BREAST CANCER, POLITICS, AND PATENTS

Tamsen Valoir*

I. INTRODUCTION ................................................................. 65

II. THE RISE OF BREAST CANCER AWARENESS IN THE UNITED STATES ....... 69

A. Early Breast Cancer Activism ............................................. 69

B. The Revolution of Breast Cancer Treatment ................................. 70

C. Modern Breast Cancer Activism ............................................ 72

III. THE RISE AND FALL OF THE BRCA GENE PATENTS ................. 73

A. The Role of Genetic Testing in Breast Cancer Detection ............ 73

B. The Myriad Tests ............................................................... 76

IV. LITIGATION OF MYRIAD’S BREAST CANCER GENE PATENTS ......... 77

A. The ACLU Challenges Myriad’s BRCA Patents Under § 101 of the Patent Act .............................................................. 77

1. Diamond v. Chakrabarty Illuminates § 101’s Definition of “Patentability” ................................................................. 79

2. USPTO Practice Following Chakrabarty Supported the Patentability of Isolated DNA ............................................................ 81

B. The Association for Molecular Pathology v. Myriad Case Works its Way Up to the Supreme Court ........................................ 82

C. The Supreme Court Decision .................................................. 84

V. ANALYSIS: THE FALLOUT FROM THE SUPREME COURT’S HOLDING IN MYRIAD ............................................................ 85

A. The Supreme Court’s Holding that Isolated DNA is not Patentable is Inconsistent with Prior USPTO Practice ....................................................... 85

B. The Myriad Patents Did Not Impede Cancer Research .................. 87

C. The Myriad Tests were not Inaccessibly Expensive ....................... 89

D. The Myriad Patents Did Not Confer Ownership of Information ....... 93

* © 2016 Tamsen Valoir. Tamsen Valoir has a PhD in Molecular Biology, a law degree and an L.L.M. in intellectual property, and is a founding member of the intellectual property boutique form of Boulware & Valoir. She focuses her practice on intellectual property and FDA regulation in the life sciences, but she also has extensive experience in copyright and trademark enforcement. Her work includes patent prosecution, infringement and patentability opinion work, licensing, due diligence, FDA patent term extensions and data exclusivities, as well as litigation related to copyright, trademark, and patent infringement.
E. Alternative, Non-Infringing Methods of BRCA Gene Testing are Available to Researchers, Clinicians, and Patients ................................................. 94
F. Trade Secrets Provide an Informational Advantage That, if Not Remedied, Will Continue to Hinder the Advancement of Personal Medicine ........................................................................................................ 95
G. Invalidating the Myriad Patents Does Not Remedy the Informational Concerns ............................................................................................... 98
H. Though the Supreme Court’s Ruling May Further Legitimate Policy Goals, the Myriad Decision was not the Proper Vehicle Through Which to Effect Such Drastic Change ........................................ 99

1. The Legislature, Rather Than the Judiciary, Should Make Important Policy Decisions .......................................................... 99
2. The Court’s Decision Did Not Compel Myriad to Reveal the Valuable Genetic Developments it now Maintains as a Trade Secret .................................................... 101
3. The Supreme Court’s Decision did not Markedly Impact Myriad’s Market Dominance in the Field of BRCA1 and BRCA2 Genetic Testing ........................................................................ 102
4. The American Public Must Take Additional Action to Remedy the Informational Concerns Raised by Myriad’s Behavior .................................................................................. 105

I. Despite the Supreme Court’s Ruling, the Immediate Future for “Isolated and Purified” Natural Products is not Bleak ........................................ 107

VI. CONCLUSION ........................................................................................................ 109

LIST OF TABLES

1. TABLE 1. Comparison of Cost-per-Base-Pair among Genetic Tests ...... 92

LIST OF FIGURES

2. FIGURE 1. Figure 1 .................................................................................................. 66
I. INTRODUCTION

In 2015, breast cancer is the focus of complex medical research, widespread media attention, high stakes litigation, and heated political debate—a fact that can be explained, in part, by the long and tumultuous history associated with the disease. Breast cancer has threatened the lives of women, and men, since as early as 3,000 B.C. As the average human lifespan increases, the incidence of breast cancer cases likewise increases, and today the lifetime risk for breast cancer is one in eight for U.S. women.

Breast cancer has long been treated surgically. Indeed, one of the earliest proposals for surgical removal of the breast—a procedure known as "mastectomy"—to treat breast cancer was put forth by Aetios, a physician at the Byzantium court, in the sixth century. There are several forms of mastectomy, but one early form known as the "radical" mastectomy involved removing the entire breast, the axillary lymph nodes, and the pectoralis major and minor muscles behind the breast.

Dr. William S. Halsted of Johns Hopkins University is credited with popularizing the radical mastectomy in the United States. Halsted was one of a

---

4. See id.
5. See Cordelia Shaw Bland, The Halsted Mastectomy: Present Illness and Past History, 134 W.J. MED. 549, 549 (1981); ROBERT A. ARONOWITZ, UNNATURAL HISTORY: BREAST CANCER AND AMERICAN SOCIETY 88 (Cambridge Univ. Press 2007) (“[Halsted] is generally credited with extending breast cancer surgery in the 1880s and early 1890s to include not only the pectoralis minor but also the pectoralis major muscles.”).
number of surgeons who believed that the failure to cure cancer came from failure to cut out its “invisible roots.” In 1882, this notion led Halsted to devise the radical mastectomy procedure.

Figure 1.

Halsted feared that cutting into the cancerous tissue would allow cancer cells to break free, contaminating both the surgical site and the rest of the body. As a result, he believed 1) that biopsies were dangerous and should be avoided and 2) that a surgeon’s macroscopic diagnosis was superior to a pathologist’s

---

7 See ARONOWITZ, supra note 5, at 88.

8 See Bland, supra note 5, at 549 (“[R]adical mastectomy ... was introduced in 1882 by American surgeon William S. Halsted.”).

9 ARONOWITZ, supra note 5, at 89.

10 See id. at 89-90, 97-98.

11 Visible to the naked eye.
microscopic diagnosis. These beliefs led Halsted to promote the "one-step" procedure, wherein a patient might not even learn she had cancer until she awoke, post-surgery, absent a breast and considerable amounts of muscle.

Between 1894 and 1895, Halsted reported that he had treated fifty cases of breast cancer using the radical mastectomy, and only three (6%) patients experienced local recurrences. Halsted’s enthusiasm for the operation, however, was founded on a reduction in local recurrences, rather than its use as an ultimate cure for cancer. Deaths from metastases—the spreading of the cancer—were not his responsibility, even though metastases are usually the cause of death in cancer. In addition, he followed up with his mastectomy patients via letters rather than appointments, and, for purposes of reporting, he accepted a patient’s mere failure to mention her local recurrence in correspondence as proof that she experienced none.

For several decades, this disfiguring and debilitating surgery was performed on virtually every woman who presented with the disease, regardless of the degree of the cancer’s severity at the time of diagnosis. All decisions were

---

12 ARONOWITZ, supra note 5, at 98.
13 Id. at 99-100. The one-step procedure required that the breast tissue, the pectoral muscle, and the axillary lymph nodes be removed in one piece ("en bloc") in order to prevent surgeons from cutting into the cancerous tissue itself, which Halsted believed might spread the cancer. See id. at 88-90; Michael P. Osborne, William Stewart Halsted: His Life and Contributions to Surgery, 8 LANCET ONCOLOGY 256, 260 (2007).
14 Osborne, supra note 13, at 260.
15 See ARONOWITZ, supra note 5, at 92 ("Halsted’s own notion of the superiority of the complete operation over more limited surgery was much more closely tied to claims about reducing local recurrence rates than saving women’s lives."); Bland, supra note 5, at 553.
16 See ARONOWITZ, supra note 5, at 95-96.
17 Alain Puisieux, Metastasis: A Question of Life or Death, 6 NATURE REVS.: CANCER 449, 449–58 (June 2006) ("Metastases are the cause of 90% of human cancer deaths.").
18 See ARONOWITZ, supra note 5, at 87.
19 Id. at 96.
20 Id. at 86, 88–89, 93; Bland, supra note 5, at 551.
made by physicians.\textsuperscript{21} A woman whose doctor discovered cancerous tissue during the one-step procedure learned of her cancer diagnosis upon waking up from surgery—absent one breast and without enough arm muscle to even comb her hair.\textsuperscript{22}

In spite of the paucity of efficacy data, surgeons believed so strongly in the surgery’s benefit that it was even performed for benign conditions, such as chronic mastitis, on the theory it was better to do too much and leave a scar than to do too little and have the patient die a “hopeless death” from cancer.\textsuperscript{23} Indeed, the one-step radical mastectomy was the treatment norm for more than 80 years, used extensively in the United States even as late as the early 1980’s.\textsuperscript{24}

There were always doubts about the value of removing muscle, which was long known to typically not be compromised, even in cancerous patients.\textsuperscript{25} Yet, it wasn’t until 1971 that the National Cancer Institute (“NCI”) finally initiated a study that ultimately concluded that the Halsted operation achieved no higher cure rate than the simple mastectomy, which saved the pectoral muscles and uninvolved lymph nodes.\textsuperscript{26}

Cordelia Shaw Bland, writing in 1981 about the reasons underlying the extraordinarily common use of a radical surgery, the value of which was questionable even from its inception, concluded that the surgery proliferated in

\begin{itemize}
\item \textsuperscript{21} Bob Riter, History of Breast Cancer Advocacy, CANCER RES. CENTER FINGER LAKES (Apr. 5, 2005), http://www.crcfl.net/content/view/history-of-breast-cancer-advocacy.html.
\item \textsuperscript{22} See id.; Bland, supra note 5, at 552.
\item \textsuperscript{23} ARONOWITZ, supra note 5, at 93 (“Surgeons believed so strongly in the efficacy of radical cancer surgery that it was sometimes done on women who were known to have newly described benign conditions that were classified and understood as having some increased probability of later developing into cancer.”).
\item \textsuperscript{24} See id. at 88; Bland, supra note 5, at 550 (“The American Cancer Society estimated in 1979 that 25,000 women (a fourth of newly diagnosed cases) would undergo a radical mastectomy that year. So this 19th century operation continues into the 1980s . . . .”).
\item \textsuperscript{25} See Bland, supra note 5, at 553 (“Volkmann found that cancer did not extend to the muscles, a finding in which Halsted concurred, to wit, ‘His observations were correct, and they have been confirmed in almost every detail . . . .’” (citation omitted)).
\item \textsuperscript{26} See id. at 549.
\end{itemize}
part because it was complicated and, consequently, expensive. She also opined that, by nature of its complexity, the surgery (1) allowed surgical practitioners to compete locally with general practitioners and (2) put American surgeons intellectually ahead of preeminent German surgeons abroad.

