad Genetics case challenges the gene patent itself, Supreme Court precedent indicates the Court is unlikely to create any new prohibitions on gene patenting. First, in deciding Chakrabarty, the Court was very clear that it wanted Congress to make the tough policy decisions involved in patenting organic material, and the Court refused the argument for an outright judicial ban on such patenting. Because of this strong stance, the Court is unlikely to go back on its own reasoning and ban all gene patenting—it is more likely to suggest that it is up to the legislature to take such action. Additionally, in Chakrabarty the Court upheld the patent on the microorganism because it was not naturally occurring, and based on that reasoning the Court may also accept the gene-patent proponents’ argument that the patented genes are also not naturally occurring—isolated and purified human genes are not found in nature. Therefore, opponents of gene patents are likely to have to find

206. See generally Ray, supra note 10.
207. Prometheus, 581 F.3d at 1348.
208. Complaint, supra note 1, at 23 ("What is patented is . . . thinking 'there are differences.'").
209. Chakrabarty, 447 U.S. at 317. When called upon to end the patenting of microorganisms, the Court responded that:

[t]he choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democracy system is the business of elected representatives.

Id.

210. Id. at 305.
211. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001); In re Bergstrom, 166 U.S.P.Q. 256, 261–62 (1970). The court concluded that the substances in question were “new,” even though there were isolated and purified form of substances existing in nature, reasoning:

At the outset we would observe that what appellants claim—pure PGEsub2 and pure PGEsub3—is not “naturally occurring.” Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encom-
other avenues if they want a complete halt to gene patenting.

B. **CONGRESSIONAL ACTION TO LIMIT GENE PATENTING, NOT BAN THEM ALTOGETHER, IS A MORE PLAUSIBLE OPTION THAT CAN BALANCE PUBLIC HEALTH WITH ECONOMIC REALITIES**

As per the Supreme Court's suggestion in the *Chakrabarty* decision,\(^{212}\) congressional legislation is the most obvious avenue for any major changes to the United States patent statutes. Nevertheless, judging by its lack of action thus far, it is extremely unlikely that Congress will invalidate patents on human genes entirely. First, Congress has had several opportunities to take specific action but has chosen not to follow through.\(^{213}\) If such legislation has previously been opposed by the biotechnology industry, that opposition is unlikely to fade with more gene patents being granted and more investments being made. With nearly twenty percent of genes already subject to patents, it appears Congress has missed a timely opportunity to intervene.

A more plausible option includes a limit on gene patents—not complete eradication.\(^{214}\) While the U.S. patent law does not have an exception that bans patents on treatment and diagnostic methods, a limited exception from liability does exist for "medical activity" practiced on the human body.\(^{215}\) Experts have suggested that such an exception, if expanded to include diagnosis and testing, is the most reasonable solution that the biotechnology industry can also accept.\(^{216}\) European patent law has a slightly broader exception,\(^{217}\) but it also has not yet been expanded to specifically include diagnostic methods involving the analysis of human genes.\(^{218}\) An exception that only includes diagnostic and testing methods is more likely to be accepted by the biotechnology industry because it would not be as costly a loss as having gene patents invalidated across the board.

As the Department of Health and Human Services explained in its recommendations on gene-patent practice, the need for a patent is not as significant when not much more investment and research is needed to develop the patent.\(^{219}\) Therefore, a patent on a gene itself might be needed to justify the investment to find a drug and therefore recoup research costs. However, a patent on the diagnostic method is not as neces-

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\(^{212}\) *Chakrabarty*, 447 U.S. at 317.

\(^{213}\) See Genomic Research and Diagnostic Accessibility Act, *supra* note 10; see also Ray, *supra* note 10.

\(^{214}\) See Matthijs, *supra* note 88, at 101.


\(^{216}\) Matthijs, *supra* note 88, at 100.

\(^{217}\) European Patents Convention, *supra* note 10, art. 53(c).

