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Personalized Medicine in the Information Age: Myriad's De Facto Monopoly on Breast Cancer Research

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PERSONALIZED MEDICINE IN THE INFORMATION AGE: MYRIAD'S DE FACTO MONOPOLY ON BREAST CANCER RESEARCH

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I. INTRODUCTION

In the mid-1990s,[1] Myriad Genetics, Inc. (Myriad) discovered the location and deoxyribonucleic acid (DNA) sequence of the BRCA1 and BRCA2 genes.[2] These two genes remain critically important in the field of cancer research, principally because individuals with genetic mutations in either gene live with a drastically heightened predisposition to breast cancer and ovarian cancer.[3] The National Cancer Institute reports that approximately 12 percent of women in the general population will develop breast cancer during their lifetimes and approximately 1.4 percent of women will develop ovarian cancer.[4] However, these percentages shift dramatically if a woman has a harmful mutation in her BRCA1 or BRCA2 genes. Recent studies estimate that 55 to 65 percent of women who carry a harmful BRCA1 mutation and about 45 percent of women with a harmful BRCA2 mutation will develop breast cancer by the age of seventy.[5] The numbers increase similarly for ovarian cancer—about 39 percent of women carrying a harmful BRCA1 mutation and 11 to 17 per-

1. *Patent Act of 1952—Patentable Subject Matter*—Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 127 Harv. L. Rev. 388 (2013).

2. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2110–11 (2013) ("Myriad").

3. *See Myriad*, 133 S. Ct. at 2112.

4. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, National Cancer Institute at the National Institutes of Health, http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA#r5 (last updated Jan. 22, 2014).

5. *Id.*; *see also* A. Antoniou, *Average Risks of Breast and Ovarian Cancer Associated with BRCA1 or BRCA2 Mutations Detected in Case Series Unselected for Family History: A Combined Analysis of 22 Studies*, 72 Am. J. Hum. Genetics 1117 (May 2003), *available at*

cent of women with a harmful BRCA2 mutation will develop ovarian cancer by the age of seventy.[6] The gravity of these genetic mutations recently rose to the forefront of the public consciousness when American actress Angelina Jolie announced that she had undergone a preventative double mastectomy upon learning that her BRCA1 gene carried harmful mutations, giving her an 87 percent risk of developing breast cancer.[7] As her story illustrates, when an individual discovers the presence of a mutation in one of these two genes, understanding the *significance* of that mutation—whether the mutation is harmful or benign—is critical to that individual's health care decisions.

Myriad used its discovery of the BRCA genes to develop diagnostic tests to detect whether an individual's genes contain mutations.[8] As expected, Myriad obtained a portfolio of patents related to the BRCA genes, including patents covering the actual DNA sequences and patents covering methods for identifying the presence of a mutation. Even after the U.S. Supreme Court's decision in *Association of Molecular Pathology v. Myriad Genetics*, which invalidated a subset of Myriad's BRCA-related patents,[9] Myriad sought to aggressively maintain its control over the breast cancer gene testing market. Myriad filed lawsuits against seven biotechnology companies alleging infringement of patents left untouched by the Supreme Court's decision.[10] These remaining patents contain sixty-six method and primer claims (all related to techniques for identifying harmful DNA mutations).[11]

With the recent announcement[12] that Myriad has settled these infringement suits, allowing each competitor to sell the allegedly-infringing gene testing kits,[13] it may appear that the fight to end exclusive gene testing services is over. In the broader realm of patents on diagnostic testing methods, however, the battle may be just beginning. Method claims on diagnostic testing, including genetic testing, remain viable despite recent

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http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1180265/pdf/AJHGv72p1117.pdf (compiling estimates).

6. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NATIONAL CANCER INSTITUTE AT THE NATIONAL INSTITUTES OF HEALTH, http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA#r5 (last updated Jan. 22, 2014).

7. Angelina Jolie, Op-Ed., *My Medical Choice*, N.Y. TIMES (May 14, 2013), http://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html?_r=0. More recently, Ms. Jolie Pitt wrote about her subsequent decision to undergo further preventative surgery due to her uniquely heightened risk of developing ovarian cancer. Angelina Jolie Pitt, Op-Ed., *Angelina Jolie Pitt: Diary of a Surgery,* N.Y. TIMES (Mar. 24, 2015), http://nyti.ms/1LQT who.

8. *Myriad*, 133 S. Ct. at 2112–13.

9. *See generally Myriad*, 133 S. Ct. 2107 (holding that isolated segments of DNA are not patentable subject matter).

10. *See generally* John T. Aquino, *Myriad, GeneDx Settle Patent Dispute Over BRCA Screening, Ending Litigation*, BLOOMBERG BNA LIFE SCIENCES LAW & INDUSTRY REPORT (Feb. 20, 2015) (discussing the history of Myriad's post-Supreme Court decision litigation).

11. *Id.*

12. *Id.*

13. *See id.; see also, e.g.*, Stipulation for Dismissal with Prejudice at 1, Univ. of Utah Research Found. v. GeneDx, Inc., No. 2:13-cv-00954-RJS (D. Utah Feb. 13, 2015) (parties agreeing to dismissal of the suit with prejudice).

court decisions regarding the unpatentability of isolated DNA sequences.[14] The data obtained from the exclusive use of these patented method claims remains both important to individuals seeking to understand the implications of their test results and invaluable to the future of personalized medicine. To put it concisely, "[i]nterpreting the clinical significance of genomic information depends on broad access to DNA sequence variants and clinical information about [the individuals] tested."[15]

For most patients, the results of BRCA gene testing are readily discernible—either their genes match the normal, innocuous gene sequence, or their genes harbor a clearly harmful mutation.[16] For some patients, however, the effect of the mutations in their BRCA genes cannot be determined—their genes contain variants of unknown significance (VUS).[17] Myriad, through its patent-conferred role as the exclusive testing laboratory for BRCA gene testing, created a database full of VUS data.[18] Its vast database "relates variants of uncertain significance to phenotype, details their frequency in various populations and includes genetic studies on patient families."[19] This wealth of information enables Myriad to analyze an individual's test results and return a result of "variant of unknown significance" in just 3 percent of cases. In contrast, other genetic testing companies return the dreaded result of "variant of unknown significance" in 20 to 30 percent of cases.[20] For individuals living in fear of an increased risk of cancer due to the presence of a mutation with unknown significance, this ability to provide greater certainty regarding the significance of test results is critical.

While Myriad's recent settlement negotiations have allowed other companies to provide BRCA gene testing to determine the presence of mutations,[21] those companies do not possess the data required to properly interpret those test results. As such, Myriad's monopoly persists. Likewise, similar monopolies may soon emerge as other companies with exclusive diagnostic testing services begin to maintain similar databases. As some scholars have noted, "[a]s personalized medicine continues to grow and the market for personal health risk prediction expands, more companies will create proprietary databases containing information about genes and other biomarkers."[22]

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14. *See infra* Part III.B.

15. Robert Cook-Deegan et al., *The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?*, 21 EUR. J. HUM. GENETICS 585 (2013), *available at* http://www.nature.com/ejhg/journal/v21/n6/full/ejhg2012217a.html.

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *See* Aquino, *supra* note 10.

22. John M. Conley et al., *Myriad After Myriad: The Proprietary Data Dilemma*, 15 N.C. J. L. & TECH. 597, 600 (2014).

A. The Emerging Proprietary Database Issue

When a company's patents expire, the company's rightful, patent-facilitated monopoly should end. However, in this information age, a new problem has arisen: the data obtained through the use of patented diagnostic method claims has now become more valuable than the patented claims themselves.[23] Through November 2004, Myriad was a "major contributor to public databases of BRCA mutations,"[24] contributing its data to the Breast Cancer Information Core (the largest database for BRCA mutation information).[25] Since November 25, 2004, however, Myriad has kept a tight handle on its data set, retaining its important data as proprietary.[26] Thus, Myriad has entrenched itself as the company able to produce the most meaningful interpretation of the significance of an individual's genetic mutations.[27]

The issues surrounding Myriad's vast database of genetic information are not unexpected. In fact, amici in support of both parties (and of neither party) identified this very issue in amicus briefs submitted to the Supreme Court in *Myriad*.[28] Although not unexpected, the results are alarming. As one amici noted, if doctors and researchers could access the vast set of data held by Myriad, they could more fully understand the "universe" of BRCA1 and BRCA2 mutations and their effect on breast and ovarian cancer.[29] Instead, "[t]he consequence . . . is a broader monopoly on information that patients and their physicians may obtain about the contents of an individual's own DNA, including the patient's own heightened risks of life-threatening disease."[30]

At least one court has expressed an aversion to Myriad's conduct.[31] A federal district court recognized that, by hoarding its vast database, Myriad "distorts rather than serves the patent system's goal of public disclosure in exchange for exclusive rights. In this way, Myriad has chosen a

23. Monya Baker, *Policy Paper: Myriad Turns Cancer Genetic Data into Trade Secrets*, Nature News Blog (Oct. 31, 2012, 11:14 PM), http://blogs.nature.com/news/2012/10/policy-paper-myriad-turns-cancer-genetic-data-into-trade-secrets.html ("[T]he BRCA mutation data Myriad has collected is becoming more valuable than the original patents.").