This article explores the political history surrounding breast cancer, then traces breast cancer's continuing political importance to the recent Supreme Court holding that Myriad Genetics' patents on isolated breast cancer genes are not patent eligible. Finally, the article explores the outcome and unintended repercussions that may arise from this change in patent jurisprudence.

II. **THE RISE OF BREAST CANCER AWARENESS IN THE UNITED STATES**

A. **Early Breast Cancer Activism**

Not surprisingly, with such a ghastly medical history, breast cancer has long been an intensely political issue. The breast cancer movement began to take shape in the 1970s, arguably sparked by First Lady Betty Ford's frank discussions of her own radical mastectomy in 1974. The First Lady publicly credited breast cancer screening for the early detection and successful treatment of her cancer. Her public discussion of her cancer led to a spike in self-examination and an increase in reported cases of breast cancer, a phenomenon known as the "Betty Ford blip."

Case rates were high until non-practicing physician and NCI Deputy Associate Director for Cancer Control John C. Bailar III went public with his

27 See id. at 552.

28 See id. at 552, 554. An overpopulated medical field in the United States led surgeons to seek out ways to distinguish themselves from the relatively unskilled masses of general practitioners. See id. at 552. Nationalism, in combination with 19th century American medical practitioners' continued reliance on European research for scientific developments, bred an intense rivalry between American medical leaders and their counterparts abroad. See id. at 554.


criticisms of the mammogram, noting that the mammogram—an X-ray of the breast—was not without its own radiation risks. The reduction in screenings that followed Bailar's critique was dramatic, with the number of screenings dropping from 24,000 per month to 17,000. Bailar's comments sparked a decades-long debate about early screening, which continues to this day.

B. The Revolution of Breast Cancer Treatment

Rose Kushner, who came to be known as the mother of breast cancer activism, led the movement to abandon Halsted's one-step radical breast removal procedure. Upon discovering a lump in her breast, Kushner decided that she would not agree to a one-step procedure in which she would not learn whether the suspicious lump was cancerous or benign until she gained consciousness following surgery, possibly absent a breast. Kushner eventually found a surgeon who agreed in writing to first perform a biopsy and refrain from doing an immediate mastectomy, even if the lump was diagnosed as cancerous. Her surgeon agreed to the arrangement because he was sure the lump was benign, but when the biopsy showed that the lump was cancerous, the surgeon "was furious that he had signed away his right to perform a radical mastectomy." Kushner later articulated the reasons underlying her vehement opposition to the Halsted

---

32 Klawiter, supra note 30, at 92–93. Prominent figures within the NCI dismissed Bailar's criticisms even before he made them public. See id. at 93; Barron H. Lerner, To See Today With the Eyes of Tomorrow: A History of Screening Mammography 10 (Mar. 2001) (unpublished background paper), https://iom.nationalacademies.org/-/media/Files/Activity%20Files/Disease/NCI/ToSeeTodaywiththeEyesofTomorrowAHistoryofScreeningMammography.pdf ("Since the earliest days of the [NCI's Breast Cancer Detection Demonstration Project ("BCDDP")], [Bailar] had voiced numerous concerns to Rauscher, Berlin, and others . . . . Although others at NCI and across the country shared Bailar's reservations, those in charge of the BCDDP concluded that it should proceed as planned.").

33 Klawiter, supra note 30, at 93.

34 See Lerner, supra note 32, at 9 ("The individual most responsible for the heated debates over mammography in the 1970s was John C. Bailar, III.").

35 See Klawiter, supra note 30, at 106.

36 See id. at 106–07.

37 See id. at 107.

38 Id.

In 1979, with Kushner on its panel of experts, the National Institutes of Health ("NIH") finally published a consensus statement repudiating the one-step procedure and the radical mastectomy. Shortly thereafter, states began to pass informed consent laws, which required that women be informed of their diagnoses and agree to a surgical option only after being told of all the treatment alternatives. By the end of the 1980s, breast cancer informed consent laws had been adopted in fourteen states, and today some form of medical informed consent is legally required in every state. Today, the radical mastectomy is rarely used, and the number of inpatient modified mastectomy and lumpectomy procedures has also declined significantly in recent years.

---

39 See id. at 107 ("‘My ideas may differ from those of other women,’ Kushner wrote, ‘but the point of this book is to show that we women should be free, knowledgeable, and completely conscious when the time comes for a decision, so that we can make it for ourselves.’ ‘Our lives are at stake,’ she added, ‘not a surgeon’s.’").


41 See Klawiter, supra note 30, at 108.

42 See, e.g., Mass. Ann. Laws ch. 111, § 70E (LexisNexis 2015) ("Every patient or resident of a facility shall be provided by the physician in the facility the right . . . (h) in the case of a patient suffering from any form of breast cancer, to complete information on all alternative treatments which are medically viable.").

43 See Klawiter, supra note 30, at 108.


C. Modern Breast Cancer Activism

By the 1990s, several breast cancer organizations had been established, following on the success of early AIDS activism. Groups including the National Breast Cancer Coalition and Breast Cancer Action, alongside many local breast cancer support organizations, successfully lobbied for dramatically increased funding for breast cancer research.

Despite the progress generated by these groups, various disputes over breast cancer continue, including the debate over the value and timing of mammograms, the current pink backlash in response to the commercialization of various breast cancer awareness and funding campaigns, and the argument over the costs and benefits of genetic screening for breast cancer genes. Now, even the stay decreased by 32 percent, and the inpatient lumpectomy rate declined by 45 percent” between 1997 and 2004).


See generally Susan Braun, The History of Breast Cancer Advocacy, 9 Breast J. (Supp. 2) S101, S101 (2003) (“[P]olitical action... became possible when breast cancer advocates joined together in the 1980s and 1990s to work toward legislative, regulatory, and funding changes, such as passage of the Mammography Quality Standards Act and increased funding for the National Cancer Institute. These efforts contributed to a more than quadrupling of federal funding for breast cancer research in the 1990s.”).

Supreme Court has entered the fray by invalidating patent claims to certain breast cancer genes.49

III. THE RISE AND FALL OF THE BRCA GENE PATENTS

A. The Role of Genetic Testing in Breast Cancer Detection

Approximately five to ten percent of breast cancer patients are more likely to develop breast cancer because of the particular genes they inherited from their parents.50 BRCA1 and BRCA2 are human genes that code for proteins that suppress tumors.51 These tumor suppressor proteins repair damaged DNA and help ensure the stability of a cell's genes.52 When either of the BRCA genes is mutated such that it either (1) does not produce the appropriate protein or (2) produces a protein that fails to function correctly, damage to DNA is not repaired.53 Consequently, the DNA damage may accumulate, with the result that the damaged cells are more susceptible to developing cancer.54

Myriad Genetics was among the first companies to discover the BRCA genes and some of the genetic mutations that lead to an increased risk of breast cancer.55 BRCA1 and BRCA2 are both large, complex genes; the BRCA1 gene

49 See Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2120 (2013).
52 Id.
53 Id.
54 Id. This article focuses on breast cancer in women, but BRCA1 and BRCA2 mutations also increase the risk of other cancers, including ovarian cancer, in women. See id. In fact, even men with BRCA 1/2 mutations suffer an increased risk of breast cancer, prostate cancer and other types of cancer. See id.
55 See E. Richard Gold & Julia Carbone, Myriad Genetics: In the Eye of the Policy Storm, 12 GENETICS MED. (SUPP.) S39, S41 (2010). Myriad owns some of the gene patents outright, but others are co-owned and/or licensed. See id. at S42, S44. The original breast cancer work was performed by a number of different entities, including the University of Pennsylvania and the University of Utah and was funded in part by the NIH. See Ambry Genetics Corp.'s Answer at
covers roughly 127,000 base pairs, contains 22 exons and encodes a large protein made up of 1,863 amino acids. BRCA1 is found on chromosome 17, which itself contains around 81 million base pairs. The BRCA2 gene covers roughly 11,000 base pairs, with 27 exons encoding an even larger protein made up of 3,418 amino acids, and it is found in chromosome 13, which contains approximately 115 million base pairs.

There is no single mutation that causes breast cancer. Rather, there are a number of mutations distributed throughout the two large BRCA genes that can


57 See 113705: *Breast Cancer 1 Gene*, supra note 56.


lead to an increased risk of cancer. Some mutations are known to create risk, while others are of uncertain significance, although as more and more data accumulates, some mutations will be dismissed as benign and others may eventually be associated with a particular risk level. Scientists continue to discover new BRCA1 and BRCA2 mutations and probably have not yet identified all potentially harmful ones. As a result, although the original BRCA1 patents began to expire in 2014 and 2015, patents covering various BRCA mutations and testing methods continued to be applied for and/or issued.

See generally 113705: Breast Cancer 1 Gene, supra note 56 (describing the various functions of the BRCA1 gene and the impact various mutations or failures have on the body’s susceptibility to breast and ovarian cancers); 600185: BRCA2 Gene, supra note 60 (describing the same facets of the BRCA2 gene).