\(^{218}\) Matthijs, *supra* note 88, at 100.

sary because once the diagnostic method is known, not much more investment is needed and there is not as much potential for future payout.\textsuperscript{220} Because a much smaller amount of potential proceeds are at stake in such a solution, it might have more of a chance to pass in Congress.

Additionally, the Bayh–Dole Act justifies such a step by Congress because the Act was one of the main reasons gene patenting became prevalent in the first place.\textsuperscript{221} It only makes sense that the public reaps at least some benefits—benefits to public health in this case—from genetic research that is supported with public funds. Additionally, Congress would be justified because several agencies have already taken steps to show their concern with the recent developments in gene patenting. First, the CDC has indicated how concerned it is with the growing monopolization of gene patents by taking action during the SARS outbreak.\textsuperscript{222} Fearing that a private company will monopolize the gene and not allow anyone else access, the CDC itself applied for the patent.\textsuperscript{223} Because new genetic links and mutations are still being discovered at a fast pace,\textsuperscript{224} this should have sent a strong message to Congress on the urgent need for reform.

Moreover, the Department of Health and Human Services has also indicated its desire to limit the scope of gene patents. While the Department cannot bind the Patent Office or the patent applicants or patent holders, it has addressed the gene-patent controversy through recommendations that suggest gene patents should not be granted to include diagnostic and testing methods.\textsuperscript{225}

In its recommendations, the Department acknowledged that it is singling out just one specific area of patent law in need of limitations, but it also explained that limits are especially important in this area because of the amount of controversy gene patenting has caused.\textsuperscript{226} As a second and less restrictive alternative, the Department recommended fewer restrictions on licensing of gene patents by the patent holders, especially when it comes to uses not involving development of therapeutics.\textsuperscript{227} But because the Department can only issue recommendations, without any

\begin{itemize}
\item \textsuperscript{220} Id.; Merz, supra note 13, at 328.
\item \textsuperscript{221} See Best Practices for the Licensing of Genomic Inventions, 70 Fed. Reg. 18413, 18413 (Apr. 11, 2005) (final notice) (suggesting that the National Institutes of Health can make suggestions to gene patent holders based on the reasoning that the government is such a big financial contributor to genetic research through the Bayh-Dole Act); see also Ledbetter, supra note 14, at 315.
\item \textsuperscript{222} Scientists Race to Patent SARS Virus, supra note 78.
\item \textsuperscript{223} Id.
\item \textsuperscript{224} See sources cited supra note 189.
\item \textsuperscript{226} Id. at 18413.
\item \textsuperscript{227} Id. at 18415. The Department gave an example of a scenario calling for loosening of license restrictions: For example, patent claims to gene sequences could be licensed exclusively in a limited field of use drawn to development of antisense molecules in therapeutic protocols. Independent of such exclusive consideration, the same intellectual property rights could be licensed non-exclusively for diagnostic
\end{itemize}
authority to bind, the problems it aimed to address still persist today.228

V. CONCLUSION

This comment has examined the development of gene patent law in the United States. It explained the early development of gene patent law, and recapped and analyzed the most recent developments in the area, including a host of potential resolutions to the ongoing policy debate. Finally, the Comment analyzed the possible resolutions and the potential for the end of gene patenting in the United States, as well as the more likely limitations on gene patenting.

The numerous ways229 in which different governmental bodies have attempted to address the patenting of organic material, and human genes in particular, should be more than enough indication to Congress that binding action is needed to address the controversy. From the Supreme Court's implicit invitation in Chakrabarty for elected officials to address policy issues relating to patents on organic material to the CDC's attempt to patent genes so that no one else can gain a monopoly, an overhaul, or at least an exception for diagnostics and testing, is long overdue in United States patent law.

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Id. See generally Complaint, supra note 1. Patenting the process of analyzing human genes to note mutations and therefore determine predisposition to breast or ovarian cancer is the type of process the recommendations suggested should no longer be patented.

228. See generally Complaint, supra note 1. Patenting the process of analyzing human genes to note mutations and therefore determine predisposition to breast or ovarian cancer is the type of process the recommendations suggested should no longer be patented.