24. Brief of Amici Curiae Christopher M. Holman and Robert Cook-Deegan in Support of Neither Party at 27, Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013) (No. 12-398), 2010 WL 4853323.

25. Cook-Deegan et al., *supra* note 15.

26. Brief of Amici Curiae Christopher M. Holman and Robert Cook-Deegan in Support of Neither Party, *supra* note 24, at 27.

27. Baker, *supra* note 23.

28. *See* Brief of Intellectual Property Owners Association as Amicus Curiae in Support of Respondents at 29, Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 1122810; Brief of Genformatic LLC as Amicus Curiae in Support of Petitioners at 23 n.23, Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 417735; Brief of Amici Curiae Christopher M. Holman and Robert Cook-Deegan in Support of Neither Party, *supra* note 24, at 27.

29. Brief of Kaiser Permanente as Amicus Curiae in Support of Petitioners at 8, Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013) (No. 12-398), 2012 WL 122280.

30. *Id.* at 8.

31. *See In re* BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litig., 3 F. Supp. 3d 1213, 1276 (D. Utah 2014).

commercial path that turns much of our patent system policy on its head."[32] This Comment addresses possible responses—rooted in patent law, antitrust law, and public policy—to curb the effects of such conduct.

B. Overview of This Comment

Part II of this Comment provides an overview of the academic scholarship related to proprietary databases of genetic mutation data. Part III reviews the current state of the law as it relates to patents on DNA sequences and diagnostic testing methods, including gene testing. Specifically, Part III.B emphasizes why this Comment will remain relevant in the foreseeable future. As personalized medicine rises to the forefront of medical research, patents on diagnostic methods—though more difficult to obtain than in previous years—will continue to thrive. Part IV discusses the possibility of Myriad and other similarly-situated companies maintaining their proprietary databases through trade secret protection. Part V analyzes potential avenues for preventing the development of proprietary databases during the term of a patent. Part VI then evaluates the viability of restricting such monopolistic practices through reliance on the federal antitrust laws. Finally, Part VII suggests alternative solutions for curbing the impact of proprietary databases of genetic information. Although significant privacy concerns related to broad access to genetic data exist, a discussion of such an important, in-depth topic is beyond the scope of this Comment.

II. LITERATURE REVIEW

Although prior to the *Myriad* decision many scholars analyzed the merits of whether isolated DNA should be patentable,[33] few scholars have analyzed the emerging issues surrounding proprietary databases of genetic information from a legal perspective.

Dr. Barbara Evans, one of the leading scholars to address this issue, penned the most in-depth article to date on the subject of Myriad's proprietary database.[34] In her article, Dr. Evans provided a summary of the regulatory principles that surround this issue and found that the "genetic testing industry has a void where an economic regulatory framework needs to be."[35] Aside from the helpful regulatory discussion, Dr. Evans also offered a brief analysis of how federal antitrust principles may relate to the proprietary data dilemma.[36] She ultimately concluded, however, that "[t]here is no way to predict"[37] the viability of an antitrust counterclaim after the Supreme Court's decision in *Verizon Communications v.*

32. *Id.*

33. *See, e.g.*, Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 Tex. Intell. Prop. L.J. 221 (2003).

34. *See generally* Barbara J. Evans, *Economic Regulation of Next-Generation Sequencing*, 42 J.L. Med. & Ethics 51 (2014).

35. *Id.* at 55.

36. *Id.* at 58–64.

37. *Id.* at 61.

Law Offices of Curtis V. Trinko.[38]

Also at the forefront of scholarship on this issue are Dr. John Conley, Dr. Robert Cook-Deegan, and Dr. Gabriel Lázaro-Muñoz.[39] In their recent article, the authors emphasized the importance of Myriad's "ace up its sleeve"—that its "unparalleled array of data correlating gene mutations with health outcomes, family histories, and other phenotypic factors gives it a unique ability to interpret BRCA gene test results, especially those that yield ambiguous findings, or variants of unknown significance."[40] The authors provided context for the discussion by explainingthe extent to which Myriad relies on its proprietary database. In 2012, Myriad opened a new testing laboratory in Germany.[41] The authors speculated that Myriad's confidence in opening such a facility was based not on Myriad's ability to enforce its patents in Europe,[42] but largely on Myriad's "other competitive advantages" obtained through access to its voluminous proprietary database.[43] Regarding relevant legal principles, the authors briefly noted that such a database could be afforded trade secret protection.[44]

III. THE CURRENT STATE OF PATENT LAW AS RELATED TO GENETICS

The much-discussed case of *Association of Molecular Pathology v. Myriad Genetics* appeared to sound the death knell for the prospect of gene patenting—and in some ways it did.[45] After *Myriad*, companies cannot patent isolated DNA sequences.[46] However, sequences of complementary DNA (cDNA) remain patentable.[47]

Prior to the Court's *Myriad* decision,[48] the United States Patent and

38. *See generally* Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004).

39. *See generally* Conley et al., *supra* note 22.

40. *Id.* at 599–600.

41. Conley et al., *supra* note 22, at 612 (citing *Myriad Genetics Opens Molecular Diagnostic Testing Lab in Munich, Germany*, BIOM NEWS (Mar. 15, 2012), http://www.bio-m.org/en/news/myriad-genetics-opens-molecular-diagnostic-testing-lab-in-munich-germany.html).

42. John M. Conley et al., *How Will Myriad Respond to the Next Generation of BRCA Testing?*, GENOMICS LAW REPORT (Mar. 1, 2011), http://www.genomicslawreport.com/index.php/2011/03/01/how-will-myriad-respond-to-the-next-generation-of-brca-testing (noting that the chances for Myriad to succeed in enforcing its patents in Europe are "somewhere between slim and none").

43. Conley et al., *supra* note 22, at 612 & n.73 (quoting Myriad CEO Peter Meldrum, as quoted in John M. Conley, Dan Vorhaus & Robert Cook-Deegan, *How Will Myriad Respond to the Next Generation of BRCA Testing?*, GENOMICS LAW REPORT (Mar. 1, 2011), http://www.genomicslawreport.com/index.php/2011/03/01/how-will-myriad-respond-to-the-next-generation-of-brca-testing/).

44. Conley et al., *supra* note 22, at 616–17.

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

46. *Id.* at 2120.

47. *Id.* at 2119.

48. *See generally id.*

Trademark Office (USPTO) had issued thousands of gene patents.[49] After *Myriad*, which held that isolated DNA is not patent eligible, many of those patents may be wholly or partially invalid.[50] However, *Myriad* did not address the patentability of diagnostic method claims.[51] The following two sections discuss the patentability of composition of matter claims and method claims related to DNA after *Myriad*.

A. Composition of Matter Claims: Isolated DNA Is Not Patentable, but Complementary DNA Is Patentable in Some Instances

At this point in time, the law regarding composition of matter claims directed to DNA—patents that claim the actual DNA sequences—is fairly clear. As the Supreme Court noted in *Myriad*, the discovery of a law of nature, however "groundbreaking, innovative, or even brilliant"[52] it may be, is insufficient to satisfy the subject matter patentability requirements of 35 U.S.C. § 101.[53] Thus, the Court held that isolated segments of DNA are not patentable because they are merely "products of nature."[54] Complementary DNA (cDNA)—DNA that has been transcribed to mRNA, has had its introns spliced out, and has been transcribed back into DNA—however, remains patentable under the Court's analysis.[55] The Court did not consider cDNA to be a "product of nature" because cDNA rarely, if ever, occurs naturally.[56] Yet, according to the Court's decision, in some circumstances even cDNA may not be patent eligible subject matter if it is "indistinguishable from natural DNA" due to its short length that mirrors a section of DNA without introns.[57]

B. Diagnostic Method Claims: A Claim Must Practically Apply the Recited Law of Nature to be Patent Eligible

In its *Myriad* decision, the Court specifically noted that no method claims (such as a method for identifying the presence of a genetic muta-

49. Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 Stan. Tech. L. Rev. 257, 259 (2013) (citing Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1355 (Fed. Cir. 2011)).