See generally 113705: Breast Cancer 1 Gene, supra note 56; 600185: BRCA2 Gene, supra note 60 (for example, “BRCA2 C-terminal deletions lead to radiation sensitivity and cancer predisposition”).


BRCA1 and BRCA2: Cancer Risk and Genetic Testing, supra note 51.


B. The Myriad Tests

Myriad offers BRCA1 and BRCA2 genetic testing, but the cost of comprehensive testing of the entire BRCA1 and BRCA2 regions can be as high as $5000. Presently, there are more than 1,800 known or suspected mutations of each of the BRCA1 and BRCA2 genes, and full gene sequencing is considered to be the most sensitive method of detecting these mutations. Indeed, Myriad's BRCA1 test sequences more than 5,000 base pairs, and its BRCA2 test provides more than 10,000 base pairs of sequence information. A third Myriad test, known as the "BRACAnalysis® Rearrangement Test" ("BART"), tests for large-scale gene rearrangements that can also predispose a patient to cancer. Insurance companies typically pay for these tests when a patient's existing risk factors suggest that the

---

of the c-MAF gene for the existence of abnormal expression levels associated with the development of estrogen receptor positive breast cancer metastasis).

69 See Genetic Testing Facilities and Cost, BREASTCANCER.ORG, http://www.breastcancer.org/symptoms/testing/genetic/facility_cost (last updated Aug. 21, 2014) ("The cost of testing ranges from approximately $300 to $5,000, depending on whether you are being tested for only a specific area(s) of a gene known to be abnormal or if hundreds of areas are examined within multiple genes.").


71 See Robert Cook-Deegan et al., Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers, 12 GENETICS MED. (SUPP.) S15, S24 (2010) ("The most expensive but also most sensitive method is full-sequence testing.").


73 See id.
patient is at increased risk for a particular type of mutation, but insurance companies will not usually pay across the board for every test for every patient.

IV. LITIGATION OF MYRIAD'S BREAST CANCER GENE PATENTS

A. The ACLU Challenges Myriad's BRCA Patents Under § 101 of the Patent Act

In 2009, the American Civil Liberties Union ("ACLU") filed a complaint against the United States Patent and Trademark Office ("USPTO"), Myriad Genetics and various directors of the University of Utah Research Foundation, asserting that:

The patenting of human genes, the concept of looking at or comparing human genes, and correlations found in nature between certain genes and an increased risk of breast and/or ovarian cancer violates long established legal principles that prohibit the patenting of laws of nature, products of nature, and abstract ideas.

---

74 See Rachael Rettner, Breast Cancer Genetic Testing Gets Covered by Health Care Reform, LIVESCIENCE (Mar. 6, 2013, 11:42 PM), http://www.livescience.com/27701-genetic-testing-breast-cancer-insurance-coverage.html ("To be eligible for coverage of the test under the Affordable Care Act, a woman needs to be considered at high risk for breast and/or ovarian cancer, typically as a result of having a family history of the diseases, and she must have an insurance plan that is not grandfathered."). The Affordable Health Care Act requires that all new commercial health insurance plans cover 1) mammograms for women starting at age 40 and 2) BRCA1 and BRCA2 genetic testing and counseling for women who have a family history of breast and ovarian cancer. See id.; Breast Cancer Prevention and Early Detection, AM. CANCER SOC'y, http://www.cancer.org/acs/groups/cid/documents/webcontent/003165-pdf.pdf (last updated Aug. 19, 2015).

75 See, e.g., BRCA Testing, Prophylactic Mastectomy, and Prophylactic Oophorectomy, AETNA, http://www.aetna.com/cpb/medical/data/200_299/0227.html (last updated July 21, 2015) ("Aetna considers molecular susceptibility testing for breast and/or epithelial ovarian cancer (‘BRCA testing’) medically necessary once per lifetime in any of the following categories of high-risk adults . . . ." (emphasis added)).

One of the Plaintiffs was Dr. Haig Kazazian, who received a cease and desist letter from Defendant Myriad due to his oversight of work that was being carried out in the Genetic Diagnostic Laboratory of the Department of Genetics at the University of Pennsylvania School of Medicine.\textsuperscript{77} According to the complaint, Dr. Kazazian was prohibited from carrying out routine BRCA1 and BRCA2 gene screening, either for research purposes or as part of his clinical practice, without Myriad's permission.\textsuperscript{78} Several other research scientists were named in the complaint,\textsuperscript{79} but none of them, aside from Dr. Kazazian, had ever received a cease and desist letter from Myriad.\textsuperscript{80} Medical and political groups also joined the suit as Plaintiffs.\textsuperscript{81}

A number of patient plaintiffs were also named, some of whom could not afford testing or could only afford some of the tests, and one of whom allegedly sought a second opinion and could not obtain one due to the restrictions the Myriad patents imposed upon physicians who did not have licenses to deploy the Myriad tests.\textsuperscript{82}

\textsuperscript{77} Id. at 5.
\textsuperscript{78} Id. at 5–6.
\textsuperscript{79} See id. at 1, 6–8.
\textsuperscript{80} See id. at 6–8.
\textsuperscript{81} See Complaint, supra note 76, at 1, 9–10. The Association of Medical Pathology (AMP) also was a named plaintiff. See id. at 1, 3. The American Medical Association (AMA) along with several other medical groups, filed amicus briefs in support of the plaintiffs. See, e.g., Brief for AMA et al. as Amici Curiae in Support of Plaintiffs' Opposition to Defendants' Motion to Dismiss and in Support of Plaintiffs' Motion for Summary Judgment, Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515). Not all groups, however, sided with the plaintiffs; indeed, the Biotechnology Industry Organization (BIO) and another group including BayBio, Celera Corporation, the Coalition for 21st Century Medicine, Genomic Health, Inc., QIAGEN, N.V., Target Discovery, Inc., and XDx, Inc. filed amicus briefs in support of Defendant Myriad. See, e.g., Brief for Biotechnology Industry Org. as Amicus Curiae in Support of Defendants' Opposition to Plaintiffs' Motion for Summary Judgment, Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515); Brief for BayBio, Celera Corp. et al. as Amici Curiae in Support of Defendants' Opposition to Plaintiffs' Motion for Summary Judgment, Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515).

\textsuperscript{82} Complaint, supra note 76, at 1, 10–13, 27.
According to the complaint, “Defendant Myriad did not invent, create or in any way construct the differences found when genes are compared or the correlations between certain mutations and an increased risk of breast and/or ovarian cancer. Nature did that.” The Complainants went on to argue that “an ‘isolated and purified’ gene includes one that is simply removed from the body and removed from other content of the cell. Removing a product of nature from its natural location does not make it any less a product of nature.”

1. Diamond v. Chakrabarty Illuminates § 101’s Definition of “Patentability”

The crux of the plaintiffs’ argument in Association for Molecular Pathology v. Myriad was that the Myriad patents were invalid because the subject matter of the patents was a natural product, and natural products simply are not patent eligible under 35 U.S.C. § 101. § 101 states:

> Whoever 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 therefor, subject to the conditions and requirements of this title.

In the past, § 101 has been read quite broadly to include “anything under the sun that is made by man.” Diamond v. Chakrabarty is the seminal case in this area. Chakrabarty, a researcher, created a genetically engineered bacterium that contained at least two, and up to four, plasmids that enabled the bacterium to

---

83 Id. at 18.
84 Id. at 19.
85 Id.
88 See generally id. at 315 (“Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose. Here, we perceive no ambiguity. The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting ‘the Progress of Science and the useful Arts . . .’ Broad general language is not necessarily ambiguous when congressional objectives require broad terms.”).
effectively metabolize crude oil.\textsuperscript{89} The original bacterium Chakrabarty worked with could not metabolize oil at all, but after genetic modification it was capable of degrading four components of oil.\textsuperscript{90} The USPTO deemed patentable both (1) claims to the process of making the bacteria and (2) claims relating to an inoculum comprised of a floating material plus the bacteria.\textsuperscript{91} The USPTO, however, rejected Chakrabarty's claims to the bacteria themselves, stating that they were products of nature and therefore not patent eligible.\textsuperscript{92} The Supreme Court reversed, stating that Chakrabarty "has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."\textsuperscript{93}

The Supreme Court was not persuaded by the Chakrabarty plaintiffs' argument that a "gruesome parade of horribles"\textsuperscript{94} would ensue if the Court were to permit the patenting of genetically engineered microorganisms:

The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available

\textsuperscript{89} See id. at 305. A plasmid is a "hereditary unit physically separate from the chromosome of the cell." See id. at 305 n.1.

\textsuperscript{90} See id. at 305 & nn.1–2.

\textsuperscript{91} See id. at 305–06.

\textsuperscript{92} See Chakrabarty, 447 U.S. at 306.

\textsuperscript{93} Id. at 310.

\textsuperscript{94} See id. at 316–17 ("Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that, with Hamlet, it is sometimes better 'to bear those ills we have than fly to others that we know not of.' It is argued that this Court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter under § 101. We disagree.").
suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.95

While the Court found that the particular claims at issue in Chakrabarty were in fact patentable, it took the opportunity to reiterate the oft-quoted principle that:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity: $F = ma$. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.”96

2. USPTO Practice Following Chakrabarty Supported the Patentability of Isolated DNA

Following the Chakrabarty decision, the USPTO determined that isolated and purified DNA was patentable.97 Its conclusion rested on two premises: (1) the isolated and purified product is created through the severance of chemical bonds, whereby the DNA is released from its normal environment (“isolated”) and (2) the DNA is then “purified” from the remaining components of the cell.98 Thousands

---

95 Id.

96 Id. at 309 (internal citations omitted).

97 See, e.g., U.S. Patent No. 4,703,008 col. 40 l. 1–7 (filed Nov. 30, 1984) (claiming “[a] purified and isolated DNA sequence . . . encoding . . . erythropoietin”). Although the Myriad claims recite “isolated” DNA, most DNA-based patents claim “isolated and purified” DNA, perhaps following the USPTO Guidelines.

