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Duty to Deal: The Antitrust Antidote to the Gene Patent Dilemma

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INTRODUCTION

The objective of our nation's patent system is to maintain an equitable balance between the rights of individual innovators and the interests of the general public.¹ Ideas are intangible knowledge goods that are characterized by high fixed costs of initial development and low marginal costs of production.² Individuals in a perfectly competitive market would refrain from investing in the creation of new knowledge goods since they would not be able to recoup their upfront fixed costs.³ Patent law alleviates this concern by granting an inventor an exclusive right to market and license her knowledge good for a limited duration. These exclusive property rights confer market power upon the inventor and impose static efficiency losses on society.⁴ The underlying premise of patent rights is that dynamic gains from increased innovation and creativity outweigh the static efficiency losses arising from the legal creation of market power.⁵ The economic incentives conferred by the patent system are especially relevant to inventors within the biopharmaceutical sector, an industry that is burdened by enormous research and development (R&D) costs.⁶ The existence of gene patents may have played a crucial role in the rise of the biotechnology industry in the United States.⁷

* J.D., 2013, University of California, Irvine School of Law; Ph.D., California Institute of Technology; B.S., Suffolk University. The author thanks Professors Christopher R. Leslie, R. Tony Reese, and Steven Nataupsky for their guidance and assistance throughout the development of this Note—"I remain your apprentice forevermore." The author would also like to thank Dr. James J. Mullen III, who inspired her to pursue the subject matter two years ago, and Dr. Yimeng Dou and Azure De M. Wilkins for their unwavering support. The author would also like to acknowledge Howard Tan and the rest of the Tan and Fernandes clans for believing in the dreams of their daughter. This Note was originally submitted and awarded third place in the 2012 IDEA Student Writing Competition.

1. WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 13–14 (2003); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–28 (1989); Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws*, 24 J. PAT. OFF. SOC'Y 159, 175–77 (1942).

2. RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 38, 42 (7th ed. 2007).

3. *Id.* at 38.

4. *Id.*

5. LANDES & POSNER, *supra* note 1, at 20–21.

6. Biopharmaceutical companies face significant risks in the research and development process because most or all of their investment will be lost. The patent system provides biopharmaceutical companies with a sufficient term of exclusivity to recoup sunk costs, prevent competitors from imitating their inventions, and generate adequate capital to invest in future drug development pipelines. James H. Davis & Michele M. Wales, *The Effect of Intellectual Property on the Biotechnology Industry*, in *PERSPECTIVES ON THE PROPERTIES OF THE HUMAN GENOME PROJECT* 427, 433–34 (F. Scott Kieff ed., 2003) ("If other companies were permitted to copy biotechnology or pharmaceutical products as soon as they were approved, no rational drug company would expend the cost and effort of developing new drugs."); PHARM. RESEARCH & MFRS. OF AM. (PHARMA), *Pharmaceutical Industry Profile 2011*, PHARMA 15 (Apr. 13, 2011), http://report.nih.gov/investigators_and_trainees/acd_bwf/pdf/Pharma_Industry_Profile_2011.pdf ("The biopharmaceutical industry is the most R&D-intensive manufacturing sector in the [U.S.]. In the last five years, these companies have invested \$316 billion on research and development of new medicines." (citation omitted)); see JANICE M. MUELLER, *PATENT LAW* 7 (3d ed. 2009).

7. Many small but promising biotech firms probably would not have been able to attract

Indeed many advances in gene-based technologies—such as life-saving diagnostic tools and clinical therapeutics⁸—owe their existence to the patent system.⁹ But if left unchecked, the broad monopoly power wielded by gene patent holders can be detrimental to both the biomedical community,¹⁰ which is charged with innovating new technologies and providing access to such services,¹¹ and the general public—the intended beneficiaries of such breakthroughs.¹²

About twenty percent of human genes are currently patented,¹³ many of which are implicated in prevalent diseases including breast cancer, Alzheimer's disease, and Huntington's disease.¹⁴ These gene sequences comprise important research tools that are essential for the development and improvement of all gene-based diagnostics and therapeutics. Gene patents are unique compared to other product patents because they cannot be designed around.¹⁵ Furthermore, there are

venture capital funding without their portfolio of gene patents. See John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 139–40 (2001) (“[T]he biotechnology industry does engage in substantial basic research, and, to the extent that it does, its funding is most likely to come from venture capital. Indeed, most biotechnology firms start out as venture-capital-financed ‘spin-outs’ from a university or research institute, beginning their existence as research and development companies that leverage relatively narrow technical expertise, as well as intellectual property, for both financing and limited amounts of revenue.”). For the purposes of this Note, the term gene patents is defined broadly to include patents on unaltered naturally occurring gene sequences that have been isolated from their source, isolated naturally occurring gene sequences that have been further modified by human manipulation, and artificially synthesized gene sequences (i.e., cDNA).

8. RICKI LEWIS, *HUMAN GENETICS* 377–95, 397–416, 426–27, 433–46 (7th ed. 2007); TOM STRACHAN & ANDREW READ, *HUMAN MOLECULAR GENETICS* 497–716 (4th ed. 2011); J.D. WATSON, *DNA: THE SECRET OF LIFE* 303–07 (2003).

9. Davis & Wales, *supra* note 6, at 428; Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173, 174–75 (1986) (showing that at least sixty percent of pharmaceutical inventions would not have developed without a patent system); Emily Marden et al., *Genomics and Intellectual Property: Considering Alternatives to Traditional Patenting*, 17 HEALTH L. REV. 12, 16 (2008) (“[P]roducts such as instruments and protein therapeutics . . . are on the market because [of] the patent system. . . .”); Jasmine Chambers, Note, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan*, 34 GEO. WASH. INT’L L. REV. 223, 224 (2002) (stating that the U.S. patent system has played a critical role in the growth of the multibillion dollar biotechnology industry).

10. Throughout this Note, the term “biomedical community” refers to basic and clinical researchers in academia and the biotech/pharmaceutical industry, as well as health care practitioners.

11. See Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1364 (2002) (“Developing new products that enhance human health and welfare should not be like walking through a mine field, with risk of severe consequences should a loosely-related patent claim be infringed.”).

12. Lori Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL’Y 65, 67 (2002) [hereinafter Andrews, *Gene Patent Dilemma*]; Lori Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REV. GENETICS 803, 803 (2002) [hereinafter Andrews, *Genes and Patent Policy*].

13. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239–40 (2005).

14. *Id.* at 240; see Katrien Vlassak en Kees Schüller, *The Effect of Patents on Research and Development of Diagnostic Kits*, in GENE PATENTS AND PUBLIC HEALTH 99, 106–07 (Geertrui Van Overwalle ed., 2007).

15. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in*

no available non-infringing substitutes for gene sequences, allowing a gene patent owner to control the entire market for any given application of the patented gene.¹⁶ This phenomenon, commonly known as the “bottleneck effect” of gene patents, is disconcerting because gene patent holders can potentially determine which inventions are practiced.¹⁷ This effect is especially pronounced in the gene diagnostic market where the patentee holds the rights to a particular gene sequence and a genetic testing method that screens for mutations within the same patented gene.¹⁸ Such conditions enable gene patent owners to bar others from entering into a specific gene diagnostic market by refusing to license their patented gene sequences, an input that is necessary to compete within that market.¹⁹ Consequently, entities that own the patent rights on disease-specific gene sequences can exercise complete control over the gene diagnostic market. The well-publicized controversy of Myriad Genetics (Myriad) and its unilateral refusal to license its patents on the breast and ovarian cancer genetic markers (i.e., the *BRCA* genes) epitomizes this exact trend.

In 2009, over 240,000 American women were diagnosed with either invasive or noninvasive breast cancer, making it the most prevalent cancer diagnosis in women.²⁰ The American Cancer Society reported that more than 21,000 women were diagnosed with ovarian cancer within the same year, accounting for three percent of all cancers among women.²¹ Mutations in the breast cancer susceptibility genes (*BRCA1* and *BRCA2*) account for five to ten percent of all breast cancers.²² *BRCA*-positive women are also nine to thirty-five times more likely to develop ovarian cancer.²³ Disease-causing *BRCA* mutations can be identified through genetic testing, which allows for early detection and treatment of ovarian and breast cancer. Genetic test results thus play a significant role in guiding medical decision making with respect to treatment options including

Biomedical Research, 280 SCI. 698, 700 (1998) (“[T]he lack of substitutes for certain biomedical discoveries (such as patented genes or receptors) may increase the leverage of some patent holders Rivals may not be able to invent around patents in research aimed at understanding the genetic bases of diseases as they occur in nature.”).

16. *Id.*

17. See Lorelei Perez Westin, Note, *Genetic Patents: Gatekeeper to the Promised Cures*, 25 T. JEFFERSON L. REV. 271, 273–74, 280–81 (2002).

18. See Andrews, *Gene Patent Dilemma*, *supra* note 12, at 89–91.

19. See *id.*; see also Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 3–8 (2003).

20. *Cancer Facts and Figures 2009*, AM. CANCER SOC’Y 9 (2009), <http://www.cancer.org/acs/groups/content/@nho/documents/document/500809webpdf.pdf>.

21. *Id.* at 16.

22. *Breast Cancer Facts and Figures 2009–2010*, AM. CANCER SOC’Y 11 (2009), <http://www.cancer.org/acs/groups/content/@nho/documents/document/f861009final90809pdf.pdf>.

23. 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 with Colon Cancers*, 12 GENETICS MED. S15, S19 (2010).

chemoprevention and prophylactic surgery,²⁴ both of which result in gains in patient life expectancy.²⁵ Although technological advancements have facilitated the early detection of breast and ovarian cancer via genetic screening, improvements in *BRCA* diagnostic testing have been stymied by the conduct of a single company.

Myriad, a molecular diagnostic company based in Salt Lake City, is currently the sole provider of genetic tests that diagnose ovarian and breast cancers.²⁶ Myriad owns patents on its genetic testing methods²⁷ and on naturally occurring *BRCA* gene sequences²⁸ that have been isolated from human cells. The patents on the *BRCA* gene sequences effectively preclude the exploitation of gene-based technologies in diagnosing and treating both breast and ovarian cancers because exclusive ownership of a gene sequence essentially means that the patentee “own[s] the exclusive rights to that genetic sequence, its usage, and its chemical composition.”²⁹ Myriad strategically used the bottleneck effect of its gene patents to deter both commercial and noncommercial³⁰ laboratories from (1) conducting any existing form of *BRCA* testing³¹ and (2) developing new *BRCA* genetic tests for clinical use.³²

From a patent law perspective, the *BRCA* gene patents remain impervious to attacks because existing gene patents satisfy all the statutory requirements of patentability and their scope cannot be narrowed under existing patent law doctrines.³³ Although the Myriad controversy culminated in an extensive legal

24. These surgical categories consist of invasive and irreversible measures such as mastectomy, oophorectomy, or tubal ligation.

25. Cook-Deegan et al., *supra* note 23, at S15.

26. The U.S. patent rights to the *BRCA* gene sequences were originally split between Myriad and OncorMed, a rival diagnostic company. Myriad acquired full control over the *BRCA* gene patents after waging a protracted legal battle against OncorMed. *Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 206 (S.D.N.Y. 2010); SHOBITA PARTHASARATHY, *BUILDING GENETIC MEDICINE* 115–20 (2007); Bryn Williams-Jones, *History of a Gene Patent*, 10 *HEALTH L.J.* 123, 131–33 (2002).

27. U.S. Patent No. 6,033,857 (filed Mar. 20, 1998); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995).

28. U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,693,473 (filed June 7, 1995).

29. Lamis G. Eli, Case Note, *When Myriad Genetics Prohibited a Myriad of Options*: Association for Molecular Pathology v. USPTO, 21 *DEPAUL J. ART TECH. INTELL. PROP. L.* 357, 364 (2011).