50. *See Myriad*, 133 S. Ct. at 2120.

51. *See id.* at 2119–20.

52. *Id.* at 2117.

53. 35 U.S.C. § 101 (2012) ("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.").

54. *Myriad*, 133 S. Ct. at 2120 ("[G]enes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.").

55. *Id.* at 2112, 2119.

56. *Id.* at 2119 n.8 ("The possibility that an unusual and rare phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.").

57. *Id.* at 2119.

tion) were before the Court.[58] Thus, that decision did not alter or add to the Court's previous decision regarding method claims in *Mayo Collaborative Services v. Prometheus Laboratories*.[59] In *Mayo*, the Court held that claims that merely inform a physician of a recently discovered law of nature are not patent eligible subject matter.[60] Such natural phenomena are the "'basic tools of scientific and technological work'"[61] and "monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it."[62] Thus, the Court held that to be patent eligible, a method claim must demonstrate some *practical application*—the claim cannot be a law of nature crafted artfully into the form of a method claim.[63] As the Court aptly explained, Archimedes would not have been able to patent his principle of flotation by simply drafting a method claim directing boat-builders to refer to the principle of flotation to determine if an object would float.[64] The Court focused on whether the steps of the claimed method, other than the steps reciting the law of nature, were "in context obvious, already in use, or purely conventional."[65] In analyzing the steps of the claimed method in *Mayo*, the Court found that the claimed steps "add[ed] nothing specific to the laws of nature other than what [was] well-understood, routine, conventional activity, previously engaged in by those in the field."[66]

The *Mayo* Court, however, affirmed that some diagnostic method claims are still patent eligible subject matter. The Court first pointed to its earlier decision in *Diamond v. Diehr*.[67] In *Diehr*, the Court found patentable a method for molding rubber into various products.[68] The claimed method in *Diehr* involved "(1) continuously monitoring the temperature on the inside of the mold, (2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold-opening time, and (3) configuring the computer so that at the appropriate moment it would signal 'a device' to open the press."[69] The *Diehr* Court recognized that the applicant had not attempted to patent the Arrhenius equation, but instead focused on implementing that mathematical algorithm to achieve a larger, practical application.[70] The Court noted that the inventors "[did] not seek to pre-empt the use of that

58. *Id.*
59. *See generally* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).
60. *Id.* at 1298.
61. *Id.* at 1293 (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).
62. *Id.*
63. *Id.* at 1297 ("If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.").
64. *Id.*
65. *Id.* at 1299.
66. *Id.*
67. *Id.* at 1298. *See generally* Diamond v. Diehr, 450 U.S. 175 (1981).
68. *See generally Diehr*, 450 U.S. 175.
69. *Mayo*, 132 S. Ct. at 1298 (summarizing the claimed process in *Diehr*).
70. *Diehr*, 450 U.S. at 187.

equation. Rather, they [sought] only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process."[71] This, according to the *Mayo* Court, "transformed the process into an inventive application of the formula."[72]

Similar to the decision in *Diehr*, but more appropriate for a discussion of medical diagnostics, is the Federal Circuit's decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*.[73] The claimed method in that case involved comparing multiple human immunization schedules, identifying the schedule that would produce the lowest risk for an individual, and then immunizing the individual based on that lower risk schedule.[74] In finding the claimed method patentable, the Federal Circuit cited the logic of the *Diehr* Court.[75] This sort of method claim—applying a newly discovered law of nature in a practical, yet broad manner—may serve as a useful model for future diagnostic method claim drafting.

1. Recent Case Law Regarding Method Claims on Diagnostic Gene Testing

In December 2014, the Federal Circuit addressed two of Myriad's method claims related to gene testing and found both claims invalid as unpatentable subject matter.[76] Both claims involved methods for comparing an individual's BRCA gene sequences with the wild-type (normal, not mutated) BRCA sequence.[77] Although the defendant in the case, Ambry Genetics Corporation, argued that the method claims should be invalidated under the rationale of *Mayo*, the Federal Circuit refused to address the claims under the *Mayo* Court's "law of nature" analysis.[78] Instead, the court found the claims invalid as an attempt to patent an "abstract idea."[79] Thus, the court's analysis employed the two-step approach used by the Supreme Court in *Alice Corp. v. CLS Bank International*[80] to analyze whether patents that claim abstract ideas are patentable.[81] First, the court determined that the claims were directed to a patent-ineligible concept—here, the "abstract idea of comparing BRCA sequences and determining the existence of alterations."[82] Second, the court examined whether the claims presented an additional "inventive concept" such that the additional concept sufficed to "transform the nature of the claim into

71. *Id.*
72. *Mayo*, 132 S. Ct. at 1299.
73. *See generally* Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1060 (Fed. Cir. 2011).
74. *Id.* at 1060–61.
75. *Id.* at 1064.
76. *In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 762 (Fed. Cir. 2014) ("In re BRCA").
77. *Id.* at 761–62 (reproducing claim language).
78. *Id.* at 762.
79. *Id.*
80. Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014) (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1296–97 (2012)).
81. *In re BRCA*, 774 F.3d at 763.
82. *Id.*

a patent-eligible application."[83] In finding that the claims remained ineligible under step two of this analysis, the Federal Circuit used language reminiscent of the language in *Mayo*.[84] Specifically, the court noted that the additional claim elements did "nothing more than spell out what practitioners already knew—how to compare gene sequences using routine, ordinary techniques. . . . [T]hose comparison techniques were the well-understood, routine, and conventional techniques that a scientist would have thought of when instructed to compare two gene sequences."[85] After the Federal Circuit's decision, it is clear that diagnostic method claims that merely compare DNA sequences will not be patentable subject matter. If, however, the claims go beyond mere comparison and include an additional "inventive concept," the claims may still be eligible for patent protection.

2. *U.S. Patent and Trademark Office Guidelines After* Mayo *and* Myriad

To further confirm the continued viability of diagnostic method claims, the USPTO recently published an updated set of guidance documents for its Patent Examining Corps (the individuals who grant or deny patent applications) to use when evaluating whether a claimed process is patentable under 35 U.S.C. § 101.[86] The quick reference document outlines a two-step process for determining whether a claim contains patent eligible subject matter.[87] First, an Examiner asks whether the claim is directed to one of the four statutory subject matter categories: process, machine, manufacture, or composition of matter.[88] Second, the Examiner invokes the two-part inquiry from *Alice Corp. by first asking if* the claim is directed to a "judicial exception" to patentability (a law of nature, a natural phenomenon, or an abstract idea).[89] If so, the Examiner then asks "whether any element, or combination of elements, in the claim is sufficient to ensure that the claim as a whole amounts to *significantly more* than the judicial exception."[90] Additional guidance documents provide examples to illustrate when a claim is "significantly more" than a law of nature or an abstract idea.[91] The analytical process outlined in the USPTO's guidance documents closely resembles the logic used by the Federal Circuit in its December 2014 decision invalidating Myriad's

83. *Id.*
84. *Id.* at 764.
85. *Id.*
86. *See generally* USPTO, 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,619 (Dec. 16, 2014) (request for comments); USPTO, "2014 Interim Eligibility Guidance Quick Reference Sheet" (Dec. 2014) ("USPTO Quick Reference Document").
87. *Id.* at 1.
88. *Id.*; *see also* 35 U.S.C. § 101 (listing the categories of patentable subject matter).
89. USPTO Quick Reference Document, *supra* note 86, at 1.
90. *Id.* (emphasis in original).
91. *See* USPTO, Nature-Based Product Examples (Dec. 16, 2014); USPTO, Abstract Idea Examples (Jan. 27, 2015).

method claims. Either analysis—based on judicial guidance or USPTO guidance—leaves room for patent eligible diagnostic method claims if the claims include an "inventive concept"[92] or something "significantly more."[93] Thus, we should continue to see patent applications for diagnostic method claims, including diagnostic method claims related to gene testing. Although the rules regarding patent eligibility under § 101 are now more strict,[94] diagnostic method claims are not historical relics.

IV. KEEPING THE DATA AS A TRADE SECRET

The VUS data obtained from Myriad's period as the exclusive provider of BRCA gene testing will likely be eligible for trade secret protection. Trade secret protection falls under state law, though the vast majority[95] of states have adopted some version of the Uniform Trade Secrets Act (UTSA). As such, the law of trade secrets is somewhat uniform nationwide. Professor Mark Lemley argues that trade secret law should be considered in the context of intellectual property law.[96] He describes trade secret protection as conferring on a "developer of new and valuable information the right to restrict others from using it, and therefore the prospect of deriving supracompetitive profits from the information."[97]

A. Whether Myriad's Proprietary Database Qualifies for Trade Secret Protection

Myriad will likely be able to maintain its proprietary database as a trade secret, at least for a period of time. The set of subject matter that qualifies for trade secret protection is much broader than the subject matter eligible for patent protection.[98] Whether something is eligible for trade secret protection is a question of law, but one that involves a fact-intensive inquiry.[99] Three primary definitions of what constitutes a trade secret currently exist. The traditional definition of a trade secret, found in the Restatement (First) of Torts, defines a trade secret as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."[100] The definition under the Restatement of Unfair Competition—though not adopted by many

92. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1299 (2012).