98 See generally U.S. Patent & Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 4, 1092, 1093 (Jan. 5, 2001) (“DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified, and when the application meets the statutory criteria for patentability.”).
of patents have issued to isolated genetic material\textsuperscript{99} and a $99 billion biotech industry\textsuperscript{100} has developed since Cohen and Boyer filed the first patents on genetic engineering methodologies.\textsuperscript{101}

B. The Association for Molecular Pathology v. Myriad Case Works its Way Up to the Supreme Court

Although the USPTO had already granted thousands of patents on isolated and purified DNA at the time the American Civil Liberties Union’s complaint was filed against Myriad, the plaintiffs in the suit encouraged the Court to declare that human genes are not patent eligible because human genes are products of nature.\textsuperscript{102} The District Court ruled in the plaintiffs’ favor, finding that claims to isolated and purified DNA are not patentable because such DNA is a product of nature.\textsuperscript{103}


\textsuperscript{100} See ERNST & YOUNG GLOBAL LTD., BIOTECHNOLOGY INDUSTRY REPORT 2014: BEYOND BORDERS: UNLOCKING VALUE 37 (2014), http://www.ey.com/Publication/vwLUAssets/EY-beyond-borders-unlocking-value/$FILE/EY-beyond-borders-unlocking-value.pdf (“The performance of the biotechnology industry was strong in 2013, with revenues of publicly traded companies in the four established centers of the US, Europe, Canada and Australia increasing by a robust 10% relative to 2012.”).

\textsuperscript{101} See U.S. Patent No. 4,237,224 (filed Jan. 4, 1979). In 1980, Stanford University was granted a patent on a process for making recombinant DNA, a.k.a. genetic engineering, invented in the laboratories of Stanley Cohen and Herbert Boyer. See id. at [45], [75], col. 1–2. These early discoveries paved the way for the development of the biotechnology industry.

\textsuperscript{102} See Complaint, supra note 76, at 3; BRCA—Plaintiff Statements, ACLU (May 12, 2009), https://www.aclu.org/free-speech_womens-rightslbrca-plaintiff-statements#kazazian (“[G]enes and their mutations are naturally occurring substances that should not be patented.”)

\textsuperscript{103} See Ass’n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 231–32, 238 (S.D.N.Y. 2010), aff’d in part, rev’d in part, 689 F.3d 1303 (Fed. Cir. 2013).
On appeal, the Federal Circuit reversed, holding that isolated DNA is patent eligible because "isolated DNA must be removed from its native cellular and chromosomal environment, [and] it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body." The Federal Circuit recognized that a gene-in-hand was not chemically the same as a gene located in a chromosome inside a cell inside a body.

Scientifically speaking, the Federal Circuit was correct. In nature, the BRCA1 gene is chemically bound to the DNA of chromosome 17—a complex winding structure including some 81 million base pairs of DNA and many proteins. Myriad's patent claims do not cover the BRCA genes as they exist in bodies, or cells, or even in a single chromosome: the patents cover isolated DNA that has been severed from the chromosomal DNA where it normally exists. Even if an isolated gene were to be placed back inside the human body, it would not function as the chromosomal copy of the gene does because it would exist outside of the regulatory constraints imposed by the complete chromosomal structure. Therefore, the claimed DNA molecules are in fact different from the natural form of the gene, although they encode the same protein.

104 Ass'n for Molecular Pathology v. USPTO, 653 F.3d 1329, 1352 (Fed. Cir. 2011).
105 See id. at 1363.
106 BCRA1, supra note 58.
108 See Chromosome 17, supra note 59.
109 What is a Chromosome?, supra note 107.
110 See, e.g., '282 Patent col. 153-54 (filed June 7, 1995) ("What is claimed is . . . [a]n isolated DNA coding for a BRCA1 polypeptide . . .").
111 See Brief for American Intellectual Property Law Association as Amicus Curiae in Support of Reversal, But in Support of Neither Party at 14–15, Ass’n for Molecular Pathology v. USPTO, 689 F.3d 1303 (Fed. Cir. 2011) (No. 2010–1406), 2010 WL 4853327 at *14 ("[B]y divorcing the claimed purified/isolated DNA molecules from native chromosomes, the inventors introduced fundamental structural changes that render them incapable of performing in exactly the same fashion as they do in the human body.").
The Plaintiffs appealed to the Supreme Court, which vacated the Federal Circuit’s decision without opinion and remanded the case to the Federal Circuit to be reconsidered in light of the Supreme Court’s holding under *Mayo v. Prometheus*, which stated that personalized dosing method claims were not patent eligible as reading on laws of nature. Even on reconsideration, however, the Federal Circuit maintained the principle that isolated DNA claims were patent eligible, although it did affirm the District Court’s holding that genetic method claims that recite only a single active verb of “comparing” or “analyzing” DNA were not patent eligible because they contained only “abstract, mental steps.”

C. *The Supreme Court Decision*

The Plaintiffs appealed again following the Federal Circuit’s ruling, and the Supreme Court again granted certiorari. The Court held that “genes and the

---


113 See id. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court held that a patent claim to a method of optimizing a patient’s treatment by administering a drug and measuring its metabolite levels was not patent eligible because the claim read on a law of nature. 132 S. Ct. 1289, 1294–95, 1305 (2012). This article does not discuss *Mayo* in any depth because its holding is difficult to analyze and apply. There is no natural law that governs the metabolism of a drug in a patient—indeed, every patient metabolizes a given drug at a different rate, which is why drug usage must be optimized for each patient. For an analysis of the Court’s holding in *Mayo*, see Tamsen Valoir, *Mayo v. Prometheus: Natural Law or Mental Step?*, INTELL. PROP. & TECH. L.J., Dec. 2012, at 1, 3–5.

114 See *Mayo*, 132 S. Ct. at 1294–95, 1305.

115 Ass’n for Molecular Pathology, 689 F.3d at 1328–29.

116 Id. at 1309 (“We affirm the court’s decision, however, that Myriad’s method claims directed to ‘comparing’ or ‘analyzing’ DNA sequences are patent ineligible; such claims include no transformative steps and cover only patent-ineligible abstract, mental steps.”). This portion of the decision relates back to the Supreme Court’s discussion of claimed “steps” in the *Mayo* opinion. See *Mayo*, 132 S. Ct. at 1293–94, 1297, 1300.

information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.”118 According to the Court, “Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.”119 Although the patented genes were chemically severed from the millions of bases in the native chromosomal environment, the Court stated that, “Myriad’s claims [are not] saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule.”120

V. ANALYSIS: THE FALLOUT FROM THE SUPREME COURT’S HOLDING IN MYRIAD

A. The Supreme Court’s Holding that Isolated DNA is not Patentable is Inconsistent with Prior USPTO Practice

The Supreme Court’s holding that isolated DNA is not patent eligible because it is (or was) a natural product will have far-reaching and unintended consequences, and will possibly invalidate many therapeutic patents.

Every pharmaceutical purified from a plant or animal is derived from a natural product, and yet many have been the subjects of patents once purified.121 Insulin is a good example. It was first patented when Banting partially purified it from a dog pancreas,122 and it has saved countless lives since.123 Many existing

118 Myriad, 133 S. Ct. at 2120.

119 Id. at 2117.

120 Id. at 2118.


122 See U.S. Patent No. 1,469,994 (filed Jan. 12, 1923) (“[E]xtract obtainable from the mammalian pancreas or from the related glands in fishes, useful in the treatment of diabetes mellitus, and a method of preparing it . . . .”).

biological patents might be at risk under the Supreme Court’s holding in *Myriad* because proteins are also natural products.\(^{124}\)

It’s difficult to articulate a scientific rationale for treating DNA as somehow different from proteins that can be purified from natural sources. Arguably, DNA is more changed by being isolated and purified than a protein is: during the isolation process, the chemical bonds that bind DNA to the rest of the chromosomal DNA are severed,\(^{125}\) whereas insulin, like other proteins, is merely purified from the remaining cell components and otherwise remains unchanged.\(^{126}\) Therefore, the Supreme Court’s holding in Myriad would appear to invalidate many protein patents as well.

In unofficial discussions, a USPTO Examiner has indicated that if presented today, a purified insulin claim would be rejected under § 101, just like any claim to isolated and purified DNA. Indeed, the USPTO Guidance published in March of 2014 confirms that protein patent claims are subject to rejection as natural products under § 101.\(^{127}\)

Thus, if an insulin patent were presented today (assuming it wasn’t already long known), it would be rejected as ineligible. Indeed, it’s not just proteins and DNA patents at risk—a very large percentage of small molecule


\(^{125}\) See generally GRIFFITHS ET AL., supra note 56.

\(^{126}\) Insulin is found in the cell cytosol, “[t]he aqueous component of the cytoplasm of a cell, within which various organelles and proteins are suspended.” Cytosol, OXFORD DICTIONARIES, http://www.oxforddictionaries.com/us/definition/american_english/cytosol (last visited Dec. 5, 2015). The insulin need not be cut from anything, unlike segments of DNA, which must be cut out of the chromosome and those chemical bonds severed. Compare ‘994 Patent, with GRIFFITHS ET AL, supra note 56, at 368–69.

\(^{127}\) See MARCH 2014 UPDATE, supra note 124, at 60 (“Blood and protein . . . are not markedly different from what exists in nature. They are judicial exceptions (natural products).”).
drugs are natural products,\textsuperscript{128} and could have their patents revoked.\textsuperscript{129} One wonders how many of these drugs would have been developed without patent protection.\textsuperscript{130}

\textbf{B. The Myriad Patents Did Not Impede Cancer Research}

One consequence of the continued validity and enforcement of the Myriad patents listed in the ACLU’s “parade of horribles” was that the enforcement of the BRCA1/2 patents impeded basic research, though this view was supported only by evidence that a single research scientist received a cease and desist letter.