30. Two professors at the University of Pennsylvania designed tests to screen for *BRCA* mutations in their lab and provided screening to approximately five hundred patients per year starting in 1996. The faculty members ceased their *BRCA* testing efforts in response to Myriad's cease-and-desist letters. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 187.

31. This was true even if the genetic testing protocols differed significantly from Myriad's own patented testing methods. *Id.* at 204–05; see also PARTHASARATHY, *supra* note 26, at 115–20.

32. See Cho et al., *supra* note 19, at 3–8.

33. The existing patents on gene sequences that are inputs to gene diagnostic testing and gene therapy fulfill the novelty, non-obviousness, utility, and disclosure requirements. See, e.g., *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed. Cir. 2003) (affirming the patentability of

battle that challenged the patent eligibility of man-made *BRC A* gene sequences, the status quo of the *BRC A* gene patents ultimately remains unaffected.³⁴ In 2011, the Federal Circuit in *Ass'n for Molecular Pathology v. USPTO* affirmatively held that any gene sequence that had been isolated from natural sources via human intervention constituted patentable subject matter under section 101 of the Patent Act.³⁵ A year later, the U.S. Supreme Court vacated the Federal Circuit's decision and instructed³⁶ the Federal Circuit to reconsider the dispute in light of its recent holding in *Mayo*,³⁷ where the Court established heightened restrictions on the patent-eligibility of processes or methodologies that exploit natural biological correlations. As a result, there was considerable speculation as to whether the *Mayo* limitations would extend to compositions of matter like isolated gene sequences. On remand, the Federal Circuit once again upheld the validity of the

erythropoietin gene sequences); *In re Deuel*, 51 F.3d 1552, 1560 (Fed. Cir. 1995) (affirming the patentability of Heparin-Binding Growth Factor gene sequences); *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993) (affirming the patentability of Insulin-like Growth Factor gene sequences). These claimed gene sequences satisfy the novelty and non-obviousness requirements because they predate the release of the Human Genome project and would not have been obvious to a person having ordinary skill in the art at the time of the invention. Gene identification was an extremely difficult feat in the 1990's because gene-cloning technology was still at its nascent stage. In fact, it was not uncommon for researchers to spend anywhere from three to seven years to identify a particular gene sequence. See WATSON, *supra* note 8, at 303–06; see also LEWIS, *supra* note 8, at 434; STRACHAN & READ, *supra* note 8, at 499. Existing gene patents also satisfy the heightened “specific” and “substantial” utility standards under *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005), and comply with the very high disclosure standard because the patent applications contain the actual sequence information of the claimed genes. *Regents of Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1567 (Fed. Cir. 1997) (“No sequence information indicating which nucleotides constitute human cDNA appears in the patent . . . [T]he specification does not provide a written description of the invention. . . .”); *Fiers v. Revel*, 984 F.2d 1164, 1170–71 (Fed. Cir. 1993) (“An adequate written description of a DNA requires more than a mere statement that it is part of the invention . . . ; what is required is a description of the DNA itself.”); see also Dan L. Burk, *Tailoring Patent Policy to Specific Industries*, 7 MARQ. INTELL. PROP. L. REV. 1, 13 (2003) (“You must give us the DNA sequence if you want to claim a DNA sequence. You can't [just] tell us the function . . . [or] how to get that DNA sequence, even if you have really an assurance that method will work you've got to give us the structure.”). These high disclosure standards also provide assurance that courts will continue to construe gene sequence claims broadly, thereby diminishing a competitor's chance of escaping infringement during litigation. Finally, the reverse doctrine of equivalents, a judicially created doctrine that theoretically narrows the scope of a patent, cannot successfully narrow the scope of gene patents given the Federal Circuit's decision in *Amgen*. 314 F.3d at 1351 (holding that the unlicensed use of patented gene sequences does not qualify for a defense based on the reverse doctrine of equivalents). The reverse doctrine of equivalents was initially espoused in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608–09 (1950), which stated that the reverse doctrine of equivalents shields an accused infringer from liability where the allegedly infringing device, although literally falling within the scope of the patent, “is so far changed in principle from the patented article that it performs the same or similar function in a substantially different way” (emphasis added).

34. See *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1325 (Fed. Cir. 2012).

35. *Ass'n for Molecular Pathology v. USPTO*, 653 F.3d 1329, 1329 (Fed. Cir. 2011).

36. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 80 U.S.L.W. 3380 (Mar. 26, 2012).

37. *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 80 U.S.L.W. 4225 (Mar. 20, 2012).

BRCA gene patents, explaining that “[w]hile *Mayo* and earlier decisions concerning method claim patentability provide valuable insights and illuminate broad, foundational principles, the Supreme Court’s decision[] in *Chakrabarty* . . . set[s] out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules.”³⁸ In *Chakrabarty*, the Court held that genetically modified bacteria qualified as patent-eligible subject matter because these man-made compositions had “markedly different characteristics” from their natural counterparts.³⁹ Applying this test, the Federal Circuit found that isolated gene sequences were patent eligible under section 101 because their distinctive chemical structure and properties were “markedly different” from naturally occurring gene sequences in living cells.⁴⁰ Thus, it appears that patent law in its current state is unlikely to curb the detrimental effects of broad gene patents.

Perhaps, a more effective solution to the gene patent dilemma lies in antitrust law, which aims to promote innovation and maximize consumer welfare by proscribing the effects of monopoly power. Some scholars have suggested that antitrust law may play a role in alleviating the bottleneck effect of biotech patents.⁴¹ Using the Myriad controversy as a test case, this study analyzes whether a patent holder’s unilateral refusal to license its gene patents can give rise to antitrust liability under section 2 of the Sherman Act. Here, I apply two antitrust doctrines—“essential facilities” and “refusal to deal”—and conclude that Myriad’s unilateral refusals to license its *BRCA* gene patents do indeed violate section 2 of the Sherman Act. The Myriad controversy is an excellent illustration of a situation where a duty to deal should be imposed on the patent holder. Applying these antitrust doctrines to gene patents mediates the tension between providing adequate incentives for genetic research and circumventing the problems associated with patenting these indispensable resources. Part I of this study explains how broad upstream gene patents can impede downstream innovation and stifle market competition. Part II explains how the bottleneck effect of the *BRCA* gene patents can be significantly mitigated by the application of the essential facilities doctrine and the refusal to deal doctrine in antitrust law. Part III briefly describes how antitrust law may provide plaintiffs with much needed injunctive relief in the form of compulsory licensing.

38. *Ass’n for Molecular Pathology*, 689 F.3d at 1326 (citation omitted).

39. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

40. *Ass’n for Molecular Pathology*, 689 F.3d at 1328–30.

41. Amy Rachel Davis, Note, *Patented Embryonic Stem Cells: The Quintessential “Essential Facility”?*, 94 GEO. L.J. 205 *passim* (2005); Westin, *supra* note 17, at 271, 281–97; see, e.g., John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449, 450 (1997) (“[P]revious work has generally emphasized intellectual property issues; yet, there are parallel and related antitrust issues.”); Sandeep Vaheesan, *Reviving an Epithet: A New Way Forward for the Essential Facilities Doctrine*, 3 UTAH L. REV. 1, 38–40 (2010) (contending that essential facilities doctrine should be applied to a small segment of intangible assets including gene sequences that have acquired de facto natural monopoly status).

I. UPSTREAM GENE PATENTS: AN IMPEDIMENT TO DOWNSTREAM INNOVATION AND MARKET COMPETITION

Advances in DNA sequencing technology and the completion of the Human Genome Project have revolutionized patient care by bringing many promising clinical applications to fruition.⁴² Such breakthroughs include gene-based technologies such as gene therapy, genetic testing, and personalized medicine, all of which harness the genetic information conveyed in a patient's gene sequences. The number of gene patents grew exponentially in the 1990s⁴³ after the landmark case *Diamond v. Chakerabarty*,⁴⁴ in which the Supreme Court upheld the patentability of genetically engineered living organisms for the first time. Gene patents pervade the diagnostic, therapeutic, and biomedical innovation markets within the United States and are regarded as the "gatekeeper patents" because they constitute an indispensable input for every single gene-based technology.⁴⁵ The scope of gene patents is extremely broad because the patent holder claims *the isolated gene sequence as its invention*. Thus, the patent owner's rights are not restricted to the product that is generated by the method or process disclosed in the patent application. This is in stark contrast to the vast majority of patents where the actual market power of the patent owners is not as significant. For most patents, the prevailing property regime is not problematic because of the availability of non-infringing, functionally equivalent substitutes.⁴⁶ So even though the intellectual property (IP) owner has an exclusive property right over a specific invention, it does not possess significant market power, because many other functional equivalents may compete in the relevant market.⁴⁷

The broad scope of gene patents and the absence of non-infringing substitutes for gene sequences allow patent holders to control every existing and potential application of their patented sequences. This excessive concentration of power in the hands of the upstream gene patent owner can adversely affect market competition, patient care, and innovation.⁴⁸ Specifically, patent owners have the

42. LEWIS, *supra* note 8, at 377–95, 397–416, 426–27, 433–46; STRACHAN & READ, *supra* note 8, at 497–716; WATSON, *supra* note 8.

43. Martin Enserink, *Patent Office May Raise the Bar on Gene Claims*, 287 SCIENCE 1196, 1196 (2000); Tom Hollon, *Gene Patent Revisions to Remove Some Controversies*, 6 NATURE MED. 362, 362 (2000).

44. *Chakerabarty*, 447 U.S. at 310.

45. See Brian A. Jackson, *Innovation and Intellectual Property: The Case of Genomic Patenting*, 22 J. POL'Y ANALYSIS & MGMT. 5, 11–12 (2003); Westin, *supra* note 17, at 280–81.

46. See *Ill. Tool Works, Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42–43 (2006).

47. Rochelle Dreyfuss, *Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface*, in EUROPEAN COMPETITION LAW ANNUAL 2005: THE INTERACTION BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY LAW 199, 200 (Claus-Dieter Ehlerman & Isabela Atanasiu eds., 2005).

48. See Richard Li-dar Wang, *Biomedical Upstream Patenting and Scientific Research*, 10 YALE J. L. & TECH. 251, 251–88 (2008); see also Andrews, *Gene Patent Dilemma*, *supra* note 12, at 89–91; Arti K. Rai,

right to (a) preclude the use of their relevant gene for diagnostic or therapeutic purposes, (b) prevent a physician from testing or disclosing test results for a disease-associated mutation, and (c) block improvements to existing diagnostic tests or therapy.⁴⁹ The *BRC A* gene patent controversy provides a vivid illustration of how a dominant firm's refusal to license its gene patents can result in each of these disconcerting effects. First, Myriad barred other clinical diagnostic labs from conducting any form of *BRC A* testing, even if the other labs were using completely different (and sometimes more accurate) methods⁵⁰ of genetic testing that Myriad was not conducting at the time.⁵¹ Second, Myriad prevented clinicians from telling "patients involved in research the results of their [*BRC A*] testing, leading physicians involved in breast cancer care and research unable to meet their ethical obligations to provide genetic test results to research subjects, when requested."⁵² Third, Myriad continues to use an expensive suboptimal gene testing method when cheaper and more effective *BRC A* genetic testing alternatives exist in Europe.⁵³

Overall, it appears that Myriad's refusal to license its *BRC A* gene patents results in anticompetitive effects in the gene diagnostic market for breast and ovarian cancers. First, static efficiency is impaired because consumers pay higher prices than they would in a competitive market.⁵⁴ Second, the dynamic efficiency in the gene diagnostic market for breast and ovarian cancers is also impaired because (1) Myriad is not developing and marketing more comprehensive and cost-effective versions of *BRC A* genetic testing, (2) Myriad precludes others from developing novel or improved testing methods by refusing to license the *BRC A* gene patents, and (3) Myriad continues to use mediocre genetic testing methods which are lower quality when compared to similar genetic testing services in Europe.⁵⁵

Although Myriad's questionable conduct exemplifies how gene patent owners can abuse their IP rights to hinder innovation and market competition in the biomedical field, *the categorical ban of all gene patents is not the optimal solution* to the

Fostering Cumulative Innovation in the Biopharmaceutical Industry, 16 BERKELEY TECH. L.J. 813, 831–38 (2001).