93. USPTO Quick Reference Document, *supra* note 86, at 1.

94. *See generally Mayo*, 132 S. Ct. 1289.

95. Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets As IP Rights*, 61 Stan. L. Rev. 311, 316 (2008).

96. *See generally id.*

97. *Id.* at 330.

98. *See* 35 U.S.C. §§ 101–103 (limiting the classes of subject matter eligible for patentability and requiring the invention to be novel and nonobvious).

99. *See, e.g.*, AvidAir Helicopter Supply, Inc. v. Rolls-Royce Corp., 663 F.3d 966, 971 (8th Cir. 2011).

100. Restatement (First) of Torts § 757 cmt. b (1939).

courts[101]—mirrors that original definition.[102] It defines a trade secret as "any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others."[103] Meanwhile, the widely adopted UTSA defines "trade secret" as:

> information, including a formula, pattern, compilation, program, device, method, technique, or process, that:
>
> (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
>
> (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.[104]

At least one scholar has argued that the UTSA definition of a trade secret "was designed to re-focus attention on the character of the thing to be protected and, thereby, limit the cases in which a successful trade secret claim can be brought."[105] Yet, in determining whether something qualifies for trade secret protection, even under the UTSA definition, courts often look to the six factors listed in comment b to the Restatement (First) of Torts § 757.[106] The six factors listed are:

(1) the extent to which the information is known outside of the business; (2) the extent to which it is known by employees and others involved in the business; (3) the measures taken to guard its secrecy; (4) the value to the business and its competitors; (5) the effort or money expended in developing the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.[107]

Under any of these definitions, Myriad's database of genetic variants will most likely qualify as a trade secret. Certainly, as discussed above, the value of the VUS database is incomparable, as it is the only database containing such a wealth of important genetic information. As such, the database likely "derives independent economic value, actual or potential, from not being generally known."[108] Regarding efforts to maintain se-

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101. *See* Annemarie Bridy, *Trade Secret Prices and High-Tech Devices: How Medical Device Manufacturers Are Seeking to Sustain Profits by Propertizing Prices*, 17 TEX. INTELL. PROP. L.J. 187, 201 & n.76 (2009) (noting that courts rarely invoke the provisions of the Restatement of Unfair Competition that address trade secrets).

102. *See* RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 39 (1995).

103. *Id.*

104. U.T.S.A. § 1(4) (amended 1985).

105. Sharon K. Sandeen, *A Contract by Any Other Name Is Still A Contract: Examining the Effectiveness of Trade Secret Clauses to Protect Databases*, 45 IDEA 119, 129 (2005).

106. RESTATEMENT (FIRST) OF TORTS § 757 cmt. b (1939); *see also* Bridy, *supra* note 101, at 201 n.74 (emphasizing the frequent reliance on the Restatement factors when applying the UTSA definition of a trade secret).

107. RESTATEMENT (FIRST) OF TORTS § 757 cmt. b (1939).

108. *See* U.T.S.A. § 1(4).

crecy, Myriad has already kept its database secret since 2004.[109] Considering the unique value of the database (and the success the company has had in keeping the database secret thus far), it is likely that Myriad has in place strong policies to maintain secrecy in the future.[110] Thus the requirement of secrecy under any definition will likely be satisfied.

The primary issue regarding eligibility for trade secret protection is the requirement under the UTSA that the information not be "generally known" and "readily ascertainable."[111] This inquiry is a question of fact.[112] With respect to databases of information being kept as trade secrets, some courts have held that mere compilation of public information into a database cannot qualify as a trade secret because the information is generally known.[113] Other courts, however, have found the opposite. For example, an Indiana Court of Appeals allowed for trade secret protection for a database of publicly available information because "the integration of separate pieces of raw data, taken together, constitutes a unique compilation which, in order to duplicate, would require a substantial investment of time, expense, and effort."[114] When the database contains less accessible information, a database of customer information is more likely to be protected.[115] Myriad's database would almost certainly fall in this second category of databases and, thus, would qualify for trade secret protection. The information in Myriad's database is not a mere compilation of publicly available data, but rather a set of individual genetic information obtained through Myriad's time as the exclusive provider of BRCA gene testing services. Thus, this information is not "generally known" nor "readily ascertainable."[116] As discussed below,[117] it is possible that a comparable database could developed through joint efforts in the research community. As the Eighth Circuit has noted, however, "[t]he fact that information can be ultimately discerned by others—whether through independent investigation, accidental discovery, or reverse engineering—does not make it unprotectable."[118] Thus,

109. *See* Brief of Amici Curiae Christopher M. Holman and Robert Cook-Deegan in Support of Neither Party, *supra* note 24, at 27.

110. *See id.*

111. U.T.S.A. § 1(4).

112. Zoecon Indus., a Div. of Zoecon Corp. v. Am. Stockman Tag Co., 713 F.2d 1174, 1179 (5th Cir. 1983).

113. *See, e.g.*, *id.* at 1179 ("[A] customer list of readily ascertainable names and addresses will not be protected as a trade secret."); *see also* Hamer Holding Grp., Inc. v. Elmore, 560 N.E.2d 907, 918–19 (1990) (holding that a database of names, addresses, and phone numbers did not qualify for trade secret protection under the Illinois Trade Secrets Act because "[a]nyone equipped with a public telephone directory could have collected the contact information").

114. N. Elec. Co. v. Torma, 819 N.E.2d 417, 426 (Ind. Ct. App. 2004) (citing Amoco Production Co. v. Laird, 622 N.E.2d 912, 919 (Ind. 1993)).

115. *See, e.g.*, *Zoecon*, 713 F.2d at 1176 (holding that "a memorandum containing the names, addresses, and purchasing characteristics of a business's customers is a trade secret under Texas law").

116. *See* U.T.S.A. § 1(4).

117. *See infra* Part VII.B.

118. AvidAir Helicopter Supply, Inc. v. Rolls-Royce Corp., 663 F.3d 966, 973 (8th Cir. 2011).

for the time being, Myriad's database would likely qualify for trade secret protection.

B. The Benefits of Relying on Trade Secret Protection

To recover for trade secret misappropriation under the UTSA, a trade secret owner must show that a trade secret existed and that the acquisition, disclosure, or use of that trade secret was improper.[119] If trade secret misappropriation is established, the trade secret owner may receive injunctive relief as well as damages.[120]

A party may receive injunctive relief for the period of time during which the trade secret would exist, and that time period may be extended to account for a commercial advantage or "lead time" period.[121] If, however, a court does not find complete injunctive relief appropriate, the court may allow for use of the trade secret upon a payment of reasonable royalties for the time period during which the trade secret would have existed.[122] The Commissioner's Comment to the Restatement notes that such an arrangement may be appropriate when there is an "overriding public interest which requires the denial of a prohibitory injunction."[123]

Moreover, a trade secret owner may also recover actual damages and damages for unjust enrichment upon a showing of trade secret misappropriation.[124] Furthermore, punitive damages may be awarded for "willful and malicious misappropriation."[125] Monetary damages, however, typically will not be available for any time period that injunctive relief is also granted.[126]

C. The Limits of Relying on Trade Secret Protection

The downside of relying on trade secret protection is that proper means exist for using and disclosing the trade secret.[127] Notably, if another party independently invents or reverse engineers the trade secret, then the trade secret owner has no recourse against that party because no misappropriation has occurred.[128] One of the primary limits Myriad will face regarding trade secret protection is the possibility of independent creation by other researchers of a comparable database of VUS information. Once such a database is created, Myriad's trade secret protection evaporates.