\textsuperscript{128} Daptomycin, for example, was isolated from a soil bacteria, and some of its patents could be challenged based on the Myriad holding. HETEROCYCLIC SCAFFOLDS II: REACTIONS AND APPLICATIONS OF INDOLES 10–11 (G.W. Gribble ed., 2010); see also Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluation, U.S. FOOD AND DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021572&Product_No=002&table1=OB_Rx (listing the Orange Book patents for Daptomycin).


\textsuperscript{130} Himanshu Gupta et al., Patent Protection Strategies, 2 J. PHARM. BIOALLIED SCI. 2 (2010), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/ (“Without patent protection, the pharmaceutical company is unlikely to invest the capital needed to develop innovative medications. . . . Some estimates indicate that the cost for developing and marketing a single pharmaceutical product has risen from $54 million in the 1970s to greater than $800 million by 2000. Patent protection and the market exclusivity that comes with it help to ensure a return on investment.”).
relating to the patents. Indeed, ACLU rhetoric frequently mentioned that the Myriad patents restricted basic research.

In fact, Myriad did send a cease and desist letter to the University of Pennsylvania’s Genetic Diagnostic Laboratory (“GDL”) in 1998, after Myriad obtained its BRCA2 patent, even though the University of Pennsylvania was a co-owner of the BRCA2 patent and had licensed its use to Myriad. GDL ensured that the letter was highly publicized as an example of Myriad’s efforts to impede basic scientific research.

It appears, however, that the cease and desist letters sent by Myriad were related to clinical testing services, not basic research, and Myriad had agreed (though apparently not publicly) to provide at-cost or below-cost testing to researchers who were using their own grant money to fund the tests. Myriad has

131 See Complaint, supra note 76, at 5–6. My own research at PubMed.gov didn’t show any reduction in BRCA1/2 publications after the time of the Myriad patents’ issuance but rather showed a steady rise in publication numbers every year.


133 See Gold & Carbone, supra note 55, at S44.

134 See id. at S44.

135 See, e.g., BRCA—Plaintiff Statements, supra note 102 (statement of Haig H. Kazazian, Jr., M.D.).

136 See Gold & Carbone, supra note 55, at S42 (“Myriad entered into a Memorandum of Understanding (MOU) with the NCI to provide at cost or below cost testing to the NCI and any researcher working under a NCI-funded project. (Myriad had similarly offered to provide NIH researchers with at cost testing given that the NIH was a co-owner of some of the relevant patents). The MOU defined research testing services as ‘part of the grant supported research of an investigator, and not in performance of a technical service for the grant supported research of another (as a core facility, for example’) (MOU between Myriad Genetics Laboratories and the NCI). Research testing services are further defined as paid for by grant funds and
also publicly stated that it had been, and, as of 2010, still was, "Myriad’s policy and practice to allow scientists to conduct research studies on the BRCA1 and BRCA2 genes freely."[137] Further, Myriad claims to have collaborated with more than "440 outside researchers ... in more than 110 research programs ..."[138]

Our own search of PubMed shows that almost 8,000 articles referencing BRCA1 or BRCA2 in the abstract or title were published by 2009, suggesting that basic research was not actually being impeded. Even if only those publications showing actual gene testing are counted, the issuance of the BRCA patents did not result in an apparent decline in the number of publications created each year. The limited information available suggests while clinical testing may have been impeded by the Myriad patents’ issuance, basic research was not.[139]

C. The Myriad Tests were not Inaccessibly Expensive

Cost of testing was another concern voiced in the ACLU complaint, which alleged that some of the named female plaintiffs couldn’t afford the Myriad gene tests, and therefore had not undergone BRCA testing as of the filing date.[140] Theoretically, patents can increase the costs of genetic tests because the patent

---


138 Id.

139 See CHRISTOPHER M. HOLMAN, GEORGE MASON UNIV. SCH. OF LAW: CTR. FOR THE PROT. OF INTELL. PROP., THE CRITICAL ROLE OF PATENTS IN THE DEVELOPMENT, COMMERCIALIZATION, AND UTILIZATION OF INNOVATIVE GENETIC DIAGNOSTIC TESTS 6 (July 2014), http://cpip.gmu.edu/wp-content/uploads/2014/04/Holman-Christopher-The-Critical-Role-of-Patents-in-Genetic-Diagnostic-Tests.pdf (“In fact, empirical studies have shown that basic researchers follow a norm of ignoring patent infringement, and that patent owners do not enforce their patents against basic researchers, resulting in a de facto research exemption from liability. Patent owners have little if any incentive to enforce patents against basic researchers—to the contrary, patent owners often welcome third-party basic research on patented subject matter, since it tends to promote and enhance the value of the patented subject matter.”).

140 See Complaint, supra note 76, at 10–13.
owner can charge more without the threat of price competition. At first glance, the $4,000 to $5,000 Myriad price tag seems excessive, especially when alternative provider 23andMe offers gene testing for $99. The 23andMe test, however, involves looking at a subset of single nucleotide polymorphisms ("SNP" s), whereas the BRCA tests involve actual genomic sequencing and the study of large-scale rearrangements of the BRCA1 and BRCA2 genes. The 23andMe tests are far less comprehensive than the Myriad tests, so the prices are not easily comparable. Further, the steep Myriad price of $5,000 gets a patient comprehensive testing, but, if desired, a SNP can be tested for a much-reduced price of approximately $300. A SNP test would be suitable if a patient’s parent or sibling is known to possess a particular SNP, which would lead doctors to search for a copy of that SNP in the patient.

In a price study published by the Secretary’s Advisory Committee on Genetics, Health, and Society (the “SACGGH” Report), little evidence of a Myriad-implemented price premium was found. The SACGGH Report compared

---


142 See id. at 2; Genetic Testing Facilities and Cost, supra note 69.

143 See Agus, supra note 141.

144 See id. ("23andMe uses a technology called genotyping, which identifies specific variants (or markers) within the genes that are associated with diseases rather than sequencing the genes the way Myriad does—which makes the process much easier and, admittedly, less comprehensive in its analysis."); About the 23andMe Personal Genome Service, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/202908020-About-the-23andMe-Personal-Genome-Service (last visited Sept. 28, 2015).

145 MYRIAD GENETIC LABS. INC., supra note 72, at 1.

146 See Genetic Testing Facilities and Cost, supra note 69 (“The cost of testing ranges from approximately $300 to $5,000, depending on whether you are being tested for only a specific area(s) of a gene known to be abnormal or if hundreds of areas are examined within multiple genes.”).


148 SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH AND SOC’Y, DEP’T OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON
BRCA1/2 testing prices, where Myriad has the dominant patent portfolio, against Lynch gene testing, wherein “the involved gene patents are predominantly held by non-profit institutions, and licensed non-exclusively.” Both tests involve full gene sequencing, meaning that the two categories of tests are more comparable to each other than either is to the 23andMe test.

After normalizing prices for gene size, the SACGGH Report concluded that:

The price comparisons may be surprising to some, as normalized prices show little if any price premium. This, in turn, suggests the main market impact of the BRCA patents is not on price but rather on volume, by directing BRCA full-sequence testing in the United States to Myriad, the sole provider.

---

149 Id. at A-2.
150 Id.
151 See id.; MYRIAD GENETIC LABS., INC., supra note 72, at 1.
Indeed, the data provided in the report shows that BRCA1/2 test prices are roughly comparable to the genetic testing prices set by other institutions:

Table 1. Comparison of Cost-per-Base-Pair among Genetic Tests.\textsuperscript{153}

<table>
<thead>
<tr>
<th>Disease</th>
<th>Genetic Test</th>
<th>Total Amplicons</th>
<th>Test Provider</th>
<th>Provider’s Charge\textsuperscript{*}</th>
<th>Charge per Amplicon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast / Ovarian Cancer</td>
<td>BRCA1 and BRCA2 full sequencing</td>
<td>35 + 47 - 82</td>
<td>Myriad\textsuperscript{a}</td>
<td>$3,120</td>
<td>$38.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Baylor</td>
<td>$1,675</td>
<td>$19.88</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Boston</td>
<td>$1,675</td>
<td>$19.88</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Harvard</td>
<td>$1,500</td>
<td>$35.71</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Huntington</td>
<td>$1,200</td>
<td>$28.57</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Univ. of PA</td>
<td>$1,360</td>
<td>$32.38</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mayo Clinic</td>
<td>$1,300</td>
<td>$30.95</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Myriad\textsuperscript{a}</td>
<td>$1,795</td>
<td>$40.80</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Baylor</td>
<td>$3,200</td>
<td>$53.33</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Boston Univ.</td>
<td>$2,995</td>
<td>$49.92</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>City of Hope</td>
<td>$464.16</td>
<td>$77.44</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Harvard</td>
<td>$2,700</td>
<td>$45.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Huntington</td>
<td>$1,800</td>
<td>$30.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mayo Clinic\textsuperscript{b}</td>
<td>$3,100</td>
<td>$51.67</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Myriad\textsuperscript{a}</td>
<td>$2,950</td>
<td>$49.17</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>U. Pennsylvania</td>
<td>$2,840</td>
<td>$47.33</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Quest Diagnostics</td>
<td>$4,760</td>
<td>$79.33</td>
</tr>
</tbody>
</table>

Notes: Cost per base-pair represents authors' calculations based on costs reported by the testing facilities and the size of each gene as reported by NCBI.
\textsuperscript{*} Includes major rearrangement testing (5 common insertions/deletions and analysis for any other rearrangements in high-risk individuals)
\textsuperscript{v} Includes Southern Blot analysis for rearrangements and 2 MYH mutations (an additional 2 PCR amplicons) with full sequence of MYH if one of the 2 common mutations is detected.
\textsuperscript{a} Includes rearrangement analyses

Further refuting the ACLU’s allegations that Myriad tests are prohibitively expensive, Myriad claims that “[m]ore than 90% of the BRACAnalysis tests ordered by healthcare providers are covered by insurance.”\textsuperscript{154}

\textsuperscript{153} Id. at A-17.