49. See Andrews, *Genes and Patent Policy*, *supra* note 12, at 803–08.

50. Myriad's standard test originally consisted of full sequencing of the *BRC A* genes. Full sequencing of an entire gene can miss large rearrangements and thus yield false negatives. Other labs had developed tests that were more effective in detecting these large rearrangements. *Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 199, 203 (S.D.N.Y. 2010).

51. *Id.* at 205 ("In 2005, Dr. Matloff sought permission from Myriad for the Yale DNA Diagnostics Lab to conduct screening for mutations caused by large rearrangements, which Myriad was not conducting at the time. Her request was denied.")

52. *Id.* at 209. See PARTHASARATHY, *supra* note 26, at 119.

53. See *infra* notes 124–26.

54. See PARTHASARATHY, *supra* note 26, at 93–95; Cook-Deegan et al., *supra* note 23, at S16–S17.

55. See *infra* notes 124–26.

gene patent dilemma. This is because gene patents provide inventors with incentives to develop new products that exploit naturally occurring gene sequences in a way that either improves the existing properties of a gene sequence or bestows novel therapeutic properties. In other words, gene patents incentivize firms specializing in gene-based technologies to compete vigorously by developing (a) many tailor-made genetic products that combat specific diseases and (b) gene therapeutics that simultaneously combat multiple symptoms or multiple diseases.⁵⁶ Without patent protection, innovators may feel compelled to maintain their socially valuable genetic inventions as trade secrets in order to prevent others from free riding on their efforts. Such an outcome is unacceptable in the biotech field where technological advancements depend heavily on both the incentive-to-invest and incentive-to-disclose aspects of the patent system.⁵⁷ Thus, despite the problems caused by existing gene patents, as indicated by the Myriad controversy, the abolition of *all* gene patents would be unwise given the potential for gene-based inventions in enhancing public health. Instead the proper resolution to the gene patent dilemma lies in optimally balancing the interests of individual inventors with the needs of the biomedical community and the general public. This balance can be achieved by providing legal remedies under antitrust law to parties seeking access to essential patented gene sequences.

II. ANTITRUST LAW: A SOLUTION TO THE GENE PATENT DILEMMA

Section 2 of the Sherman Act condemns the illegal acquisition of monopoly power by a dominant firm through unilateral conduct.⁵⁸ A firm's unilateral conduct rises to the level of monopolization under section 2 only if it satisfies the two-element test set forth in *Grinnell*: (1) the firm must possess monopoly power in the relevant market, and (2) the firm willfully acquired and maintained its

56. See, e.g., Albert M. Maguire et al., *Safety and Efficacy of Gene Transfer for Leber's Congenital Amaurosis*, 358 NEW ENG. J. MED. 2240, 2240–48 (2008) (describing the treatment of an inherited blinding disease using a recombinant gene containing adeno-associated virus DNA and human RPE65 DNA); David L. Porter et al., *Chimeric Antigen Receptor-Modified T Cells in Chronic Lymphoid Leukemia*, 365 NEW ENG. J. MED. 725, 725–33 (2011) (describing how researchers designed a new gene that can be inserted into T cells to trick them into attacking cancerous B cells, the cause of chronic lymphocytic leukemia); Jocelyn Kaiser, *Gene Therapy Halts Brain Disease in Two Boys*, SCIENCE NOW (Nov. 5, 2009, 12:00 AM), <http://news.sciencemag.org/sciencenow/2009/11/05-01.html>.

57. See David C. Hoffman, Note, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1022 (2004) (“For many [biotech] companies, a patent portfolio is the only potentially lucrative asset available for exploitation. These companies rely upon patent licensing revenues for much of their operating capital until they can develop a steady revenue stream. Thus, by granting expansive patent protection to biotechnological inventions, the government arguably subsidizes the biotechnology industry.”).

58. 15 U.S.C. § 2 (2006) (“Every person who shall monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony.”).

monopoly power by engaging in predatory or anticompetitive conduct.⁵⁹ Possession of monopoly power is not sufficient because a firm may legally acquire a monopoly through competition on the merits such as selling a superior product that is protected by patent rights. Patent owners, however, are not immune to antitrust liability just because they have legally acquired a monopoly through their patented inventions. Courts have held that patentees cannot use their exclusive rights to gain a monopoly in a market that is *beyond the scope of the patent*.⁶⁰ An excellent example of this concept are tying arrangements—where a firm leverages its power in the market for a patented product (the tying market) to impair competition in a complementary market (the tied market) by effectively coercing buyers of the tying product to also buy the tied product from the firm at supracompetitive prices, regardless of the buyer's preference.⁶¹

Monopoly leveraging⁶² is linked to unilateral refusals to deal in some situations and may rise to the level of exclusionary conduct that is subject to antitrust liability under section 2 of the Sherman Act.⁶³ Although unilateral

59. United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

60. *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000) (condemning tying arrangements involving patented products because “the patent holder cannot use his statutory right to refuse to sell patented parts to gain a monopoly in a market beyond the scope of the patent”); *see also* Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990) (“[A] patent owner may not take the property right granted by a patent and use it to extend his power in the marketplace improperly, i.e. beyond the limits of what Congress intended to give in the patent laws.”).

61. Tying arrangements may be illegal under either section 1 of the Sherman Act or section 3 of the Clayton Act if:

(1) there are two separate products, a “tying” product and a “tied” product; (2) that those products are in fact “tied” together—that is, the buyer was forced to buy the tied product to get the tying product; (3) that the seller possesses sufficient economic power in the tying product market to coerce buyer acceptance of the tied product; and (4) involvement of a “not insubstantial” amount of interstate commerce in the market of the tied product.

Technical Resource Serv. v. Dornier Med. Sys., 134 F.3d 1458, 1464 (11th Cir. 1998) (citing *Tic-X-Press, Inc. v. Omni Promotions Co.*, 815 F.2d 1407, 1414 (11th Cir. 1987)). For tying arrangements involving patented products see *Int'l Salt Co. v. United States*, 332 U.S. 392, 397–98 (1947); *Morton Salt Co. v. G. S. Suppiger Co.*, 314 U.S. 488, 491 (1942).

62. The term “monopoly leveraging” has two separate definitions in the context of antitrust law. On one hand, a firm that is a monopolist in one market has engaged in monopoly leveraging when it uses its power to gain an unmerited competitive advantage in a second market. Christopher R. Leslie, *Cutting Through Tying Theory with Occam's Razor: A Simple Explanation of Tying Arrangements*, 78 TUL. L. REV. 727, 732 (2004). Alternatively, monopoly leveraging can refer to situations where a firm exploits its dominant position in one relevant market to eliminate competition and illegally expand its monopoly power in a related downstream or parallel market. *Eastman Kodak v. Image Technical Servs.*, 504 U.S. 451, 480 n.29 (1992) (“[P]ower gained through some natural and legal advantage such as a patent . . . can give rise to liability if ‘a seller exploits his dominant position in one market to expand his empire into the next.’”) (quoting *Times-Picayune Publishing Co. v. United States*, 345 U.S. 594, 611 (1953)); Louis Kaplow, *Extension of Monopoly Power Through Leverage*, 85 COLUM. L. REV. 515, 516–17 (1985). For the purposes of this Note, the term monopoly leveraging refers to the latter definition.

63. Marina Lao, *Unilateral Refusals to Sell or License Intellectual Property and the Antitrust Duty to Deal*, 9 CORNELL J.L. & PUB. POLY 193, 195 (1999). A principal issue in monopoly leveraging cases is defining the two relevant markets. In other words, there would be no monopoly leveraging if the

refusals to deal do not typically involve coercion, they can sometimes achieve the same damaging effects on market competition as tying arrangements.⁶⁴ A dominant firm in a primary market can effectively diminish competition in a downstream or complementary market by denying competitors in that market access to its primary product, which “essentially forces buyers of the primary product to also buy . . . the complementary product [from the firm] because the lack of competition in the complementary market leaves buyers with no other choice.”⁶⁵

Myriad satisfies the first prong of the *Grinnell* test because it possesses monopoly power in the gene diagnostic market for breast and ovarian cancers. Monopoly power, also known as market power, is “the power to control prices or exclude competition”⁶⁶ and can be proven by either direct or circumstantial evidence.⁶⁷ An antitrust plaintiff must define the relevant market, show that the defendant owns a dominant share of that market, and show that there are significant barriers to market entry and barriers to expansion in order to demonstrate market power circumstantially.⁶⁸ The relevant market in the present case is the gene diagnostic market for breast and ovarian cancers in the United States. This market completely belongs to Myriad because (1) the *BRCA* genes, thus far, are the only well-established genetic markers for assessing predisposition toward breast and ovarian cancers within the medical community;⁶⁹ (2) Myriad owns the patents on the *BRCA* genes; and (3) Myriad does not license its *BRCA* genes to competing diagnostic labs, allowing it to remain the sole provider of *BRCA* testing. The product market should not be expanded to include the entire

alleged primary and secondary markets constitute a single integrated market. See *infra* Part II.A.5 for an explanation of why gene sequences and the gene diagnostic services are distinct antitrust markets.

64. Lao, *supra* note 63, at 196.

65. *Id.*

66. United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956).

67. Rebel Oil Co. v. Atl. Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995).

68. *Id.*

69. Mutations in *BRC A1* and *BRC A2* account for five to ten percent of all breast cancers. *Breast Cancer Facts and Figures 2009–2010*, *supra* note 22, at 11. *BRC A*-positive women are also nine to thirty five times more likely to develop ovarian cancer. Cook-Deegan et al., *supra* note 23, at S19. Researchers have recently identified new genetic markers linked to breast and ovarian cancers, but the risk factor conferred by some of these markers appears to be much lower compared to mutations in the *BRC A* genes. Bert Gold et al., *Genome-Wide Association Study Provides Evidence for a Breast Cancer Risk Locus at 6q22.33*, 105 PROC. NAT'L ACAD. SCI. 4340 (2008); Memorial Sloan-Kettering Cancer Ctr., *New Genetic Marker for Breast Cancer Identified*, SCIENCE DAILY (Mar. 4, 2008), <http://www.sciencedaily.com/releases/2008/03/080303190610.htm> (“[T]he risk associated with [the 6q22.33] genetic marker is much lower than that of *BRC A* genetic mutations . . .”). Alternatively, the risk factor conferred by the new genetic markers is dependent on the risk associated with the *BRC A* genes. Antonis C. Antoniou et al., *Common Variants at 12p11, 12q24, 9p21, 9q31.2 and in ZNF365 are Associated with Breast Cancer Risk for BRC A1 and/or BRC A2 Mutation Carriers*, 14 BREAST CANCER RES. R33-1, R33-5–R33-12 (2012); Fergus J. Couch et al., *Common Variants at the 19p13.1 and ZNF365 Loci are Associated with ER Subtypes of Breast Cancer and Ovarian Cancer Risk in BRC A1 and BRC A2 Mutation Carriers*, 21 CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION 645, 645–57 (2012).

gene diagnostic market because each gene possesses unique biological properties and is not functionally interchangeable with another gene. Specifically, different genes perform different physiological roles within a living organism and mutations in different genes can result in different pathologies. Since individual genes cannot substitute for each other, the product market should be confined to the gene diagnostic market for breast and ovarian cancers. In *United States v. Aluminum Co. of America*, the court held that ninety percent of the market constituted monopoly power.⁷⁰ Myriad is the sole provider of gene diagnostic tests for breast and ovarian cancers in the United States and thus possesses one hundred percent of the market share. Other firms are unable to compete in the gene diagnostic market for breast and ovarian cancers because Myriad's *BRCA* patents operate as absolute barriers to entry. No other party can compete in the relevant market unless they have permission to use the patented *BRCA* gene sequences. Because of its status as the upstream gene patent holder, Myriad has the ability to increase the price of *BRCA* testing services without consumers switching to a substitute product. Therefore, Myriad possesses the requisite monopoly power in the *BRCA* gene sequence market⁷¹ and the gene diagnostic market for breast and ovarian cancers in the United States.