The time period for which Myriad would be able to keep its database as a trade secret may be severely limited by the fact that other efforts are

119. *See* U.T.S.A. § 1(4) (defining "misappropriation").
120. U.T.S.A. §§ 2–3.
121. *See* U.T.S.A. § 2(a); U.T.S.A. § 2(a) Commissioner's Comment.
122. *See* U.T.S.A. § 2(b).
123. U.T.S.A. § 2 Commissioner's Comment.
124. U.T.S.A. § 3(a).
125. U.T.S.A. § 3(b).
126. *See* U.T.S.A. § 3 Commissioner's Comment.
127. *See* U.T.S.A. § 1 Commissioner's Comment (listing examples of proper means).
128. *See id.*

already underway to attempt to recreate the genetic mutation database.[129] For example, Pathway Genomics valiantly proclaimed its intent to share all genetic mutation data with the public through the Free the Data movement, which encourages the submission of data to ClinVar, a public database of genetic information.[130] If researchers could create a comparable database through such efforts, it would strip Myriad of trade secret protection for its database.[131] Thus, if other companies (or the general public) create an equivalent VUS database, Myriad would lose its de facto monopoly. Until other researchers develop a comparable database, however, Myriad will be able to maintain its valuable VUS database as a trade secret.

V. EXTENDING THE SCOPE OF THE PATENT: PATENT MISUSE

A. MYRIAD'S DATABASE OF VARIANTS OF UNKNOWN SEQUENCE IS NOT COVERED BY ITS PATENT CLAIMS

To be sure, patent protection does not extend to the data obtained from the use of Myriad's patented gene testing technologies. A patent must include "one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."[132] As the Federal Circuit has noted, "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude."[133] Thus, the claims of a patent identify the scope of the invention for patentability and infringement purposes.[134] Claim language serves to delineate the precise "metes and bounds" of a patent; thus, patent protection simply does not extend to anything beyond the scope of the claims.[135] As the Supreme Court has noted, "[t]he scope of every patent is limited to the invention described in the claims contained in it, read in the light of the specification."[136] However, a patent owner is entitled to all "uses and advantages" of the patent.[137]

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129. *See infra* Part VII.B; *see also* Kevin E. Noonan, *Good News, Bad News and More Inflammatory Rhetoric in Myriad Genetics Case*, PATENT DOCS (June 17, 2014, 11:59 PM), http://www.patentdocs.org/2014/06/good-news-bad-news-and-more-inflammatory-rhetoric-in-myriad-genetics-case.html.

130. *See infra* Part VII.B; *see also* Press Release, Pathway Genomics, Pathway Genomics Announces Commitment to Free the Data Movement at NSGC Conference (Sept. 9, 2014), *available at* https://www.pathway.com/pathway-genomics-announces-commitment-to-free-the-data-movement-at-nsgc-conference.

131. *See* Noonan, *supra* note 129.

132. 35 U.S.C. § 112(b) (2012).

133. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted).

134. *See id.*

135. *See* Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1367 (Fed. Cir. 2012) ("It is the claims that define the metes and bounds of the patentee's invention.").

136. Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 510 (1917).

137. *See, e.g.*, Kennicott Co. v. Holt Ice & Cold Storage Co., 230 F. 157, 161 (7th Cir. 1915).

The method claims Myriad asserted in its post-*Myriad* litigation do not claim the genetic data obtained from the use of the patented method claims.[138] Thus, the once-enforceable method claims in Myriad's patent did not protect the data acquired through those claims because such data was not within the claimed scope of the invention.

Even if Myriad had attempted to patent the gathering, storage, and analysis of the data in its vast database, it is unlikely that the database would have qualified for patent protection. Instead, the database—and the method of comparing a new test result with contents of the existing database—would likely be considered abstract ideas, thus falling outside the realm of subject matter that may be patented.[139] The Federal Circuit found a similar patent claim invalid in *Content Extraction & Transmission LLC v. Wells Fargo Bank, National Association*.[140] In that case, the patent claimed a method for scanning paper documents, extracting certain information from those documents, and storing that information in a database.[141] In finding the method claim invalid as an attempt to patent an abstract idea, the court specifically emphasized that "[t]he concept of data collection, recognition, and storage is undisputedly well-known."[142]

Because the database of genetic information is not covered by the patent, an argument could be made that Myriad attempted to extend its patent beyond its intended scope by maintaining such a proprietary database. Such an improper extension of patent scope is the hallmark of the patent misuse defense.

B. The Patent Misuse Defense to Patent Infringement

Patent misuse is a traditional defense that a party accused of patent infringement may assert.[143] If the accused party establishes patent misuse, the patent owner's patent will be rendered unenforceable—meaning the patent owner cannot sue to enforce its patent rights.[144] As articulated by the Federal Circuit, the essence of the patent misuse doctrine is this: "the patentee may exploit his patent but may not 'use it to acquire a monopoly not embraced in the patent.'"[145] The doctrine "arises from the equitable doctrine of unclean hands, and relates generally to the use of patent rights to obtain or to coerce an unfair commercial advantage."[146]

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138. U.S. Patent No. 5,753,441 (filed Jan. 5, 1996) (asserted in *In re* BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litig., 3 F. Supp. 3d 1213, 1244 (D. Utah 2014)).

139. *See supra* Part III.B for a discussion of patent-eligible subject matter.

140. Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n, No. 2013-1588, 2014 WL 7272219, at *1 (Fed. Cir. Dec. 23, 2014).

141. *Id.*

142. *Id.* at *3.

143. *See* Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 519 (1917) (fashioning the foundation of the patent misuse doctrine).

144. *See* Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318, 1327–28 (Fed. Cir. 2010) (en banc).

145. *Id.* at 1327 (quoting Transparent–Wrap Mach. Corp. v. Stokes & Smith Co., 329 U.S. 637, 643 (1947)).

146. C.R. Bard v. M3 Sys., 157 F.3d 1340, 1372 (Fed. Cir. 1998) ("C.R. Bard").

Essentially, the patent misuse doctrine addresses instances where a patent owner's actions "extend the economic effect beyond the scope of the patent grant."[147]

Despite the doctrine's seemingly broad scope, courts have found patent misuse in only a handful of instances, specifically noting that patent misuse "does not include a general notion of 'wrongful' use."[148] Historically, patent misuse has been used primarily to prevent patent owners from conditioning patent licenses on the purchase of another unpatented product.[149] The Federal Circuit, however, has continually narrowed the scope of the doctrine.[150] Moreover, Congress further limited the scope of patent misuse in 35 U.S.C. § 271(d) by specifically listing five types of conduct that will *not* be considered patent misuse.[151] One important limitation was added when Congress passed the Patent Misuse Reform Act of 1988.[152] The statute now provides that conditioning a license or sale of a patented product on purchase of a separate product is not patent misuse unless "the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned."[153] The doctrine is further limited by the narrow circumstances in which it applies. Because patent misuse exists only as an affirmative defense to patent infringement, it does not provide a cause of action against a patent owner for alleged misuse of its patent. Thus, this doctrine only becomes relevant during the life of a patent, when the patent owner seeks to enforce its patent.

Although at first blush it appears obvious that collecting data from patients through the use of patented method claims, then maintaining that database for use beyond the term of the patent "extend[s] the economic effect beyond the scope of the patent grant,"[154] courts have yet to apply the patent misuse doctrine in this context. Because this conduct does not mirror the typical scenarios of patent misuse, such as tying arrangements, courts would need to evaluate this particular scenario on a case-by-case basis. One potential avenue for a patent misuse defense might be if Myriad had conditioned the sale of its BRCA genetic test on the patient's surrender of her genetic and personal information for use in Myriad's database. Although the patient would not be required to *purchase* an unpatented item, as is the case in the traditional tying cases, the parallels are self-evident.

147. *Id.*
148. *Id*. at 1373.
149. *See Princo*, 616 F.3d at 1327.
150. Geoffrey D. Oliver, Princo v. International Trade Commission: *Antitrust Law and the Patent Misuse Doctrine Part Company*, 25 SPG ANTITRUST 62, 66 (2011).
151. 35 U.S.C. § 271(d) (2012).
152. *See* 35 U.S.C. § 271(d)(5).
153. *Id.*
154. C.R. Bard v. M3 Sys., 157 F.3d 1340, 1372 (Fed. Cir. 1998).

C. Even if Established, Patent Misuse Cannot Prevent a De Facto Monopoly

Even if patent misuse could be established, no remedy is available to the party alleging misuse.[155] Rather, the only "remedy" is that the patent owner cannot receive any remedy for infringement of its patent by others—i.e. the patent is unenforceable—until the patent misuse is purged.[156] Thus, as long as the company with the proprietary database continues to gather genetic information and create such a database, the company would not be able to enforce its gene testing patent against any infringers. As a result, competitors could enter the gene testing market without fear of infringement litigation. Considering, however, an individual's strong desire to understand the significance of gene testing results, individuals would likely continue to seek out the patent owning company, even if other companies (with small, less helpful databases) could offer the same patented genetic test for a cheaper cost, without fear of infringement litigation. Therefore, even if patent misuse could be established, it would not remedy the de facto monopoly retained by the patent owner.