\textsuperscript{154} CAPONE, supra note 139, at 1; see also, U.S. PATENT AND TRADEMARK OFFICE, REPORT TO CONGRESS: REPORT ON CONFIRMATORY GENETIC DIAGNOSTIC TEST ACTIVITY 3–4 (Sept. 2015), http://www.uspto.gov/sites/default/files/documents/USPTO_Report_on_Confirmatory_Genetic_DiagnosticTest_Activity.pdf [hereinafter GENETIC DIAGNOSTIC TEST ACTIVITY] (concluding that “evidence is unclear as to whether exclusivity drives the cost of a given test markedly higher than if the test were offered on a non-exclusive basis” and that “this report can only emphasize that insurance coverage does appear to play significant a role in access to testing and should be taken into consideration when issues of access are examined”).
For those without insurance, Myriad offers free testing and reports that it provided more than 3,000 such tests between 2006 and 2010. While it is undoubtedly true that some people cannot afford the tests and may also be unable to access Myriad’s free testing program, cost of testing hardly seems like a valid basis for concluding that isolated and purified genes are not even patent eligible.

The SACGGH Report also arguably belies the Myriad complainants’ allegation that one of the plaintiffs was unable to get a second opinion on her BRCA1/2 tests: it appears that at least two institutions, apart from the one at which the plaintiff at issue was tested, offer Myriad’s tests. Myriad confirmed this data, noting that “[t]here are various laboratories in the US available for confirmatory testing under licenses from Myriad” and specifically naming the University of Chicago Genetic Services Laboratories and Yale DNA Diagnostic Laboratories as examples. Obtaining a second test from an additional lab appears to be possible, contrary to the complainants’ allegations.

D. The Myriad Patents Did Not Confer Ownership of Information

Another concern embedded in the ACLU complaint is that the BRCA patents somehow block the free dissemination and use of the information encoded in the BRCA1/2 gene sequences. In fact, the Complaint alleged that “[g]ene

155 CAPONE, supra note 137, at 2 (“Since 1996 when BRACAnalysis was launched, Myriad has had a financial assistance program directly providing testing at no charge to low-income, uninsured patients. Just in the last four years, more than 3,000 patients have received free BRCA testing under this program.”).

156 Complaint, supra note 76 at 11.

157 SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH AND SOC’Y, supra note 148, at 23 (Box: Genetic Testing for Breast/Ovarian Cancer and Colon Cancer).

158 CAPONE, supra note 137, at 2.

159 Insurance companies will not pay twice however. See GENETIC DIAGNOSTIC TEST ACTIVITY, supra note 154, at 24 (“Evidence from insurance policies indicated that the cost of confirmatory genetic testing is generally currently not covered.”).

160 Complaint, supra note 76, at 25 (“These genes, their effects, and the correlations between the genes and disease were created by nature and exist in nature. They are pure information, and in order to build upon them, one needs to utilize the patented sequences, which is not permissible under the patents.”); id. at 26 (“Myriad maintains the largest database of BRCA1 and BRCA2 data. It does not share the information in that database . . . .”).
patents can serve as a disincentive to innovation in molecular testing because they deny access to a vital baseline of genomic information that cannot be invented around."\(^{161}\)

In fact, all patented gene sequences and mutations are provided both in the patents themselves\(^{162}\) and in GenBank—the database that includes most of the planet’s available DNA sequence data.\(^{163}\) Further, anyone with an internet connection can access the GenBank database and copy or study the gene sequences therein.\(^{164}\) The Myriad patents do not in fact claim the sequence information, but rather encompass only the isolated and purified bits of DNA and their various uses.\(^{165}\)

E. Alternative, Non-Infringing Methods of BRCA Gene Testing are Available to Researchers, Clinicians, and Patients

It is true that the Myriad patents may deter some individuals from determining their own genetic status, at least to the extent that the tests they wish to use (1) involve isolated DNA and (2) are not performed by Myriad or one of its licensees. Other genetic testing technologies that do not rely on isolated DNA, however, have developed. For example, in whole genome sequencing (“WGS”), no DNA needs to be isolated.\(^{166}\) As WGS becomes more commonplace, patients will be able to sidestep gene patents like those at issue in Myriad by nanopore

\(^{161}\) Id. at 26.


\(^{165}\) See, e.g., ‘282 Patent col. 153 (Claim 1: “An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.”).

\(^{166}\) See W. Nicholson Price II, Unblocked Future: Why Gene Patents Won’t Hinder Whole Genome Sequencing and Personalized Medicine, 33 CARDOZO L. REV. 1601, 1603 (2012) (“Current genetic testing is usually for a specific gene . . . and determines which variant of the gene the patient has at the particular locus . . . . WGS [whole genome sequencing], on the other hand, is the technique of actually determining the entire sequence—base by base—of the full genome of a patient . . . .”).
sequencing the entire genome without isolating small pieces of the BRCA1/2 genes.\textsuperscript{167} In fact, with the cost of WGS finally dipping below a thousand dollars, widespread use of the technology is around the corner.\textsuperscript{168} Today, sequencing the entire genome can be cheaper than sequencing only the BRCA1/2 genes,\textsuperscript{169} although analysis of the billions of base pairs of data yielded from the sequencing of the entire genome still presents some challenges.\textsuperscript{170}

F. \textit{Trade Secrets Provide an Informational Advantage That, if Not Remedied, Will Continue to Hinder the Advancement of Personal Medicine}

Though the Myriad patents do not appear to meaningfully restrict patient access to genetic testing, the case does raise at least one meritorious informational concern. In 2004, Myriad stopped sharing its database of BRCA1/2 mutations with the public, and now the company considers its large database of BRCA1/2 gene variants to be a trade secret.\textsuperscript{171} To understand why this is important, we need to

\textsuperscript{167} \textit{Id.} at 1601, 1606 ("[I]solated DNA gene patents are likely not infringed by WGS. Infringement is especially unlikely for ... nanopore sequencing, which appears more likely to actually fulfill the requirements of true personalized medicine.").

\textsuperscript{168} Ed Yong, \textit{Whole-Genome Growing Pains}, \textit{The Scientist} (Mar. 11, 2014), http://www.the-scientist.com/?articles.view/articleNo/39400/title/Whole-Genome-Growing-Pains/ ("The cost of the [whole-genome sequencing] technique finally fell below the $1,000 mark earlier this year, heralding a future in which clinicians could routinely use it to diagnose people with unusual diseases, identify genes behind rare inherited disorders, and predict how patients might respond to treatments.").

\textsuperscript{169} Compare \textit{id.}, with \textit{Genetic Testing Facilities and Cost}, supra note 69.

\textsuperscript{170} See Yong, \textit{supra} note 168.

\textsuperscript{171} See Ambry Genetics Countersues Myriad Genetics in BRCA Testing Fight, \textit{The Pathology Blawg} (Aug. 12, 2013), http://pathologyblawg.com/pathology-news/pathology-vendors/myriad-genetics/ambry-genetics-countersues-myriad-genetics-brca-testing-fight/ ("In 2004, Myriad stopped contributing data to a public database it had itself set up in 1996 for storing ‘personal and family cancer histories of the patients that had purchased Myriad’s tests to understand whether they had any mutations in their BRCA1 and BRCA2 genes.’ In 2005, Myriad stated it did so so as to keep the information a trade secret.").
know more about the types of mutations that have been found to exist in the BRCA1/2 genes.

Some BRCA1/2 test results provide patients with a clear result—that is, some genetic mutations provide a clear predisposition to cancer.172 Some variants, however, are difficult to interpret because their medical effects are not yet known.173 These variants are classified as “variants of unknown significance” (“VUS”).174 Because Myriad was the main provider175 and continues to be the clinically preferred provider of the BRCA1/2 tests,176 it is the largest collector of VUS177 and the medical data associated with those VUS.178 Furthering its informational advantage even more, Myriad offers free testing to a patient’s family members if the patient’s BRCA1/2 test results reveal a VUS, “in an effort to gain more information and help determine the clinical significance of the variant.”179 The more data it collects, the more frequently Myriad is able to ascribe a particular significance to a variant, thereby removing it from the pool of VUS. The Myriad database therefore has fewer VUS in it than any other database, and Myriad has kept all of that information secret since 2004.180

175 See Stephanie Nguyen & Sharon F. Terry, Free the Data: The End of Genetic Data as Trade Secrets, 17 GENETIC TESTING & MOLECULAR BIOMARKERS 579, 579 (2013).
176 Nguyen & Terry, supra note 175, at 579.
179 Nguyen & Terry, supra note 175, at 579.
180 See McCullough, supra note 176. It is possible that Myriad may choose to patent all variants of clinical significance, thereby keeping only the insignificant VUS secret. Even if Myriad undertook to do so, however, women
This aspect of informational control raises serious concerns in the scientific community, and rightly so. The promise of personalized medicine can never be broadly realized for society as a whole if companies are allowed to maintain patient data as a trade secret.

This data secrecy means that Myriad is able to provide more information on VUS than their competitors, and indeed Myriad has asserted in recent litigation that its tests are superior because it has access to broader data on VUS. In a motion for preliminary injunction filed against Ambry Genetics, Myriad argued that:

The public interest is advanced by more patients receiving tests from Myriad because of Myriad's exclusive access to its proprietary and extensive database of known genetic variants when making a comparison with a patient test sample. This database allows Myriad to report definitive findings to over 97% of its patients. Ambry, in contrast, can do this only 70-75% of the time. Thus, Ambry will inform 25-30% of patients tested that they have a genetic variant, but will give them no further information about the clinical implications of that variant.