The second prong of the *Grinnell* test is concerned with whether Myriad's unilateral refusal to license its patents on the *BRCA* gene sequences constitutes monopoly conduct under section 2 of the Sherman Act. A unilateral refusal to license may constitute monopoly conduct if the monopolist's asset serves as a necessary input (i.e., an essential facility) in a downstream or complementary market.⁷² An essential facilities claim thus focuses on the monopolist's *status as the owner of an essential facility*. Alternatively, a unilateral refusal to license may give rise to antitrust liability under section 2 if the refusal helped the monopolist to acquire or maintain market power by foreclosing competition.⁷³ The latter approach is generally referred to as a refusal to deal claim and is narrower than an essential facilities claim because it focuses on whether the monopolist engaged in exclusionary *conduct* that contributes to monopolization.⁷⁴ The following illustrates how Myriad's unilateral refusals to license its *BRCA* gene patents can be characterized as anticompetitive through the application of (a) the essential facilities doctrine and (b) the general refusal to deal doctrine.

70. *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 429 (2d Cir. 1945).

71. *See infra* Part II.A.1.

72. *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 542 (9th Cir. 1991).

73. *Eastman Kodak v. Image Technical Servs.*, 504 U.S. 451, 482–83 (1992); *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956).

74. 1 HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 13.3d (2d ed. 2012).

A. Essential Facilities Doctrine Offers a Well-Tailored Solution for Imposing Antitrust Liability on Gene Patent Holders who own an Essential Input for Competition in Downstream Gene Diagnostic Markets

Essential facilities doctrine (EFD) is one possible antitrust approach that addresses the anticompetitive effects of unilateral refusals to license an IP right. This doctrine is unique because the *monopolist's status as the owner of an essential facility* rather than any *affirmative conduct* determines antitrust liability.⁷⁵ EFD imposes antitrust liability when a monopolist that controls an essential facility for competition denies reasonable access to a product or service that other firms must obtain to compete with the first in a downstream or related market.⁷⁶ The canonical EFD fact pattern involves a vertically integrated company that has exclusive control over some facility, and leverages that control to gain an advantage over competitors in a downstream or complementary market.⁷⁷ EFD appears to be a well-tailored solution for compelling an upstream patent holder to provide access to gene sequences that are essential to competition in multiple downstream markets that exploit genetic information such as diagnostics, therapeutics, and innovation.⁷⁸ With respect to the gene diagnostic markets for breast and ovarian cancers in the United States, Myriad controls an essential facility in the form of the *BRC A* gene patents. Myriad has denied reasonable access to the facility by refusing to license the gene sequences to competing downstream researchers in the gene diagnostic markets, thus depriving these competitors of an input that is absolutely necessary to compete in the gene diagnostic market for breast and ovarian cancers.

The legal principles underlying EFD are rooted in the Supreme Court's decisions in *Terminal Railroad Ass'n* and *Otter Tail Power Co.*⁷⁹ In *Terminal Railroad*, a group of terminal companies who jointly owned the only existing railroad bridge into or out of St. Louis refused to give competing railroads access to the

75. *Id.* § 13.3c.

76. *Alaska Airlines, Inc.*, 948 F.2d at 542.

77. *See, e.g., Otter Tail Power Co. v. United States*, 410 U.S. 366, 377–79 (1973); *United States v. Terminal R.R. Ass'n of St. Louis*, 224 U.S. 383, 393–99 (1912); *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1132–33 (7th Cir. 1983).

78. The application of EFD to patentable gene sequences is not far fetched especially since another study advocated for the application of EFD to make patented embryonic stem cells accessible for the development of downstream innovation markets. Davis, *supra* note 41. The argument is more compelling in the case of gene sequences because unlike embryonic stem cells, gene patents are (1) not nonexclusively licensed and (2) create a larger bottleneck effect because gene sequences have applications in the diagnostic, therapeutic, and innovation markets.

79. There is some debate over whether EFD provided the basis for these decisions. The Supreme Court has asserted that it has never explicitly recognized the doctrine. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 410–11 (2004). However, the EFD literature seems to suggest that the underlying principles of essential facilities were alluded to in these decisions. *See, e.g., Robert Pitofsky et al., The Essential Facilities Doctrine Under U.S. Antitrust Law*, 70 ANTITRUST L.J. 443, 445–48 (2002) (discussing the *Terminal Railroad*, *Otter Tail*, and *Aspen Skiing* cases).

facilities.⁸⁰ The Court held that such a refusal constitutes a violation under section 1 of the Sherman Act because of the *essential nature* of the single railroad bridge to the operations of all railroads in the St. Louis area.⁸¹ Although scholars point to *Terminal Railroad* as the original ancestor of EFD, the doctrine truly began to take shape in the Supreme Court's ruling in *Otter Tail Power Co. v. United States*. In *Otter Tail*, a public utility company that owned all the transmission lines into several municipalities refused to either sell electricity wholesale or wheel (i.e., carry) electricity purchased from another supplier over its lines because it wanted to keep itself in the local distribution business.⁸² The Court upheld the lower court's finding of section 2 liability because of the defendant's strategic dominance over the transmission lines in its service areas and its use of "this dominance to foreclose potential entrants into the retail area from obtaining electric power from outside sources of supply."⁸³

While the Supreme Court has only alluded to EFD as a basis for antitrust liability,⁸⁴ the vast majority of the circuit courts have expressly endorsed the essential facilities test articulated in *MCI Communications*.⁸⁵ To prevail on an

80. *Terminal R.R. Ass'n of St. Louis*, 224 U.S. at 393–94, 397–98.

81. *Id.* at 397. ("[I]t is, as a practical matter, impossible for any railroad company to pass through, or even enter St. Louis, so as to be within reach of its industries or commerce, without using the facilities entirely controlled by the terminal company. . . . The other companies use the terminal properties because it is not possible to acquire adequate facilities for themselves.") The Court found the joint owners of the bridge liable under section 1 of the Sherman Act since the companies created a "combination which is in restraint of trade." *See id.* at 394.

82. *Otter Tail Power Co.*, 410 U.S. at 378–79.

83. *Id.* at 377.

84. The Court's decision in *Otter Tail* unveils three principles that form the basis of the existing doctrine of essential facilities. *See Davis, supra* note 41, at 224. First, *Otter Tail* involves two separate markets—an upstream market, which consists of the essential facility itself, and a downstream market, which requires the essential facility as a critical input. Second, the owner of an essential facility may be subject to antitrust liability under section 2 of the Sherman Act only if it is feasible to allow downstream competitors to use an upstream facility. "There were no engineering factors that prevented Otter Tail from selling power at wholesale to those towns that wanted municipal plants or wheeling the power. . . . Otter Tail's refusals to sell at wholesale or to wheel were solely to prevent municipal power systems from eroding its monopolistic position." *Otter Tail*, 410 U.S. at 378. Third, the owner of an essential facility must have a legitimate business justification for denying access to the facility. *Id.* at 381 (explaining that there cannot be antitrust liability if compelling Otter Tail to provide or wheel wholesale power to its competitors "would impair (the utility's) ability to render adequate service to its [own] customers.") (quoting 16 U.S.C. § 824a (2006 & Supp. V 2011)) (internal punctuation omitted). These components foreshadow the Seventh Circuit's multi-element essential facilities test in *MCI Commc'ns v. Am. Tel. & Tel. Co.*, 708 F.2d 1081 (7th Cir. 1983).

85. *See* *Midwest Gas Servs., Inc. v. Ind. Gas Co.*, 317 F.3d 703, 713–14 (7th Cir. 2003); *Covad Commc'ns Co. v. BellSouth Corp.*, 299 F.3d 1272, 1285 (11th Cir. 2002); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1357 (Fed. Cir. 1999); *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1088 (D.C. Cir. 1998); *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 748 (3d Cir. 1996); *City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1380 (9th Cir. 1992); *Del. & Hudson Ry. Co. v. Consol. Rail Corp.*, 902 F.2d 174, 179 (2d Cir. 1990); *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150 (4th Cir. 1990); *City of Malden v. Union Elec.*

essential facilities antitrust claim, the plaintiff must satisfy the following four elements: “(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.”⁸⁶ Satisfaction of these elements would impose a duty “on firms controlling an essential facility . . . to make the facility available on non-discriminatory terms.”⁸⁷ Although not explicitly mentioned in *MCI*, courts also recognize the existence of a fifth phantom element that is necessary for finding an antitrust violation under EFD—the presence of two vertically related markets.⁸⁸ The following highlights why *BRCA* gene patents satisfy every element of the *MCI Communications* essential facilities test.

1. Myriad has Absolute Monopoly Power Over the BRCA Gene Sequences

The first element consists of two subparts: First, the input must be “essential” in the sense that competitors need access to it to compete, and second, the entity in control of the essential facility must be a monopolist. Courts have generally held that an input “that is controlled by a single firm will be considered ‘essential’ only if control of the [input] carries with it the power to eliminate competition in the downstream market.”⁸⁹ An input is not labeled as essential simply because of inconvenience or cost concerns.⁹⁰ Rather “denial of [an input

Co., 887 F.2d 157, 160 (8th Cir. 1989); *Aspen Highland Skiing Corp. v. Aspen Skiing Co.*, 738 F.2d 1509, 1520 (10th Cir. 1984).

86. *MCI Commc'ns Corp.*, 708 F.2d at 1132–33.

87. *Id.* at 1132.

88. *Id.* (explaining that refusing to share an essential facility is illegal “because a monopolist’s control of an essential facility . . . can extend monopoly power . . . from one market into another”); *Snake River Valley Elec. Ass’n v. PacifiCorp*, 357 F.3d 1042, 1044 n.2 (9th Cir. 2004) (“[E]ssential facilities doctrine applies to a competitor’s refusal to deal when the competitor has monopolistic control over an essential facility in one market and uses that monopoly power to leverage returns from different markets by refusing to share access to the essential facility.”); see 3B PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* ¶ 771a (3d ed. 2008); 1 HOVENKAMP ET AL., *supra* note 74, § 10.3c; Paul D. Marquardt & Mark Leddy, *The Essential Facilities Doctrine and Intellectual Property Rights: A Response to Pitofsky, Patterson, and Hooks*, 70 ANTITRUST L.J. 847, 850–55 (2003) (arguing that there is a two market requirement for proving an essential facilities claim).

89. *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 544 (9th Cir. 1991); see also *Paladin Assocs., Inc. v. Mont. Power Co.*, 328 F.3d 1145, 1163 (9th Cir. 2003) (invoking the *Alaska Airlines* test for essentiality); *Intergraph Corp.*, 195 F.3d at 1357 (same).