Given the discussion among courts regarding the purpose of the patent misuse doctrine and its distinct role in accompanying the antitrust laws, it seems that this doctrine could be expanded to encompass issues such as proprietary databases of information obtained from a patent monopoly.

VI. SOLUTIONS UNDER FEDERAL ANTITRUST LAW

Courts have long recognized the tension between patent law and antitrust law.[157] Yet, despite the seeming conflict, the two areas of law seek to serve the same purpose: "encouraging innovation, industry and competition."[158] Despite the broad protection provided through the patent system, patent owners are not entirely immune from antitrust liability related to their patents.[159] However, the conduct at issue in this Comment—maintaining a proprietary database based on the benefits received from the exclusivity of patent protection—falls outside the scope of the typical discussions at the intersection of patent law and antitrust law. This conduct falls outside the realm of *Walker Process* fraud on the USPTO[160] and outside the realm of sham litigation to enforce an invalid patent.[161]

155. Qualcomm Inc. v. Broadcom Corp., 548 F.3d 1004, 1026 (Fed. Cir. 2008).

156. *Id.*

157. *See, e.g.*, Image Tech. Servs. v. Eastman Kodak Co., 125 F.3d 1195, 1215 (9th Cir. 1997) ("Clearly the antitrust, copyright and patent laws both overlap and, in certain situations, seem to conflict. This is not a new revelation.").

158. Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990); *see also*, *e.g.*, Antitrust Guidelines for the Licensing of Intellectual Property, Dept. of Justice (1995) ("The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare.").

159. *See, e.g.*, Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965) (holding that obtaining a patent through fraud violates antitrust laws).

160. *See id.*

161. *See generally* Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998) (applying the *PRE* sham litigation test to patent law).

As such, a proper analysis of this conduct relies primarily on basic antitrust principles.

One scholar has briefly addressed the applicability of antitrust principles to Myriad's conduct surrounding its proprietary database.[162] As discussed below, her helpful analysis may underestimate the viability of an antitrust claim, especially given the unique facts surrounding Myriad's conduct in past years.

A. Establishing Monopolization Under § 2 of the Sherman Act

Under § 2 of the Sherman Act, it is a felony to monopolize or attempt to monopolize trade between the several States.[163] The text of § 2 reads:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.[164]

The term "person," of course, includes corporations.[165] In creating the § 2 offenses, Congress chose not to further define the offenses, but instead to leave the development of the law to the courts.[166]

As articulated by the Supreme Court in *United States v. Grinnell Corp.*, the offense of monopolization requires: (1) monopoly power in the relevant market; and (2) "'the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'"[167] Monopolization may exist even if the monopoly was obtained through lawful means, such as through a patent right.[168]

To receive damages for a § 2 violation, a plaintiff must also show antitrust injury.[169] Regarding equitable relief, if an antitrust violation is established, a court may order compulsory licensing of a patented product.[170]

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162. Evans, *supra* note 34, at 58–64.
163. 15 U.S.C. § 2 (2012).
164. *Id.*
165. Standard Oil Co. of New Jersey v. United States, 221 U.S. 1, 61 (1911).
166. *See* Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 454 (1993) (noting that the legislative history of the Sherman Act indicated that "much of the interpretation of the necessarily broad principles of the Act was to be left for the courts in particular cases").
167. Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966)).
168. *See* United States v. Griffith, 334 U.S. 100, 107 (1948) (noting that "the use of monopoly power, however lawfully acquired, to foreclose competition, to gain a competitive advantage, or to destroy a competitor, is unlawful").
169. Comcast Corp. v. Behrend, 133 S. Ct. 1426, 1438–39 (2013).
170. *See* United States v. Glaxo Grp., Ltd., 410 U.S. 52, 64 (1973).

1. Monopoly Power in the Relevant Market

Monopoly power has been defined as the power to control prices *or* exclude competition.[171] A company's sheer size—including clear dominance of a market—is insufficient to constitute a violation of § 2 because entities "may become monopolists by force of accident."[172] This principle reflects the congressional history of the Sherman Act, which indicated that the Sherman Act should not be construed to apply against an entity "who happens by his skill and energy to command an innocent and legitimate monopoly of a business."[173]

In determining whether a party has monopoly power, courts first define the relevant market, including the relevant product market and the relevant geographic market.[174] In defining the relevant product market, courts look to "the nature of the commercial entities involved and by the nature of the competition that they face."[175] The relevant geographic market involves an analysis of "where, within the area of competitive overlap, the effect of the merger on competition will be direct and immediate."[176] Once the relevant market is defined, courts evaluate the degree of market power possessed by the entity, looking at the market share and any actual anticompetitive effects.[177] The extent of market share that an entity controls is an important factor in establishing market power.[178] The Supreme Court has held that an entity has monopoly power when it has the "power of controlling prices or unreasonably restricting competition."[179] Possession of market power may be presumed when an entity possess a predominant share of the market.[180] Furthermore, "[w]hen a product is controlled by one interest, without substitutes available in the market, there is monopoly power."[181]

Myriad would almost certainly be found to possess market power in the relevant market of breast cancer research in the United States—and po-

171. United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956). *But see* Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir. 2007) (requiring both); Full Draw Productions v. Easton Sports, Inc., 182 F.3d 745, 757 (10th Cir. 1999) (requiring both).

172. United States v. Aluminum Co. of Am., 148 F.2d 416, 430 (2d Cir. 1945) ("ALCOA"). Although a panel of Second Circuit judges handed down the famous ALCOA decision, the opinion carries the weight of a Supreme Court decision. *See* LePage's Inc. v. 3M, 324 F.3d 141, 147–48 (3d Cir. 2003) ("Because four members of the Supreme Court were disqualified, the Supreme Court was required to apply the provision of the Expediting Act . . . currently 28 U.S.C. § 2109, to certify the case to the three most senior judges of the relevant circuit. Under the statute, the decision of that court was 'final and conclusive,' thus equating it to a decision of the Supreme Court.").

173. United States v. E.I. Du Pont De Nemours & Co., 118 F. Supp. 41, 215 (D. Del. 1953) (1956) (quoting 21 CONG. REC. 3151 (1890)).

174. United States v. Phillipsburg Nat. Bank & Trust Co., 399 U.S. 350, 360–62 (1970).

175. *Id.* at 360.

176. *Id.* at 362.

177. *See generally* Eastman Kodak Co. v. Image Technical Servs., 504 U.S. 451 (1992).

178. *See* United States v. Grinnell Corp., 384 U.S. 563, 571 (1966).

179. United States v. E. I. du Pont de Nemours & Co., 351 U.S. 377, 389 (1956) ("Du Pont").

180. *Grinnell*, 384 U.S. at 594.

181. *Du Pont*, 351 U.S. at 394.

tentially in the world. In Myriad's case, the relevant market would be at least the BRCA gene research market. However, because of the significant role the BRCA gene plays in breast and ovarian cancer research, a court may find that the market consists of the entire breast and ovarian cancer research market.[182]

2. Willful Maintenance of Monopoly Power

While satisfying the first prong of the § 2 analysis appears simple in Myriad's case, establishing the second prong of the § 2 analysis proves to be more difficult. The existence of monopoly power does not automatically result in a finding of monopolization under the Sherman Act.[183] Instead, "[t]o safeguard the incentive to innovate," courts require "an element of anticompetitive *conduct*" in addition to possession of monopoly power.[184] Thus, establishing a § 2 violation also requires proof of "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[185] As discussed below, refusing to deal with competitors may satisfy this second prong of the § 2 analysis in some circumstances.[186]

B. Refusal to Deal and The Essential Facilities Doctrine

1. Basic Refusal to Deal Principles

Although courts have placed a "high value"[187] on a company's right to refuse to deal with competitors, the Supreme Court has consistently held that in some circumstances a refusal to deal with competitors may constitute a § 2 violation.[188] The primary case cited for antitrust liability based on a refusal to deal is *Aspen Skiing v. Aspen Highlands Skiing*.[189] However, in *Verizon Communications v. Law Offices of Curtis v. Trinko*,[190] the Supreme Court significantly narrowed *Aspen Skiing* by noting that "*Aspen Skiing* is at or near the outer boundary of § 2 liability."[191] The Court characterized *Aspen Skiing*'s "limited exception" to the right of refusal to deal as one where "[t]he unilateral termination of a voluntary *(and thus presumably profitable)* course of dealing suggested a willingness