Even if every BRCA1/2 patent claim is invalidated, Myriad retains a significant advantage over its competitors because it can still offer potential customers a more definitive risk analysis based on the data it has collected and continues to collect from its patients. Thus, regardless of the drivers leading the Supreme Court to unanimously hold that isolated DNA is not patent eligible, invalidating Myriad's patents doesn't help women with VUS, who still must be

whose test results reveal VUS are unlikely to be reassured by the availability of evidence that their mutation has not be confirmed to be pathogenic; these women would rather have a straight negative result. Further, the Supreme Court holding can be expected to deter some patenting efforts in favor of trade secrets.

181 See, e.g., Robert Cook-Deegan et al., The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?, 21 EUR. J. HUM. GENETICS 585, 587 (2013) ("Current practices of proprietary databases may hinder interpretation of genomic data and impede the advance of personalized medicine.").

182 Univ. of Utah Research Found.'s Memorandum in Support of Motion for Preliminary Injunctive Relief, supra note 178, at 37, 43.

183 Id. at 43 (internal citations omitted).
tested by Myriad, at Myriad prices, if they want to know with certainty the level of cancer risk that is attributed to any variants revealed through the testing.

G. **Invalidating the Myriad Patents Does Not Remedy the Informational Concerns**

Another aspect of informational concern relates to being able to access one’s own genetic information. Sapna Kumar argues that (1) Americans have a fundamental liberty interest in their own genetic information and (2) any governmental regulation that interferes with a fundamental liberty must be narrowly tailored to serve a compelling government interest.184 Sapna Kumar articulates the concern over genetic informational control succinctly:

> Diagnostic patents may confer inventors with de facto monopolies on bodily information, such as DNA mutations. When misused, such patents can prevent patients from learning about key information in their own bodies, preventing them from making informed medical decisions and depriving them of a fundamental liberty interest. Moreover, the Patent Act is not narrowly tailored to serve a compelling governmental interest due to a lack of patient safeguards. Consequently, the Patent Act—as applied to laboratories, doctors, and patients—may be unconstitutional [under the 5th amendment Due Process clause].185

As we have seen, however, eliminating the Myriad patents will not render Myriad’s trade secret database any more available to the general public. As a consequence, eliminating gene patents doesn’t solve the information secrecy problem, except to the extent that without the limited exclusivity provided by the patents, more labs would have been collecting data all along, and Myriad would not have had such a significant head start. It’s possible that if Myriad had not established itself as the main provider of the BRCA1/2 tests, it would have been more likely to continue sharing its data in order to encourage competitors to generate and share data, too. But we will never know what Myriad might have done had it not obtained early patents on the BRCA1 and BRCA2 genes.

Over time, we will be able to assess whether the amount of genetic information that is protected as a trade secret increases, decreases, or stays the

---


185 *Id.* at 628–29.
same in the absence of patent protection. Time will also tell whether companies decide to share their data in order to allow others to contribute to the overall pool of information. We cannot guess at the answers to these questions so soon following the Supreme Court’s ruling, although, as always, academic research on the topic is expected to continue to be published and available to all.

**H. Though the Supreme Court’s Ruling May Further Legitimate Policy Goals, the Myriad Decision was not the Proper Vehicle Through Which to Effect Such Drastic Change**

As a society, we might decide that patenting human genes does not present a net social benefit and should therefore be prohibited. Perhaps we should fully embrace the principle that health is a fundamental human right and reject all burdens that impede our right to affordable health care. Indeed, one might speculate that a concern over rising health care costs was the driver behind the Supreme Court’s activity in the Mayo and Myriad cases. Further, there is considerable precedent for the idea that we should eliminate all patent burdens on the healthcare system: some 80 countries prohibit patents on certain medical procedures.186 Paragraph 3(a) of Article 27 of the International Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”) allows member nations to exclude “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” from the scope of patentable subject matter (although this exclusion does not refer to natural products *per se*).187

1. **The Legislature, Rather Than the Judiciary, Should Make Important Policy Decisions**

To the extent that the Supreme Court seeks to espouse a policy under which genes and/or their informational content should not be patent eligible, the judicial branch

---


is not the typical institution from whence policy decisions are initiated, despite the fact that precedent indicates that policy choices are, in some cases, within the purview of the High Court. The Court’s decision in Myriad, however, seems to directly conflict with the U.S.’s current foreign policy position on the patent eligibility of diagnostic procedures.

The Trans-Pacific Partnership ("TPP") is a 21st century trade agreement that the United States and ten other nations in the Asia-Pacific region recently negotiated. Although the full text of the final treaty is as yet unavailable, in 2013 WikiLeaks published an earlier draft of the treaty, including the U.S.’s

---

188 Compare U.S. Const. art. I, § 8 (granting Congress the power to enact laws and regulate commerce), with U.S. Const. art. III, § 2 (granting the Courts the judicial power to hear cases and controversies). Judicial power is generally held to be the power to interpret and apply the law, not make it.

189 See, e.g., Griswold v. Connecticut, 381 U.S. 479, 480, 482, 486 (1965) (wherein the Court invalidated a Connecticut law that prohibited married couples’ use of contraceptives, finding that the law violated the First Amendment right of privacy. In so holding, the Court stated that it “do[es] not sit as a superlegislature to determine the wisdom, need, and propriety of laws that touch economic problems, business affairs, or social conditions” but that the challenged law “operate[d] directly on an intimate relation of husband and wife and their physician’s role in one aspect of that relation” and therefore could not escape judicial notice).


192 As of October 19, 2015.
proposed Article QQ.E.1(3), which provides that "each Party . . . shall make patents available for inventions for . . . diagnostic, therapeutic, and surgical methods for the treatment of humans or animals . . . if they cover a method of using a machine, manufacture, or composition of matter . . . ." It is not yet clear whether the treaty's final form will contain the U.S.-proposed language, but it seems doubtful since it was heavily opposed by other nations, and even its proponent nation's Supreme Court held that diagnostic tests and isolated DNA are not patent eligible, as discussed herein.

Unfortunately, even if Congress were to decide that medical treatments, diagnostics and surgical methods are not patent eligible, that conclusion does not solve the informational problem created when medical information is treated as trade secret. It would seem, based on the Myriad case, that patents are not the problem, access to testing is not a significant problem, and the cost of the test is not excessive. Rather, the true problem is that Myriad has access to a plethora of information about the breast cancer genes and is not sharing that information with the rest of the scientific community.

2. The Court's Decision Did Not Compel Myriad to Reveal the Valuable Genetic Developments it now Maintains as a Trade Secret

Of course, Myriad's decision to keep certain information a "trade secret" is a time-honored method of generating a business advantage, and there is currently no legal basis for preventing the collection and protection of such data. Myriad spent millions of dollars to collect the information on BRCA1 and BRCA2 variants that it now maintains as a trade secret. According to Forbes, Myriad burned through more than $500 million over 17 years before finally turning a

---

193 See TPP, supra note 190, art. QQ.E.1(3) (addressing patentable subject matter).

194 See id. While this article was in press, the TPP was published and it does not contain the referenced language, but allows member states to exclude diagnostics from patentability. See TPP Full Text, Off. U.S. TRADE REPRESENTATIVE, https://ustr.gov/trade-agreements/free-trade-agreements /trans-pacific-partnership/tpp-full-text (last visited Dec. 24, 2015).

195 See UNIF. TRADE SECRETS ACT § 1 (Unif. Law Comm'n 1985) (defining a trade secret as secret information that "derives independent economic value from not being generally known . . . ").

profit in 2012. The total cost of bringing the BRACAnalysis test to market is alleged to be nearly $200 million. On what basis could we take this trade secret away from Myriad and make it generally available to scientists and corporations at large?

We are left to ponder important policy questions regarding the appropriate balance between incentivizing the development of new tests for disease and the very real interest the public has in promoting the freedom of scientific data and a fundamental right to our own health information.

3. The Supreme Court’s Decision did not Markedly Impact Myriad’s Market Dominance in the Field of BRCA1 and BRCA2 Genetic Testing

The Supreme Court has spoken, stating unequivocally that isolated DNA is not patent eligible. But the holding in Myriad didn’t slow Myriad down very much: the company has many other types of patent claims, which they

197 Id.

198 See id. (“After $30 million in losses and a study involving 2,000 patients, Myriad finally gathered enough evidence to earn BRACAnalysis’ inclusion among society guidelines. Wrapping up insurer coverage for the $3,340 test in 2001, the company set out to ramp up sales efforts. The total cost of bringing BRACAnalysis to market: nearly $200 million.”).

199 Of course, the government could seek to use eminent domain to accomplish such an end, and it is uncontested that the government may heavily regulate businesses affected with a public interest, such as railroads, common carriers, and providers of public utilities, including telephones. See, e.g., Communications Act of 1934, 47 U.S.C. § 151 (Supp. III 1934). Indeed, since the enactment of the Communications Act of 1934, “universal service policies have helped make telephone service ubiquitous, even in remote rural areas.” Universal Service, FEDERAL COMMUNICATIONS COMMISSION, https://www.fcc.gov/encyclopedia/universal-service (last updated Nov. 27, 2015). These principles could potentially serve as bases for crafting a universal access law relating to genetic information, but until privacy issues are satisfactorily resolved, such an idea cannot gain traction, and the current debate shows that society is not of a uniform mind in this regard.