90. See, e.g., *Midwest Gas Servs., Inc.*, 317 F.3d at 714 (finding that a specific gas pipeline was not essential when other pipelines exist because “the most economical route is not an essential facility when other routes are available”); *S. Cal. Edison Co.*, 955 F.2d at 1381 (“[I]f the fact that [plaintiffs] could achieve savings at the expense of [the defendant] . . . is not enough to turn the [power lines] into an essential facility.”).

must inflict] a *severe handicap*” on potential competitors before an antitrust claim under EFD can be found.⁹¹

The *BRC A* gene patents are an essential input because it is *literally impossible* to compete in the downstream gene diagnostics market for breast and ovarian cancers without access to the *BRC A* gene sequences.⁹² Competitors would still be precluded from competing in the market for genetic testing of *BRC A* mutations even if economic resources were not a limiting factor. The present case closely resembles the situation in *Otter Tail* where competitors who wanted to service the retail electricity market within a municipality had no choice but to wheel their electric power over the transmission lines that were exclusively controlled by the defendant. *Otter Tail*’s refusal to wheel power generated by outside power plants over its lines constituted a denial of an essential facility because it practically eliminated competition in the downstream market for retail distribution of electricity. The present case is even more compelling because unlike *Otter Tail*, which was solely concerned with maintaining a competitive market for retail distribution in a single municipality, Myriad’s anticompetitive conduct would impair competition in multiple product markets throughout the United States. Myriad’s refusal to license its exclusive rights to make and use *BRC A* gene sequences completely forecloses competition in improving gene diagnostic tools not only for breast and ovarian cancers (where the *BRC A* gene sequences serve as an input),⁹³ but also other pathologies that the *BRC A* genes may be involved in.⁹⁴ The *BRC A* gene patents are an essential input because competitors need to obtain a license to use the gene sequences in order to compete in the downstream gene diagnostic market for breast and ovarian cancers.

Furthermore, Myriad, the sole patent holder of the *BRC A* gene patents, qualifies as a monopolist in the relevant upstream market for gene sequences under antitrust laws. The scope of Myriad’s composition of matter (i.e., product) patents is extremely broad because the patent claims cover both the complete

91. See *Twin Labs, Inc. v. Weider Health & Fitness*, 900 F.2d 566, 568 (2d Cir. 1990) (quoting *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 992 (D.C. Cir. 1977)).

92. *BRC A* gene patents can also have a detrimental effect on competition in innovation markets for *BRC A* research and gene therapy markets for diseases that are causally linked to the *BRC A* genes.

93. PARTHASARATHY, *supra* note 26, at 115–20; Cho et al., *supra* note 19, at 3–8; E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S40–42 (2010).

94. Luna Kadouri et al., Letter, *Cancer Risks in Carriers of the BRCA1/2 Ashkenazi Founder Mutations*, 44 J. MED. GENETICS 461, 467–71 (2007); Deborah Thompson et al., *Cancer Incidence in BRCA1 Mutation Carriers*, 94 J. NAT’L CANCER INST. 1358, 1358–65 (2002); Breast Cancer Linkage Consortium, *Cancer Risks in BRCA2 Mutation Carriers*, 91 J. NAT’L CANCER INST. 1310, 1310–16 (1999); see also *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT’L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/risk/brca> (last visited Nov. 9, 2011) (“Harmful *BRCA1* mutations may also increase a woman’s risk of developing cervical, uterine, pancreatic, and colon cancer. Harmful *BRCA2* mutations may additionally increase the risk of pancreatic cancer, stomach cancer, gallbladder and bile duct cancer, and melanoma.” (footnotes omitted)).

BRCA gene sequences as well as every possible partial DNA fragment within the *BRCA* genes.⁹⁵ As a result, no other entity can possess any market share for making, using, selling, offering to sell, or importing the *BRCA* gene sequences within the United States during the patent term. Myriad has exclusive control over the production and use of the *BRCA* genes, thus making it the only supplier of the *BRCA* gene sequences for every downstream medical application including diagnostics, therapeutics, and research.⁹⁶ Myriad's status in the market for *BRCA* gene sequences is distinguishable from the situation in *Snake River Valley Electric Ass'n v. Pacificorp*.⁹⁷ In *Snake River Valley Electric Ass'n*, the plaintiff claimed that the defendant's refusal to sell wholesale electricity constituted a violation under section 2 of the Sherman Act.⁹⁸ The court held that there was no antitrust liability for the defendant's refusal to deal because the defendant did not have a monopoly over wholesale energy transactions.⁹⁹ In fact, there was a "vigorous competitive market for wholesale [electric] power" which permitted the plaintiff to purchase the input from many other sellers.¹⁰⁰ Unlike the plaintiff in *Snake River*, downstream researchers and clinicians have no access to the *BRCA* gene sequences unless they secure a license from Myriad. Thus Myriad has an absolute monopoly over the upstream market for *BRCA* gene sequences, which are an essential input in the gene diagnostic market for breast and ovarian cancers.

2. *The BRCA Gene Sequences Cannot Be Duplicated Without Infringing Myriad's Gene Patents*

The second element of EFD requires that there must be an "inability practically or reasonably to duplicate the essential facility."¹⁰¹ Most courts have refused to find that an input is "unable to be duplicated" simply because it provides the most economical means for downstream competitors to conduct their own business.¹⁰² Instead this language has been construed to mean that only

95. U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,693,473 (filed June 7, 1995).

96. See Westin, *supra* note 17, at 273–74, 280–81.

97. *Snake River Valley Elec. Ass'n v. Pacificorp*, 357 F.3d 1042 (9th Cir. 2004).

98. *Id.* at 1044.

99. *Id.* at 1052.

100. *Id.*

101. *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1132 (7th Cir. 1983).

102. See, e.g., *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 544 (9th Cir. 1991) ("[A] plaintiff must show more than inconvenience, or even some economic loss; he must show that an alternative to the facility is not feasible."). It is interesting to note that there have been a few cases in the past where the input was deemed as "unable to be duplicated" even though a very large expenditure would have made such duplication possible. Compare *Del. & Hudson Ry. Co. v. Consol. Rail Corp.*, 902 F.2d 174, 179 (2d Cir. 1990) (finding short haul railroad tracks covering the east coast of the United States "unable to be duplicated" because "physical duplication of [defendant's] lines would be an impractical and unreasonable project to undertake") (quoting *Del. & Hudson Ry. Co. v. Consol. Rail Corp.*, 724 F. Supp. 1073, 1079 (N.D.N.Y. 1989), *rev'd*, 902 F.2d 174 (2d Cir. 1990)), with *Corsearch, Inc. v. Thomson & Thomson*, 792 F. Supp. 305, 332–33 (S.D.N.Y. 1992) (finding online

a literal inability will satisfy this element, making it a relatively high bar for antitrust plaintiffs to clear. For example, in *City of Malden v. Union Elec. Co.*, the plaintiff alleged that the defendant utility company's refusal to transmit power to the city under a favorable tariff gave rise to antitrust liability because the defendant's transmission line was the only practical means for the city to obtain outside power.¹⁰³ However, the court found that the defendant's transmission facilities were susceptible to duplication because there were at least five alternatives the plaintiff could have used to transmit the necessary power, albeit at greater expense. By contrast, the inability to duplicate the patented *BRCA* gene sequences is not a matter of economic feasibility. It is in fact impossible to duplicate the relevant gene sequences without infringing Myriad's composition of matter patents on the *BRCA* gene sequences.¹⁰⁴ Researchers would be barred from generating the *BRCA* gene sequences in their own laboratories regardless of the method used to produce them¹⁰⁵ or whether they play a minor or peripheral role in the operation of the new invention.¹⁰⁶ Researchers would be violating Myriad's patent rights even if they used a tiny fragment of the *BRCA* genes in their inventions. The patented *BRCA* gene sequences thus qualify as an input that is unable to be "practically or reasonably" duplicated.

3. Myriad Has Denied its Competitors in the Gene Diagnostic Market Access to the *BRCA* Gene Sequences

The third element of EFD consists of two subparts: First, the monopolist denies access to the essential input by either flatly refusing to deal with a party or offering to deal only on unreasonable terms,¹⁰⁷ and second, the party seeking

state trademark computer database "able to be duplicated" because plaintiff could have built its own database at an affordable price).

103. *City of Malden v. Union Elec. Co.*, 887 F.2d 157, 160–61 (8th Cir. 1989).

104. *See* U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,693,473 (filed June 7, 1995).

105. A well-established principle in patent law is that the broad scope of a product patent is not restricted by the disclosed method of production. *See, e.g.*, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003) (holding that the scope of Amgen's patent on the erythropoietin (epo) gene sequence was not restricted to the product that was a result of the method disclosed in the patent); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1390 (N.D. Cal. 1987) (holding that Scripps' product patent on human blood clotting protein factor VIII:C was infringed regardless of the method of production used).

106. *See* Westin, *supra* note 17, at 281. It is important to note that if the patent claims to the *BRCA* gene sequences only extended to those gene sequences isolated by the process disclosed in the patent and there were other options of duplicating the *BRCA* genes, the second element of the essential facilities analysis would not be satisfied.

107. *See Del. & Hudson Ry. Co.*, 902 F.2d at 179–80 ("[T]here need not be an outright refusal to deal in order to find that denial of an essential facility occurred. It is sufficient if the terms of the offer to deal are unreasonable."). The court in *Del. & Hudson Ry. Co.* explained that demanding an eight hundred percent rate increase for the same exact service that the defendant provided for the plaintiff in the past was unreasonable. *See id.* at 177.

access is, in fact, in competition with the monopolist in an identifiable market.¹⁰⁸ In other words, “there must be a market in which [the] plaintiff and [the] defendant compete, such that a monopolist extends its monopoly to the downstream market by refusing access to the facility it controls.”¹⁰⁹

Myriad has a monopoly in the upstream market for supplying access to the *BRCA* gene sequences because its gene patents grant the firm an exclusive right to make, use, and sell the *BRCA* gene sequences. Myriad’s potential consumers in this upstream market consist of entities involved in *BRCA* research and innovation, diagnostic medicine, and clinical therapeutics. This upstream technology market is distinct from the downstream genetic testing market where researchers are competing to (a) supply patients with information concerning their predisposition toward specific genetic disorders, (b) find ways to improve the overall quality of existing genetic testing services,¹¹⁰ and (c) design novel methods of diagnosing genetic disorders that were not previously possible due to technical hurdles.¹¹¹ Myriad also competes in this downstream gene diagnostic market.

In the present case, Myriad refuses to license its gene patents to other clinical labs that wish to conduct genetic tests for *BRCA* mutations, a downstream market in which Myriad competes.¹¹² This situation is distinguishable from the *Intergraph Corp. v. Intel Corp.* case where the court held that Intel’s refusal to license its patents and trade secrets did not amount to an antitrust violation.¹¹³ In *Intergraph Corp.*, a manufacturer of computer workstations sued Intel after Intel cut off its supply of microprocessors and proprietary information. Intergraph contended that access to Intel’s chips and trade secrets was essential to its business, and that Intel should be compelled to license its patents and trade secrets to Intergraph on reasonable and nondiscriminatory terms. The Federal Circuit reasoned that an essential facilities claim could not be made out from Intel’s refusal to supply Intergraph with its microprocessor technology because the parties did not compete in any downstream market.¹¹⁴ In contrast, rival gene diagnostic labs can

108. *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1088–89 (D.C. Cir. 1998) (holding that plaintiff failed to state an essential facilities claim because plaintiff could not establish that defendant was its competitor); see Pitofsky et al., *supra* note 79, at 461 (“The competitive relationship between the parties . . . is the touchstone of liability under the essential facilities doctrine.”).

109. *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1357 (Fed. Cir. 1999).

110. See LORI B. ANDREWS, *FUTURE PERFECT: CONFRONTING DECISIONS ABOUT GENETICS* 110–16 (2001).

111. These examples include pre-implantation genetic screening, a form of prenatal diagnosis that is used to identify embryos at risk for several genetic abnormalities and paraffin embedded tissue testing that is used when patients and families lack access to a relative’s blood but potentially have access to a deceased relative’s preserved paraffin-embedded tumor sample. See Cook-Deegan et al., *supra* note 23, at S16.