182. *See id.* at 404 ("[The relevant] market is composed of products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered.").
183. Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 406 (2004) ("Trinko").
184. *Id.* at 407.
185. *Grinnell*, 384 U.S. at 570–71.
186. *See generally* Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985); Otter Tail Power Co. v. United States, 410 U.S. 366 (1973); Lorain Journal Co. v. United States, 342 U.S. 143 (1951).
187. *Aspen Skiing*, 472 U.S. at 601.
188. *Trinko*, 540 U.S. at 408.
189. *See generally Aspen Skiing*, 472 U.S. 585.
190. *See generally Trinko*, 540 U.S. 398.
191. *Id.* at 409.

to forsake short-term profits to achieve an anticompetitive end."[192]

Based on this characterization, Dr. Evans concludes that "[a] clinical laboratory's refusal to share its [variant of unknown significance] data would almost never fit in this exception."[193] Although Dr. Evans's conclusion may be correct in most instances, Myriad's conduct may fit into this narrow exception. Through November 2004, Myriad voluntarily contributed its genetic mutation data to the Breast Cancer Information Core (the largest database for BRCA mutation data).[194] Interpreting this conduct in light of the Court's language in *Trinko* indicates that the sudden "unilateral termination" of such a voluntary dealing may indicate "a willingness to forsake short-term profits to achieve an anticompetitive end."[195] It will be difficult, however, to demonstrate that Myriad forsook short-term profits by choosing to keep its data proprietary instead of sharing the data with the public. Although it appears obvious that Myriad chose to withhold its data because of its value, a court may find that Myriad's choice was motivated by "competitive zeal" instead of the required "anticompetitive malice."[196] If, however, an antitrust plaintiff demonstrates that Myriad did forsake short-term profits in altering its business model, or that Myriad based its decision on "anticompetitive malice," Myriad's conduct would likely fit into the narrow *Aspen Skiing* form of liability.[197]

The Supreme Court in *Trinko* also expressed concern regarding a court's ability to administer and supervise a solution to a party's refusal to deal with competitors.[198] Again, however, considering that Myriad already possesses an infrastructure for sharing data with the public through the well-established Breast Cancer Information Core platform, requiring Myriad to share its data would not require any judicial oversight.[199] Thus, concern with judicial oversight would not factor into the viability of an antitrust claim in Myriad's case.

2. The Essential Facilities Doctrine

Even if an antitrust plaintiff could not establish a § 2 violation using the refusal to deal principles found in *Aspen Skiing*, liability may inhere under the essential facilities doctrine. According to this doctrine, a company who refuses to deal with other companies by refusing to provide those competitors with access to an essential facility may be liable under antitrust laws.[200] As the Seventh Circuit aptly explained, "[s]uch a refusal may be unlawful because a monopolist's control of an essential facility

192. *Id.*
193. Evans, *supra* note 34, at 61.
194. Cook-Deegan et al., *supra* note 15.
195. *Trinko*, 540 U.S. at 409.
196. *Id.*
197. *See id.*
198. *Id.* at 415.
199. *See* Cook-Deegan et al., *supra* note 15.
200. MCI Commc'ns Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1132 (7th Cir. 1983).

(sometimes called a 'bottleneck') can extend monopoly power from one stage of production to another, and from one market into another."[201]

Myriad's proprietary database could be characterized as an "essential facility" to help formulate an antitrust claim against the company's actions. To establish liability under the essential facilities doctrine a plaintiff must prove: "(1) control of the essential facility by a monopolist; (2) a competitor's inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; and (4) the feasibility of providing the facility."[202] This doctrine can apply to intangible facilities, such as information.[203]

The essential facilities doctrine, based loosely on a 1912 Supreme Court decision,[204] has become entrenched in the jurisprudence of circuit courts across the nation.[205] The Supreme Court, however, has expressly noted that it has neither adopted nor repudiated the doctrine's existence.[206] Instead, the Court has emphasized that there are "few existing exceptions from the proposition that there is no duty to aid competitors."[207] And, despite the changing composition of the Court over the past few decades, the Court has yet to become interested in addressing the doctrine's viability.[208] The Court has noted, however, that this doctrine should *not* be used if a regulatory agency has the power to compel the use of an essential facility.[209] From outside the court system, the essential facilities doctrine has faced severe criticism.[210] For example, the Department of Justice in 2008 expressed its view of the doctrine, noting that "[t]he Department agrees that the essential-facilities doctrine is a flawed means of deciding whether a unilateral, unconditional refusal to deal harms competition."[211]

Nonetheless, this doctrine provides the best opportunity for establishing antitrust liability for Myriad's maintenance and exclusive use of its proprietary database. The "essential facility" would, of course, be the database of genetic information. Under the second prong of the doctrine,

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201. *Id.*

202. *Id.* at 1132–33.

203. Tri-Tech Mach. Sales, Ltd. v. Artos Eng'g Co., 928 F. Supp. 836, 839 (E.D. Wis. 1996).

204. United States v. Terminal R.R. Ass'n of St. Louis, 224 U.S. 383, 409–10 (1912).

205. *See, e.g.*, *MCI Communications*, 708 F.2d at 1132.

206. Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004) ("We have never recognized such a doctrine . . . and we find no need either to recognize it or to repudiate it here.").

207. *Id.*

208. *See, e.g.*, *Trinko*, 540 U.S. at 411; Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 611 n.44 (1985) ("[W]e find it unnecessary to consider the possible relevance of the 'essential facilities' doctrine . . . .").

209. *Trinko*, 540 U.S. at 411.

210. *See* Thomas F. Cotter, *The Essential Facilities Doctrine*, University of Minnesota Law School Legal Studies Research Paper Series Research Paper No. 08-18, at 1, *available at* http://ssrn.com/abstract=1125368.

211. *See* U.S. Dep't of Justice, Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act 129 (2008), *available at* www.usdoj.gov/atr/public/reports/236681.htm.

it is impracticable for competitors to replicate the vast amount of genetic data held by Myriad. Thus, an antirust plaintiff should be able to establish the second prong. If, in the future, Myriad refuses to allow others to utilize this database—even if those competitors attempt to pay for the product—the third prong of the test will likely be satisfied. Finally, considering that the genetic information is stored on a searchable computer database, it would be feasible for Myriad to provide access to the essential facility. Thus, all four prongs of the essential facilities doctrine would likely be satisfied.

Although Dr. Evans rightly concludes that the essential facilities doctrine "aptly describes the situation in the genetic testing industry," she further concludes that "[t]he ultimate problem with the essential facilities doctrine is that it forces courts to act as economic regulators and grapple with details of pricing and access arrangements that courts are ill equipped to administer."[212] While courts have recognized this concern in other contexts,[213] courts will not likely be forced to play any significant role in regulating the operations of these companies. As discussed above, a court decision requiring Myriad to share its vast mutation database would require no judicial supervision because Myriad already has measures in place for sharing data through the Breast Cancer Information Core.[214] Moreover, compulsory data sharing would not require judicial supervision of similarly-situated companies because the research community already maintains public databases for this very purpose.[215] Courts could simply direct the companies to share data through these existing resources.

Data formatting will not prove to be a problem because, for example, ClinVar expressly touts its "flexible data model" and lists a variety of data formats accepted by the public database.[216] And even if research companies utilize inconsistent data formats, courts could instruct the companies to provide the data in a format consistent with the format used by public databases. Although this may require a good deal of time and effort on the part of the company's computer scientists, it would not require any degree of judicial supervision. As such, courts are fully equipped to fashion a proper remedy for sharing proprietary data.

C. Antitrust Injury and Damages

After establishing antitrust liability under the above theories, to receive damages a plaintiff would also have to prove an antitrust injury and damages.[217] Establishing antitrust injury requires more than a showing of

212. Evans, *supra* note 34, at 62–63.
213. *Trinko*, 540 U.S. at 415.
214. Cook-Deegan et al., *supra* note 15.
215. *See, e.g.*, *What is ClinVar?*, NCBI, http://www.ncbi.nlm.nih.gov/clinvar/intro/ (last updated Aug. 28, 2014).
216. *How to Submit Data to ClinVar*, NCBI, http://www.ncbi.nlm.nih.gov/clinvar/docs/submit/ (last updated Dec. 17, 2014).
217. Comcast Corp. v. Behrend, 133 S. Ct. 1426, 1438 (2013).

injury in fact.[218] Rather, a plaintiff must prove that the injury suffered is "of the type the antitrust laws were intended to prevent and that flow[s] from that which makes defendants' acts unlawful."[219]

At least some evidence of antitrust injury can be found in an amicus brief submitted to the Supreme Court in *Association of Molecular Pathology v. Myriad*.[220] One health care provider, Kaiser Permanente, claimed the following:

> Kaiser Permanente is barred from obtaining full information about its own members' test results. Instead, Myriad offers summaries of these data upon request and only with a signed release from a clinician. Kaiser Permanente would compile a database of information learned from the test results of its own members—a next-best alternative to accessing the complete Myriad database—but the selective summary data provided by Myriad do not enable it to do so.[221]

As such, an antitrust plaintiff would likely be able to establish antitrust injury based on Myriad's withholding of its data from health care providers who would otherwise compile similar sets of data.