200 Press Release, Myriad Genetics, Inc., Supreme Court Upholds Myriad’s cDNA Patent Claims (June 13, 2013), http://investor.myriad.com/releasedetail.cfm?ReleaseID=771232 (“Following today’s decision, Myriad has more than 500 valid and enforceable claims in 24 different patents conferring strong patent protection for its BRACAnalysis® test.”).
continued to vigorously litigate against alleged infringers even after the Supreme Court’s holding . . . for a while, anyway.201

Eventually, in late 2014, Myriad was denied a preliminary injunction seeking to enjoin Ambry Genetics Corporation from offering BRCA1 and BRCA2 screening because the District Court questioned whether any of the allegedly infringed claims were “directed toward patent eligible subject matter under 35 U.S.C. § 101.”202 Following that denial and a subsequent Federal Circuit opinion invalidating additional BRCA-related patent claims,203 Myriad settled with most of the defendants it had sued in connection with the BRCA patents.204 Nevertheless, Myriad still retains a significant database advantage, and therefore its test, while expensive, is still preferred by many medical professionals.205 In fact, even though Myriad suffered a small dip in stock value at the time of the 2013 case,

201 See, e.g., In re BRCA1- and BRCA2-based Heredity Cancer Test Patent Litig. (In re Hereditary Cancer Test II), 774 F.3d 755, 757 (Fed. Cir. 2014) (in which Myriad unsuccessfully sought to enforce claims that covered compositions of matter and methods relating to the BRCA1 and BRCA2 genes); Myriad Settles BRCA Patent Case with Quest; Only GeneDx Lawsuit Remains, GENOMEWEB (Feb. 9, 2015), https://www.genomeweb.com/business-news/myriad-settles-brca-patent-case.quest-only-genedx-lawsuit-remains [hereinafter Myriad Settles].


203 In re Hereditary Cancer Test II, 774 F.3d at 763–65.


205 McCullough, supra note 176 (“Myriad’s comprehensive $4,040 BRCA1/2 test panel is still preferred by many doctors. The Utah company has the biggest database - which it refuses to publicly share - and, thus, the lowest rate of reporting ambiguous BRCA changes, called ‘variants of uncertain significance.’ ‘They’ve had so much experience, so their VUS rate is 2 percent or less,’ said Catherine Carruthers, director of the breast health program at the Holy Redeemer Health System in Huntingdon Valley.”).
the company's stock has since more than recovered, and Myriad still claims to have a 95 percent share of the BRCA1/2 market.

Other providers now offer BRCA testing at prices lower than those offered by Myriad, although at least some of the cheaper tests are less extensive. Invitae, for example, offers DNA sequences for at least the BRCA1/2 exons and some 10 base pairs of adjacent introns, as well as certain non-coding sequence mutants with known pathology at a much-reduced cost of $1,500.

Veritas, in contrast, offers a next generation sequencing test for $199 that "covers 16,426 base pairs of genomic sequence, including the complete coding regions and splice sites in BRCA1 and BRCA2." Veritas claims that its VUS rate


208 See, e.g., id. ("At $199, [Veritas'] myBRCA costs a fraction of other BRCA1/2 tests, most notably Myriad Genetics' BRCA1/2 tests, which list for about $4,000.").


is only 2.3%, although this data point is only available in a self-published white paper and, since the test was only launched in 2015, it seems hard to believe that the company has collected enough data to support a 2.3% VUS rate. Further, although Myriad’s test lists for about $4,000, “the average bill to patients is less than $100.” Any decline in BRCA1 and BRCA2 test prices that has followed the Myriad holding is, therefore, somewhat illusory. If the Supreme Court’s concern was one of excessive pricing, the holding doesn’t seem to have made much of a difference to most patients.

4. The American Public Must Take Additional Action to Remedy the Informational Concerns Raised by Myriad’s Behavior

Sapna Kumar’s concern over informational control has merit, but focusing on patents misses the true cause of the problem. Patents only last 20 years, and then the technology enters the public domain. Trade secrets, in contrast, can last as long as their “secret” status is maintained. Further, the Fifth Amendment due process analysis Kumar advocates is not applicable to trade secrets, since, as of now, no government regulation meaningfully impinges upon the liberty interest an individual may have in his or her own genetic information. Yet somehow it seems wrong for a company to maintain a competitive advantage using our genetic information.

Perhaps, as patients, we should stand up and lobby Congress for a freedom of medical information law requiring that all such information be made available in public databases for the benefit of all, upon request. That effort may be superfluous, however, because U.S. patients already have a right to see and

212 See Simen & Thakuria, supra note 211, at 2.
213 See Fong, supra note 207.
216 The Fifth Amendment due process clause applies only to federal and state action, and, at the present time, no federal or state law prevents individuals from accessing their own health information. See U.S. Const. amend. V, cl. 3.
obtain a copy of their own medical records. Recent amendments to the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") allow a patient to direct his or her healthcare provider to transmit copies of test reports to designated persons or entities.

In hopes of capitalizing on individuals' ability to access their own health records, a Free the Data! initiative has been organized to fill the database gap caused by Myriad's refusal to share patient data. The initiative invites those who have been tested to upload their reports without identifying information. All shared data will be incorporated into the ClinVar database and will be available to scientists all over the world. A similar organization called the Sharing Clinical Reports Project ("SCRP") also calls for submission of deidentified data direct from the doctors who ordered the tests, and all data is shared with the ClinVar database.

---


218 See id. at 7290 ("[T]his final rule amends the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to provide individuals (or their personal representatives) with the right to access test reports directly from laboratories subject to HIPAA (and to direct that copies of those test reports be transmitted to persons or entities designated by the individual) by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the provision that provides individuals with the right of access to their protected health information. These changes to the CLIA regulations and the HIPAA Privacy Rule provide individuals with a greater ability to access their health information, empowering them to take a more active role in managing their health and health care.").


221 See What is ClinVar?, NAT'L CTR. FOR BIOTECH. INFO., U.S. NAT'L LIBRARY OF MED., http://www.ncbi.nlm.nih.gov/clinvar/intro/ (last visited Sept. 25, 2015) ("ClinVar is a freely accessible, public archive of reports of the relationships among human variants and phenotypes, with supporting evidence ... ClinVar collects reports of variants found in patient samples, assertions made regarding their clinical significance, information about the submitter, and other supporting data.").
As of August 2014, SCRP reports that they have shared 5,416 variants with ClinVar. Since over a million women have been tested by Myriad, it appears the effort will be ongoing for quite a while.

I. Despite the Supreme Court’s Ruling, the Immediate Future for “Isolated and Purified” Natural Products is not Bleak

Meanwhile, we are left with the astonishing principle that isolated and/or purified “natural products” are no longer patent eligible, putting many issued patent claims at risk of invalidation. The threat of claim invalidation, as related to such isolated and purified forms of naturally-occurring materials, seems less potent on a forward-looking basis; current USPTO Guidance indicates that a patentee can patentably distinguish an invention from an unpatentable natural product merely by specifying that the claimed product boasts “markedly different properties” such as potentially increased stability over its naturally occurring counterpart. The guidance thus takes the sting out of the Supreme Court’s

---


223 Id.

224 See Univ. of Utah Research Found.’s Memorandum in Support of Motion for Preliminary Injunctive Relief, supra note 178, at 3. One possible solution is to request the rules be tweaked to require that the provider ask every patient if they want their de-identified genetic data shared on ClinVar and providing the patient with basic information about both the purpose and uses for shared data. That lies outside the scope of this paper though.

225 See U.S. PATENT AND TRADEMARK OFFICE, NATURE-BASED PRODUCTS 2–5 (Dec. 16, 2014), http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf (“Because the claim is a nature-based product, i.e., a combination of a naturally occurring substance (pomelo juice) with an added preservative, the nature-based combination is analyzed to determine whether it has markedly different characteristics from any naturally occurring counterpart(s) in their natural state. . . . This property (slower spoiling) of the claimed combination is markedly different from properties of the juice by itself in nature. Accordingly, the claimed combination . . . qualifies as eligible subject matter. . . .”). The PTO has also cited the combination of amazonic acid with a solubilizing agent leads to a stable solution which has markedly different solubility properties than its natural form. Id. (“In nature, amazonic acid is insoluble in water. . . . However, when amazonic acid is combined with a solubilizing agent, it becomes soluble in water and forms a stable solution. This changed property (solubility) between amazonic acid as a part
holding in *Myriad* because, arguably, most products are more stable when purified from their natural environment. In the future, biotechnology companies simply must draft their claims more carefully and make sure to recite actual differences between the claimed product and the originating natural product. The Guidance does not help existing patents, however, which were drafted under the previous § 101 jurisprudence, and which may lack the necessary language needed to rescue the claims.

Indeed, district courts across the nation continue to invalidate existing patents based on the Supreme Court’s recent § 101 cases.\(^\text{226}\) The Supreme Court’s holding in *Myriad* has also sparked at least one challenge to Myriad’s BRCA patents outside of the United States.\(^\text{227}\) Misinformation about the scope of DNA patents continues to abound, as illustrated by the fact that the Plaintiff in a recently resolved Australian case challenging Myriad’s Australian BRCA patents took the position that “you can’t own a piece of me.”\(^\text{228}\)

---

of the claimed stable aqueous composition and amazonic acid in nature is a marked difference. Accordingly, the claimed composition . . . qualifies as eligible subject matter.”).


VI. CONCLUSION

Following *Myriad*, one wonders if the Supreme Court’s foray into the eternally political topic of breast cancer has muddled patent law based on the Court’s vague feeling that medicine costs too much, or perhaps a belief that patient information should not be corporate owned. The Court’s actions may be well-intentioned, however, the fallout from the *Myriad* holding could plausibly include both 1) increased reluctance to share information among genetic researchers and 2) decreased investment in the development of expensive diagnostic testing methods on the part of large commercial entities, neither of which benefits society as a whole.

Only time will tell whether the *Myriad* holding produces an overall net positive or negative benefit for society, but, so far, the Court’s invalidation of Myriad’s BRCA1 and BRCA2 patent claims has not harmed Myriad’s 95% BRCA1/2 market share. This fact alone suggests that the Supreme Court has not helped women gain more affordable access to the breast cancer diagnostic test. Further, the cost in lost value for existing patents has yet to be quantitated, suggesting we have yet to realize the full import of this profound change in patent law and § 101 jurisprudence.