112. *Ass’n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 205, 207 (S.D.N.Y. 2010); see Cho et al., *supra* note 19, at 3–8; see also Gold & Carbone, *supra* note 93, at S41–42.

113. *Intergraph Corp.*, 195 F.3d at 1356–59.

114. *Id.* (explaining that Intergraph and Intel only shared a customer-supplier relationship and

satisfy the third element of EFD because (a) prior to 1997 they *competed* with Myriad in the downstream gene diagnostic market for *BRCA* testing,¹¹⁵ and (b) Myriad refuses to license the *BRCA* gene patents to its competitors on reasonable terms.

4. *Providing Access to the BRCA Gene Sequences Is Feasible*

The fourth element of EFD considers whether it is economically feasible for the controlling entity to provide access to the essential input.¹¹⁶ This element serves two purposes: (1) it limits the defendant's obligation to share a facility if doing so would be unfeasible,¹¹⁷ and (2) it offers a legitimate business justification defense which excuses facially anticompetitive conduct if the defendant can prove that its conduct is motivated by procompetitive concerns.¹¹⁸

Myriad cannot make a persuasive argument that providing access to the *BRCA* gene sequences would be unfeasible. Allowing other companies to use the *BRCA* genes to carry out their own genetic testing services would in no way diminish Myriad's ability to use the gene sequences for its own business operations. Most laboratories have the ability to synthesize or isolate the *BRCA* gene sequences on their own, using any samples and technical processes they deem appropriate. Thus, an infinite number of researchers could work with the relevant gene sequences at any given time without disrupting each other's activities.¹¹⁹ This situation is quite different from that described in *City of Anaheim v. Southern California Edison Co.*, where the plaintiff cities were arguing for guaranteed access to Edison's high-power transmission lines (the Pacific Intertie) that supplied hydroelectric power to Edison's control area. Edison shared access to the Pacific Intertie with certain other utilities and thus was only entitled to a

that a noncompetitor's asserted need for a manufacturer's business information does not convert the withholding of that information into an antitrust violation).

115. PARTHASARATHY, *supra* note 26, at 93–95, 115–19.

116. MCI Commc'ns Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1132 (7th Cir. 1983).

117. Covad Commc'ns Co. v. BellSouth Corp., 299 F.3d 1272, 1286 (11th Cir. 2002) (“[A]ntitrust laws have never required a monopolist to ‘cease using its own facility so that [a competitor] can begin using it.’”) (quoting *City of Vernon v. S. Cal. Edison Co.*, 955 F.2d 1361, 1366 (9th Cir. 1992)); *City of Malden v. Union Elec. Co.*, 887 F.2d 157, 163 (8th Cir. 1989) (providing access may be unfeasible where doing so would compel the current owner to provide access to the facility at a price below cost); *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 992–93 (D.C. Cir. 1977) (“[A]ntitrust laws do not require that an essential facility be shared if such sharing would be impractical or would inhibit [the owner's] ability to serve its customers adequately.”).

118. See *City of Vernon v. S. Cal. Edison Co.*, 955 F.2d 1361, 1367 (9th Cir. 1992) (holding that antitrust liability under EFD is excused if the monopolist has a legitimate business justification for its refusal to deal); *Oahu Gas Serv., Inc. v. Pacific Res., Inc.* 838 F.2d 360, 368–69 (9th Cir. 1988) (holding that “the desire to maintain market power—even a monopolist's market power—cannot create antitrust liability if there was a legitimate business justification for refusing to [behave in a certain manner]”).

119. In economic terms, the use of gene sequences is nonrivalrous. See N. GREGORY MANKIW, *PRINCIPLES OF ECONOMICS* 218–19 (6th ed. 2012).

certain portion of the lines' total capacity. Edison refused to grant the plaintiffs access on grounds that it expected to use its full capacity rights in the Intertie to supply electricity into its service area. The court held that there was no antitrust liability for the defendant's refusal to deal because it recognized that forcing the defendant to share its portion of a high-power transmission line would interfere with the defendant's ability to use its facility at full capacity so as to provide cheap power for its own customers.¹²⁰ Unlike the defendant in *City of Anaheim*, Myriad would neither have "to disable itself so that [its competitors]"¹²¹ can get access to the *BRCA* genes nor would licensing the gene patents prevent Myriad from providing high-quality genetic testing services to its own customers. Providing access to the *BRCA* gene patents is thus economically feasible for Myriad.

Myriad lacks any procompetitive legitimate business justification for unilaterally refusing to deal with competitors in the downstream gene diagnostic market. Myriad could potentially allege that its unilateral refusals to deal are linked to (a) fully reaping the benefits of its IP rights, (b) maintaining the quality of its genetic testing services for *BRCA* mutations, (c) maintaining the nature of its business, and (d) its desire to remain profitable in the gene diagnostic market for breast and ovarian cancers. The following will address why each of these proffered defenses lack merit.

One could argue that like the Federal Circuit's decision in *Xerox*,¹²² Myriad's refusal to license its patented product to competitors is based on a desire to profit from its IP rights and thus constitutes a legitimate business justification. In *Xerox*, a manufacturer of photocopiers refused to sell its patented replacement parts to independent service organizations (ISOs) that competed against the manufacturer in the downstream service market.¹²³ The court held that a patent owner's refusals to sell or license its patented invention are free from liability under antitrust laws because the patent owner has the statutory right to exclude others from practicing its claimed invention.¹²⁴ But Myriad's exclusive control over the *BRCA* gene sequences is distinguishable from the situation in *Xerox* because the anticompetitive effects of refusing to license gene patents are far greater than those caused by refusing to license patented mechanical parts. Despite the lack of access to patented parts, an ISO still has the ability to enter the photocopier service market, albeit at great expense, by manufacturing its own parts and machines. This reasoning does not apply to gene sequences, because unlike mechanical parts, there are no non-infringing substitutes for gene sequences.¹²⁵ In fact, tampering with the natural gene sequence can completely alter the desirable

120. *City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1381 (9th Cir. 1992).

121. *Id.*

122. *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000).

123. *Id.* at 1324.

124. *Id.* at 1327.

125. Heller & Eisenberg, *supra* note 15, at 700.

properties of the gene.¹²⁶ Thus, Myriad's justification that its conduct is motivated by its desire to maximally profit from its IP rights does not excuse the anticompetitive effects of its refusal to deal with competitors in the downstream gene diagnostic market.

Given the less-than-optimal quality of Myriad's genetic testing protocols over the past decade, the argument that Myriad's refusals to license the *BRCA* gene patents are tied to concerns over quality control is not persuasive. Myriad's *BRCA* testing protocols are unnecessarily expensive compared to the testing protocols in Europe that are just as effective or better.¹²⁷ Myriad has failed to implement these low-cost alternatives even though some of them have been around since 1995.¹²⁸ Furthermore, Myriad's testing methods are deficient because they miss between ten to twenty percent of the expected *BRCA* mutations.¹²⁹ This allegation was bolstered by the findings of a French physician who successfully identified a mutation in an American family that the Myriad test had missed.¹³⁰ Other patients were informed that they were positive for *BRCA* mutations when their test results were either normal or ambiguous.¹³¹ A court is thus likely to view this justification with a fair amount of skepticism.

Myriad could argue that providing access to the *BRCA* gene patents would cause it "to alter the nature of its business"¹³² or expand into areas it was not already in the business of pursuing to make the facility available.¹³³ In *Cavalier Telephone*, Cavalier, a competing local exchange carrier, alleged that Verizon, the incumbent local exchange carrier, was liable under section 2 of the Sherman Act, because Verizon refused to provide Cavalier access to existing essential facilities, namely, Verizon's communication network and its central offices.¹³⁴ The court

126. See Westin, *supra* note 17, at 280.

127. See Andrews, *Genes and Patent Policy*, *supra* note 12, at 804 ("[G]eneticists in France can offer genetic tests for breast cancer for less than the US \$2,680 fee per test that is charged by Myriad.")

128. Christine Sevilla et al., *Impact of Gene Patents on the Cost-effective Delivery of Care: The Case of BRCA1 Genetic Testing*, 19 INT'L J. TECH. ASSESSMENT HEALTH CARE 287, 296 (2003) ("The results of our cost-effectiveness analysis strongly suggest that negative [monopolistic] effects of this kind are occurring in the case of BRCA1. . . . [Such monopoly control] may prevent health care systems from identifying and adopting the most efficient genetic testing strategies.")

129. Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT'L CANCER INST. 80, 80–81 (2002). A 2006 U.S. study later confirmed that Myriad's testing strategy missed up to twelve percent of *BRCA* gene rearrangements. Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. AM. MED. ASS'N 1379, 1379–88 (2006).

130. Sophie Gad et al., Letter, *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. MED. GENETICS 388, 388–92 (2001).

131. Ellen Matloff & Arthur Caplan, *Direct to Confusion: Lessons Learned from Marketing BRCA Testing*, 8 AM. J. BIOETHICS 5, 7 (2008).

132. *Cavalier Tel., LLC v. Verizon Va., Inc.*, 330 F.3d 176, 193 (4th Cir. 2003).

133. *Id.* at 188.

134. *Id.* at 178.

rejected the essential facilities claim because Verizon had a legitimate business justification.¹³⁵ Specifically, compelling the defendant to share its office space and rent its telephone lines to a competing telecommunication firm would have forced the defendant to expand its telecommunications business into areas it had no desire to explore.¹³⁶ This justification would not apply to the present case because Myriad would not be forced to alter or expand its business into undesirable areas if it licensed its *BRCA* gene patents to other firms. Although Myriad could theoretically choose to expand its business by mass-producing *BRCA* gene sequences and marketing them to other researchers, the company would not be forced to do so.¹³⁷ Instead Myriad can simply license its gene patents, thus allowing competitors to spend their own time and resources isolating *BRCA* gene sequences for their own business operations.

Finally, Myriad could argue that licensing its *BRCA* gene patents would cause it to lose revenue and that its refusals to deal thus stem from its desire to remain profitable in the gene diagnostic market for breast and ovarian cancers. This argument lacks merit for two reasons. First, Myriad would not necessarily lose business in the gene diagnostic market for breast and ovarian cancers by licensing its gene patents. It could maintain its market dominance by competing on the merits. Specifically, Myriad can maintain its high profits by marketing superior, high-quality gene testing services and building goodwill among its consumers. Second, Myriad would actually profit from providing access to the *BRCA* gene sequences by demanding sizable royalties in exchange for granting others permission to make and use the *BRCA* gene sequences in their inventions. A recent study revealed that “Myriad has yet to make a profit despite revenues from its diagnostics business. [This is because profitability] . . . require[s] the development of new products, especially therapeutic products, which offer a higher financial return.”¹³⁸ Myriad has remained stagnant on this front because it has not tried to develop therapeutic products for breast and ovarian cancers either on its own or through strategic alliances with other firms. Myriad thus lacks any procompetitive legitimate business justification for refusing to license its *BRCA* gene patents.

5. Myriad's Monopoly over the Market for BRCA Gene Sequences Is Distinct from the Downstream Gene Diagnostic Market for Breast and Ovarian Cancers

The final implied element of EFD requires that the party seeking access to the facility be in competition with the monopolist controlling the facility in a

135. *Id.* at 187–88.

136. *Id.*

137. See 3B AREEDA & HOVENKAMP, *supra* note 88, ¶ 773e (explaining that antitrust laws do not impose an obligation on monopolists to “build new capacity to satisfy a would-be sharer”).