VII. OTHER SOLUTIONS TO PREVENT THE PROPRIETARY DATA HOLD

A. Congressional and Administrative Action

In *Mayo*, the Supreme Court indicated that Congress should develop more specific rules regarding diagnostic patents if such important public policy concerns exist.[222] In this vein, some industry leaders have recommended particular legislative action to ameliorate the potential for inaccessible VUS data. For example, Susan Domchek, Sean McElligot, and others at the University of Pennsylvania suggest amending the U.S. Health Insurance Portability and Accountability Act (HIPAA) to require data sharing as an aspect of Clinical Laboratory Improvement Amendments (CLIA) certification.[223] Congress's CLIA program "establish[es] quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results."[224] Because any laboratory that offers diagnostic tests, such as genetic tests, must be CLIA certified, this could be an effective means for regulating data sharing. Another recommended solution is for Congress to alter the jurisdiction of the FDA

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218. *See id.*
219. *See id.* (internal quotations omitted).
220. Brief of Kaiser Permanente as Amicus Curiae in Support of Petitioners, *supra* note 29, at 8.
221. *See id.*
222. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012) (referencing the specific statutes tailored to plant patents, the Court noted "we must recognize the role of Congress in crafting more finely tailored rules where necessary").
223. Baker, *supra* note 23.
224. *How to Obtain a CLIA Certificate*, Brochure No. 5, Centers for Medicare & Medicaid Services (Mar. 2006), https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html.

by granting it explicit authority to regulate genetic testing.[225] Then, the FDA could promulgate regulations requiring access to important genetic mutation data.[226] Although one commentator has suggested that such mandatory disclosure requirements would implicate Fifth Amendment Takings concerns, such an important discussion is beyond the scope of this Comment.[227]

With the advent of next generation sequencing, the FDA is already considering ways to regulate diagnostic gene testing in the future.[228] Next-generation sequencing techniques enable a single genetic test to sequence an individual's entire genome.[229] Such tests can "identify thousands—even millions—of genetic variants" which could be used to "diagnose or predict an individual's risk of developing many different conditions or diseases."[230] Such technology "promise[s] to accelerate 'personalized' or 'precision' medicine, the tailoring of medical treatment to the individual characteristics of each patient."[231]

B. Grass Roots Efforts by Others in the Medical Research Community

A handful of researchers are currently attempting to replicate Myriad's massive VUS database. For example, Richard Nussbaum of the University of California, San Francisco, invites patients to submit the data from their test results for use in a public database.[232] One of the best-known examples of a grass roots effort to share genetic data is the Free the Data movement, organized by Genetic Alliance.[233] Genetic Alliance is a nonprofit organization made up of over 10,000 health organizations.[234] The Free the Data movement encourages individuals to submit the results from their genetic tests to a publicly-accessible database, ClinVar, which is maintained by the National Institute of Health.[235] The ClinVar database "aggregates information about genomic variation and its relationship to human health."[236] On Free the Data's homepage, the organi-

225. *See* Baker, *supra* note 23.
226. See *id.*
227. Noonan, *supra* note 129.
228. Preliminary Discussion Paper, Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests, FDA Public Workshop (Feb. 20, 2015), *available at* http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM427869.pdf.
229. *Id.*
230. *Id.*
231. *Id.*
232. Baker, *supra* note 23.
233. *See generally* Free the Data, http://www.free-the-data.org/ (last visited Mar. 2, 2015).
234. *Genetic Alliance*, Free the Data, http://www.free-the-data.org/who (last visited Mar. 2, 2015).
235. *Sharing Genetic Testing Reports Through Free the Data: Frequently Asked Questions*, Free the Data, http://www.free-the-data.org/learn/reports (last visited Mar. 2, 2015); *see ClinVar*, NCBI, http://www.ncbi.nlm.nih.gov/clinvar (last updated Aug. 28, 2014).
236. *ClinVar*, *supra* note 235.

zation proudly lists eight laboratories that already share BRCA1 and BRCA2 mutation data through the ClinVar platform.[237]

Although efforts such as Free the Data may take years to replicate the vast database a company is able to create during its period as the exclusive provider of a particular genetic test, these efforts will at least shorten the period of time that a company will be able to keep its valuable data as a trade secret.[238] This will especially become the case if individual patients become comfortable with providing their test results to a public database immediately upon receiving their results.

C. Industry Pressure and Public Perception

The benefits of data sharing within the scientific research community extend beyond the realm of genetic testing.[239] For example, a recent Nature Biotechnology editorial noted the need for such crowdsourced data in the field of drug repurposing (using test data from failed drug compounds to identify new uses for those compounds).[240] The editorial identifies two crowdsourcing initiatives that exist to facilitate shared data and ideas regarding ways in which failed drug compounds could be repurposed for other beneficial therapeutic uses.[241] So far, eight companies have joined the effort to share such important data with other researchers in their industry.[242] If similar efforts become commonplace within the medical research community, a company such as Myriad could be pressured into sharing its data based on industry expectations.

In other industries, data sharing is becoming common—even trendy, in an entrepreneurial sort of way. In June 2014, Tesla CEO Elon Musk took the first step toward opening up the electric vehicle market to competitors by releasing Tesla's vast collection of patents to the public, with a promise to refrain from enforcing the company's patents against infringers.[243] Following Tesla's lead, Toyota announced at the Consumer Electronics Show earlier this year that it would make 5,680 of its patents available for public use.[244] Many of the patented technologies provide the

237. *See supra* note 233 (listing Ambry Genetics, Counsyl, Emory Genetics Laboratory (data shared through EmVClass), GeneDX, Invitae, Michigan Medical Genetics Lab (coming soon), Pathway Genomics, and University of Chicago's Genetic Services Laboratory).

238. *See supra* Part III.

239. *See* Editorial, *Bring Out Your Dead*, Nature Biotechnology (Jan. 9, 2015), http://www.nature.com/nbt/journal/v33/n1/full/nbt.3123.html?WT.mc_id=TWT_NatureBiotech (discussing the benefits and difficulties of sharing data within the drug repurposing community).

240. *Id.*

241. *Id.*

242. *Id.*

243. Elon Musk, *All Our Patent Are Belong To You*, Tesla Blog (June 12, 2014), http://www.teslamotors.com/blog/all-our-patent-are-belong-you ("Tesla will not initiate patent lawsuits against anyone who, in good faith, wants to use our technology.").

244. Charles Riley, *Toyota is Giving Away its Fuel Cell Patents*, CNN Money (Jan. 5, 2015, 10:59 PM), http://money.cnn.com/2015/01/05/autos/toyota-fuel-cell-patents.

foundation for Toyota's new hydrogen fuel cell car, the Toyota Mirai.[245] These data sharing efforts by large companies encourage research and development at the community level. Moreover, the willingness to share data, seemingly for the public good, facilitates positive public relations efforts. If such efforts become the norm among major companies—each company joining the cause to promote the public welfare by sharing research data—companies such as Myriad will be forced to choose between either sharing data or battling a constant public relations nightmare.

VIII. CONCLUSION

The patent system continues to serve the important purpose of promoting innovation by rewarding those who bear the initial research and development costs by providing them with a period of market exclusivity. Yet, this helpful system brings about new issues in an era where the information obtained from patented technologies, such as the genetic sequences of millions of "variants of unknown significance" obtained through use of a patented genetic testing method, becomes more valuable than the patented invention itself. With the continuing advent of next generation sequencing, the need for shared access to data regarding variants of unknown significance—in all areas of genetic research—will only increase.[246]

When Tesla announced its willingness to share its patents on its electric vehicle technology, the company emphasized its original purpose: "Tesla Motors was created to accelerate the advent of sustainable transport. If we clear a path to the creation of compelling electric vehicles, but then lay intellectual property landmines behind us to inhibit others, we are acting in a manner contrary to that goal."[247] Even if the potential legal avenues of relief discussed above prove futile in addressing the proprietary data dilemma, hope remains that Myriad and other similarly-situated industry leaders will voluntarily choose to forego potential profits offered by proprietary datasets and instead focus on promoting the public good by accelerating advances in medical research through access to shared data.

245. *Id.*

246. Cook-Deegan et al., *supra* note 15 (noting that "the biggest challenge to [whole genome analysis] implementation is properly interpreting the variants found upon analyzing any individual's genome").

247. Musk, *supra* note 243.