138. Gold & Carbone, *supra* note 93, at S42.

distinct downstream market.¹³⁹ By contrast, EFD does not apply when the parties are competitors in the market for the essential facility itself or a single integrated market.¹⁴⁰

BRCA gene sequences and gene diagnostic testing for breast and ovarian cancers are two distinct markets, because enough consumers wish to buy gene diagnostic testing services separately from gene sequences that it is efficient for competing diagnostic labs to offer *BRCA* testing services independent of the relevant gene sequences. Biopharmaceutical firms, clinical laboratories, and academic researchers are the major consumers in the upstream *BRCA* gene sequence market. In contrast, the consumers of the gene diagnostic market for breast and ovarian cancers consist of patients who might be at risk for developing breast or ovarian cancers. Myriad has an absolute monopoly in the upstream market for supplying *BRCA* gene sequences that is distinct from the downstream gene diagnostic market for breast and ovarian cancers which exploits the *BRCA* gene sequences.¹⁴¹

The *BRCA* gene patents are distinguishable from the patented cotton-tipped swab-making machine in *Q-Tips, Inc. v. Johnson & Johnson*, because unlike the *BRCA* genes, the patented machine in *Q-Tips* was not a market in and of itself. In *Q-Tips*, the Q-tips corporation had a patent on a machine that manufactured cotton-tipped swabs and Johnson & Johnson argued that Q-Tips' refusal to license the right to use the patented machine gave rise to antitrust liability.¹⁴² The court held that no antitrust violation had occurred because the defendant merely retained a monopoly that was legally granted to it by the government.¹⁴³ The machine in *Q-tips* did not constitute an essential facility because it was a facility that was part of the market for cotton-tipped swabs and not an independent market in and of itself. Q-Tips had to participate in the cotton swabs market in order to reap substantial profits as the owner of a cotton-swab-producing machine. Unlike *Q-Tips*, Myriad would not even have to enter the gene diagnostic market for breast and ovarian cancers to be profitable. Myriad could reap substantial profits by simply licensing its *BRCA* gene sequences to biopharmaceutical firms and clinical research labs that exploit these gene

139. See *Otter Tail Power Co. v. United States*, 410 U.S. 366, 378 (1973) (holding that a private power company violated antitrust laws, because it attempted to prevent municipalities from creating their own power distribution systems).

140. See *Q-Tips, Inc. v. Johnson & Johnson*, 109 F. Supp. 657, 660 (D.N.J. 1951), *aff'd*, 207 F.2d 509 (3d Cir. 1953) (holding that the patentee's refusal to license its patented machine did not violate antitrust laws, because the right to exclude others from using the machine "is the very monopoly . . . patent law grants").

141. In fact, there are multiple downstream markets, because *BRCA* sequences also have applications in gene therapeutic and innovation markets.

142. *Q-Tips, Inc.*, 109 F. Supp. at 657, 660.

143. *Id.* at 660.

sequences for different downstream applications. Thus, the vertical “two-market” requirement appears to be satisfied in the present case.

Myriad’s decision to exploit its dominant position in the *BRC A* gene sequence market to eliminate competition and illegally expand its monopoly power in the downstream gene diagnostic market for breast and ovarian cancers is exactly the sort of market overreaching EFD is designed to thwart. The above analysis demonstrates that Myriad’s *BRC A* gene patents fall within the definition of an essential facility and Myriad’s refusal to license these gene sequences to downstream competitors constitutes an antitrust violation under EFD.

6. *Dismissing Objections to the Application of EFD to Gene Patents*

a. EFD can be applied to IP

Some scholars advocate against the application of EFD to IP cases.¹⁴⁴ Central to this argument is the assumption that an obligation to share IP disrupts incentives put in place by IP laws, which in turn stifles innovation.¹⁴⁵ However, this argument overlooks the fact that EFD only applies to markets that are vertically related—an upstream market that supplies a facility and a related downstream market in which a firm cannot compete without access to the facility. IP owners would not be “ripped-off” by a duty to share” because the IP owner’s “legal reward is not altered in the primary market for the product embodying its intellectual property.”¹⁴⁶ Moreover, access to IP that serves as an essential input in downstream markets promotes innovation, increases technological output, reduces prices, and enhances consumer welfare.¹⁴⁷ These policy justifications consequently demonstrate that “the essential facilities doctrine applies to intellectual property no less than to tangible assets.”¹⁴⁸

To the extent that the majority of cases employing EFD have involved tangible property, courts have never expressly held that IP is precluded from being an essential facility to competition. In fact, the argument that “only tangible physical objects are ‘facilities’ and, as such, . . . the essential facilities doctrine does not apply [to IP],” has not been looked upon favorably.¹⁴⁹ For one thing, EFD has

144. 1 HERBERT HOVENKAMP ET AL., *supra* note 74, § 13.3c.

145. Simon Genevaz, *Against Immunity for Unilateral Refusals to Deal in Intellectual Property: Why Antitrust Law Should Not Distinguish Between IP and Other Property Rights*, 19 BERKELEY TECH. L.J. 741, 761 (2004).

146. *Id.*

147. *See* Pitofsky et al., *supra* note 79, at 452.

148. *Id.*

149. *BellSouth Adver. & Publ'g Co. v. Donnelly Info. Publ'g, Inc.*, 719 F. Supp. 1551, 1566 (S.D. Fla. 1988) (“Although the doctrine of essential facilities has been applied predominantly to tangible assets, there is no reason why it could not apply, as in this case, to information wrongfully withheld.”).

been widely applied to intangible assets such as services.¹⁵⁰ Furthermore, courts seem to accept the notion that EFD can be applied in the context of IP.¹⁵¹ Thus far, there has not been a case where the IP rights at issue were found to be essential facilities¹⁵² because none of the inputs could satisfy all the elements of the *MCI* test. Given that the *BRC A* gene patents can unequivocally satisfy every element of EFD, it is reasonable to conclude that the *BRC A* gene patents constitute an essential facility for the downstream gene diagnostic market for breast and ovarian cancers.

b. Application of EFD to gene patents will not deter innovation

EFD has been criticized by a number of scholars because of two overarching concerns: (1) the subjectivity of determining when a facility is actually “essential” to downstream competition, and (2) fears that compelled access would decrease incentives to innovate.¹⁵³ Fortunately, neither of these objections creates a true impediment to the application of EFD in the context of gene patents. The first criticism is concerned with properly defining the circumstances under which a single firm’s facility is classified as essential.¹⁵⁴ Courts have addressed this fear by making the essentiality requirement a relatively high bar for antitrust plaintiffs to clear.¹⁵⁵ Even under this elevated standard, *BRC A* gene patents would still qualify

150. *AT&T Co. v. N. Am. Indus., Inc.*, 772 F. Supp. 777, 785 (S.D.N.Y. 1991) (stating that plaintiff “adequately alleged that the central office services refused it by [defendant] are essential within the meaning of the federal antitrust laws”); see *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150–51 (4th Cir. 1990) (concluding that plaintiff adequately alleged that access to hospital patients for patient referrals constituted an essential facility).

151. *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 761 F. Supp. 185, 192 (D. Mass. 1991) (rejecting essential facilities claim in a case involving copyrighted computer diagnostic software on the grounds that the copyright holder was not a monopolist, not on the grounds that the essential facilities doctrine is inapplicable to IP), *aff’d in part and remanded*, 36 F.3d 1147 (1st Cir. 1994); *BellSouth Adver. & Publ’g Co.*, 719 F. Supp. at 1566 (holding that copyrighted telephone listings could be an essential facility necessary to the production of competing telephone directories if such listings were found to be truly essential), *rev’d on other grounds*, 999 F.2d 1436 (11th Cir. 1993); see, e.g., *Montgomery Cnty. Ass’n of Realtors, Inc. v. Realty Photo Master Corp.*, 878 F. Supp. 804, 817 (D. Md. 1995) (rejecting essential facilities claim in case involving copyrighted “multiple listing service” on the grounds of insufficient evidence, not on the grounds that the essential facilities doctrine is inapplicable to IP), *aff’d*, 91 F.3d 132 (4th Cir. 1996).

152. See, e.g., *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1357 (Fed. Cir. 1999) (ruling that an essential facilities claim could not be made out because the owner of the essential facility and the antitrust plaintiff did not compete in a downstream market that required access to the facility); *Aldridge v. Microsoft Corp.*, 995 F. Supp. 728, 753 (S.D. Tex. 1998) (finding that defendant’s computer operating system was not an essential input into the disk caching market because plaintiff’s program could theoretically be run on other operating systems in the primary market).

153. See e.g., Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841, 851–52 (1989).

154. Such caution is warranted “particularly when anything [that one firm] has that another [competing firm] wants may be called an ‘essential facility.’” *Id.* at 844.

155. See, e.g., *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 544 (9th Cir. 1991) (“[A] plaintiff must show more than inconvenience, or even some economic loss; he must show that

as essential facilities because it is not only vital to the competitive viability of individual gene testing labs but also the viability of the gene diagnostic market for breast and ovarian cancers in general. Firms that wish to enter the gene diagnostic market for breast and ovarian cancers cannot do so without access to the *BRCA* gene sequences. The *BRCA* gene sequences are not amenable to design-around given the broad scope of Myriad's composition of matter patents. Nor are there any practical non-infringing alternatives available that can assess a patient's risk of developing breast and ovarian cancers prior to manifestation of the disease. The first objection can thus be easily overcome given the nature of gene patents.

The second criticism is concerned with interfering with the rights of patent holders and how it may subsequently deter researchers from investing in upstream innovation.¹⁵⁶ Although this is a legitimate concern, it does not apply in the context of gene patents for two reasons. First, the publication of the Human Genome Project and rapid advances in gene sequencing technology have eliminated the need to incentivize researchers to discover upstream human gene sequences.¹⁵⁷ In fact, the upstream market for patented human gene sequences will most likely decrease (or disappear) by the year 2020, which marks the end of the patent term for human gene patents that were secured in the pre-Human Genome Project era. Second, gene patents actually impede innovation by prioritizing the economic interests of upstream inventors over the need to incentivize subsequent technological evolution. Gene patents are more onerous than the average product patents because they are essential for the practice of every downstream invention involving the exploitation of genetic information. As a result, the patent owner "ultimately controls all [applications] deriving from the gene's use,"¹⁵⁸ giving her tremendous power in determining what inventions are practiced. This excessive concentration of power in the hands of upstream inventors can chill downstream innovation since gene patents enable upstream patent holders "to sit on their patents in order to reap profits, while blocking new

an alternative to the facility is not feasible."); *City of Malden v. Union Elec. Co.*, 887 F.2d 157, 162 (8th Cir. 1989) (refusing to impose antitrust liability even though the defendant's transmission line was the only practical means for the city to obtain outside power); see also *Aldridge*, 995 F. Supp. at 753 ("A facility is essential under the antitrust laws only when it is vital to both the plaintiff's individual competitive viability and the viability of the market in general.").

156. See *Genevaz*, *supra* note 145, at 760–61.

157. Indeed, isolated human gene sequences that lack any newly engineered and nonobvious properties would no longer qualify for a patent. See *In re Kubin*, 561 F.3d 1351, 1361 (Fed. Cir. 2009) (rendering gene patents whose structures were already known as of September 2000 unpatentable due to obviousness).

158. Westin, *supra* note 17, at 281. For example in *Amgen*, the plaintiff accused the defendant of infringing its patent on the erythropoietin (epo) gene sequence because the defendant produced the gene using a novel cutting-edge method instead of the method disclosed in Amgen's patents. The court held that the scope of Amgen's gene patent was not restricted to the product that was a result of the method disclosed in the patent. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003).

innovations that might substitute their own.”¹⁵⁹ Because competition also plays a vital role in fostering innovation,¹⁶⁰ overprotection of gene patent holders from competition can “perversely result in less, rather than more, innovation.”¹⁶¹

c. EFD is still viable after Trinko

The final concern regarding the application of EFD to the *BRC A* gene patents is the Supreme Court’s statement in *Trinko* that the Court “ha[s] never recognized [the essential facilities] doctrine.”¹⁶² However, this rhetoric is not likely to affect the application of EFD to the *BRC A* gene patents for the following four reasons. First, the Court’s language is merely dicta and does not expressly signal the demise of EFD because the Court “[found] *no need either to recognize . . . or to repudiate* [the essential facilities doctrine].”¹⁶³ Second, even though the Court never invoked the “essential facilities” label, it has previously applied the doctrine’s underlying principles to compel access to a facility that was essential to competition in a related downstream market.¹⁶⁴ Third, the situation in *Trinko* is completely distinguishable from the present case involving the *BRC A* gene patents. In *Trinko*, the Court declined to apply EFD because it found that the Telecommunications Act of 1996¹⁶⁵ imposes an obligation on dominant firms to share their telephone networks with competitors.¹⁶⁶ Unlike *Trinko*, gene patents are not subject to any sort of regulatory regime¹⁶⁷ and EFD may be the sole means for downstream gene diagnostic firms to gain access to this essential input. Fourth, many federal courts construe *Trinko* as imposing limits on EFD rather than eviscerating it, and still continue to entertain essential facilities antitrust claims.¹⁶⁸ It thus appears that EFD is still viable after *Trinko*, and thus has no effect on its application to the *BRC A* gene patents.

159. Wang, *supra* note 48, at 275–76.

160. Rai, *supra* note 48, at 831–44.

161. Lao, *supra* note 63, at 214.

162. Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 411 (2004).

163. *Id.* (emphasis added).

164. *See* Otter Tail Power Co. v. United States, 410 U.S. 366, 377–78 (1973) (alluding to each of the elements for an essential facilities test later articulated in MCI). The Supreme Court’s contributions to the underlying principles of EFD are highlighted in note 62.

165. *Trinko*, 540 U.S. at 402 (citing 47 U.S.C. § 251(c)).

166. *Id.* at 411.

167. In fact, patent law confers strong protections against compulsory sharing. 35 U.S.C. § 271(d)(4) (2006 & Supp. V 2011) (“No patent owner . . . shall be . . . deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . refused to license or use any rights to the patent.”).

168. Z-Tel Commc’ns, Inc. v. SBC Commc’ns, Inc., 331 F. Supp. 2d 513, 541 (E.D. Tex. 2004) (stating “limitation [imposed by *Trinko*] has no bearing on Z-Tel’s claims”); N.Y. Mercantile Exch., Inc. v. Intercontinental Exch., Inc., 323 F. Supp. 2d 559, 568 (S.D.N.Y. 2004) (discussing “some of the constraints [the *Trinko* Court] imposed on the essential facility doctrine”); *see, e.g.*, Covad Commc’ns Co. v. BellSouth Corp., 374 F.3d 1044, 1050 (11th Cir. 2004) (interpreting *Trinko* to hold that “[w]here a state or federal agency is authorized to compel access to a competitor’s infrastructure, . . . an essential facilities claim should be denied”); *see also* Snake River Valley Elec. Ass’n v.

*B. The Duty to Deal Under Aspen Skiing Provides an Alternate Basis
for Imposing Antitrust Liability on Gene Patent Holders*

To the extent that the shelf life of EFD may be limited in light of *Trinko*, a patent owner's *conduct* of unilaterally refusing to license its gene sequences to downstream competitors may also constitute exclusionary conduct under section 2 of the Sherman Act. Under a duty to deal claim, the plaintiff must prove that the defendant's specific refusal to deal constitutes anticompetitive conduct that contributes to monopolization. Although there is no general antitrust duty to deal, this does not mean that a firm's right to refuse to deal is unqualified.¹⁶⁹ Refusals to deal may be subject to scrutiny under section 2 if they extend, preserve, create, or threaten to create significant market power.¹⁷⁰ In *Aspen Skiing*, a dominant ski resort operator who owned three of the four ski mountains in a town, discontinued a business arrangement with the plaintiff, its only competitor. The action was apparently taken to eliminate its competitor and to monopolize the ski resort business in the town. The Court held that a dominant firm's refusal to continue to do business with its competitors in the absence of a legitimate business justification constitutes a violation of section 2 of the Sherman Act.¹⁷¹

Myriad's refusals to deal with competing diagnostic labs should be a basis for section 2 antitrust liability because the sole objective behind its conduct was to foreclose competition in the gene diagnostic market for breast and ovarian cancers. In *Lorain Journal*, the Court held that a monopolist newspaper's refusals to sell advertising space to merchants who also purchased air advertising time from its competitor, a local radio station, was a section 2 violation of the Sherman Act.¹⁷² While acknowledging that a private business has the right to refuse to deal with specific customers, the Court held that the exercise of this right for the purpose of monopolization violates the Sherman Act.¹⁷³ Like the monopolist firm in *Lorain Journal*, Myriad refused to license the *BRC A* gene sequences to any researchers that utilized gene testing protocols that competed (or had the potential to compete) with Myriad's own gene testing services.¹⁷⁴ Myriad thus chose to forsake short-term profits in the form of licensing royalties in order to monopolize the gene diagnostic market for breast and ovarian cancers.

PacificCorp, 357 F.3d 1042, 1044 n.2 (9th Cir. 2004) (invoking MCP's essential facilities test after *Trinko* was decided, though not citing the *Trinko* decision).

169. *Trinko*, 540 U.S. at 408 (quoting *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985)).

170. 1 HERBERT HOVENKAMP ET AL., *supra* note 74, § 13.3d.

171. *Aspen Skiing Co.*, 472 U.S. at 610–11.

172. *Lorain Journal Co. v. United States*, 342 U.S. 143, 152–55 (1951).

173. *Id.* at 155.

174. *Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 205 (S.D.N.Y. 2010) ("In 2005, Dr. Matloff sought permission from Myriad for the Yale DNA Diagnostics Lab to conduct screening for mutations caused by large rearrangements, which Myriad was not conducting at the time. Her request was denied.")

One could argue that the outcome of *Lorain Journal* turned on the fact that it involved conditional refusals to deal and should thus be distinguished from the unilateral refusals to deal in the Myriad controversy.¹⁷⁵ To the extent that *Lorain Journal* can be characterized as a case dealing with conditional refusals to deal as opposed to “pure” unilateral refusals to deal, it is nonetheless applicable to the present case. In *Lorain Journal* the defendant’s willingness to deal was conditioned on its customers agreeing not to purchase advertising time from its competitor.¹⁷⁶ Likewise, Myriad only deals with parties who agree to abide by its own anticompetitive licensing conditions. Specifically, licensees are precluded from competing against Myriad in the gene diagnostic market for breast and ovarian cancers. In fact, licensees are only permitted to conduct confirmatory testing of Myriad’s initial *BRCA* test results and are barred from retesting a significant number of Myriad’s positive results and all of Myriad’s negative results, thus destroying any opportunity to improve the quality of *BRCA* genetic testing.¹⁷⁷ Most clinical labs would have no incentive to accept Myriad’s licensing agreement because the terms effectively prevent them from vigorously competing in the gene diagnostic market for breast and ovarian cancers. The present situation enables Myriad to maintain its dominant status and charge consumers supracompetitive prices for its mediocre *BRCA* genetic testing services. Myriad ultimately succeeded in monopolizing the gene diagnostic market for breast and ovarian cancers and is currently the sole provider of all *BRCA* genetic testing in the United States.

C. Limitations on Antitrust Liability for Unilateral Refusals to License IP

Antitrust law cannot treat all refusals to license patent rights like non-IP related refusals to deal because of the statutory protections of the Patent Act.¹⁷⁸ Based on the statutory language, one can infer that the patent owner has no obligation to license its patent to others. Federal patent law thus allows a patent holder to deny others access to the area claimed by the invention. It would thus be incongruous to blindly apply the *Aspen Skiing* rule in cases involving a patentee’s unilateral refusal to deal because doing so “would directly contravene the explicit statutory protections of the . . . [patent] system.”¹⁷⁹

But the statutory protections of patent law do not shield patent owners from all antitrust liability. While the patent statute explicitly allows a patentee to bar competitors from the area claimed by the invention, it does not address whether a

175. See 1 HERBERT HOVENKAMP ET AL., *supra* note 74, § 13.4b2 (noting that the rules governing conditional refusals to deal are quite different from those that pertain to unilateral refusals to deal).

176. *Lorain Journal*, 342 U.S. at 148.

177. *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 207.

178. The Patent Act grants the patent holder the exclusive right to make, use, or otherwise exploit its invention for a limited time. 35 U.S.C. § 154 (2006).

179. Lao, *supra* note 63, at 198.

patentee's refusal to license a patent may be considered an antitrust violation if the practice bars others from participating in a related or downstream market in which the firm would have otherwise faced competition.¹⁸⁰ If there were no limits to the scope of the patent grant, the patent holder would have unrestricted freedom to set any licensing conditions it desires while being completely immune to antitrust liability. The fact that the Supreme Court has held that tying arrangements involving patents are subject to antitrust laws,¹⁸¹ demonstrates that the statutory protections of the Patent Act are limited to the area of the grant.

Some federal appellate courts have agreed that a monopolist's refusal to license an IP right can be the basis of antitrust liability in limited circumstances—particularly where an IP owner leverages its monopoly in one market to substantially foreclose competition in a related downstream market.¹⁸² In an attempt to harmonize the principles of both antitrust law and patent law, several circuit courts have held that an IP owner's refusal to deal with competitors based on a desire to profit from its IP rights is a presumptively legitimate business justification.¹⁸³ This presumption can nonetheless be rebutted by showing that the procompetitive effects of a firm asserting its IP rights are outweighed by the anticompetitive effects of its conduct.¹⁸⁴ In *Grumman*, a manufacturer refused to license its copyrighted software to third party maintainers who competed against it in the downstream service market.¹⁸⁵ The court found that the plaintiffs were unable to rebut the presumption that the defendant's refusal to license was not exclusionary because there was no evidence that competitive conditions existed in the service market before the defendant chose to discontinue dealing with its competitors.¹⁸⁶ The court thus determined that it was inappropriate to impose a duty to deal on the defendant IP owner since there was no showing of anticompetitive conduct.

Unlike *Grumman*, antitrust plaintiffs can overcome the presumption that Myriad's refusal to license the *BRC A* patents is not exclusionary because competitive conditions prevailed in the gene diagnostic market for breast and ovarian cancers before Myriad exercised its rights not to deal with other gene diagnostic labs. Prior to 1997, there were four major providers of *BRC A* genetic testing: University of Pennsylvania's Genetic Diagnostic Laboratory, OncorMed,

180. *Id.*

181. *Int'l Salt Co. v. United States*, 332 U.S. 392, 397–98 (1947); *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 490–91 (1942).

182. *Image Technical Serv. v. Eastman Kodak*, 125 F.3d 1195, 1215–16 (9th Cir. 1997); *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1188 (1st Cir. 1994) (determining whether there is anticompetitive conduct “turns on a comparison of the behavior of firms in a competitive market . . . with a monopolist's behavior once competition has been curtailed”), *abrogated on other grounds*.

183. *Eastman Kodak*, 125 F.3d at 1219; *Grumman*, 36 F.3d at 1187.

184. *Eastman Kodak*, 125 F.3d at 1219–20; *see Grumman*, 36 F.3d at 1187 n.64.

185. *Grumman*, 36 F.3d at 1154.

186. *Id.* at 1188–89.

Genetics and IVF Institute, and Myriad.¹⁸⁷ Prices for *BRC A* testing ranged from seven hundred to four thousand dollars and each testing center utilized its own genetic testing protocols, provided varying degrees of post-test clinical care, and offered variable forms of specialized genetic counseling.¹⁸⁸ Beginning in 1997, Myriad dispatched cease-and-desist letters to its competitors in the gene diagnostic market while simultaneously refusing to license its *BRC A* gene patents.¹⁸⁹ Myriad successfully drove the other *BRC A* testing providers out of the market by 1999, making it the sole provider of gene diagnostic testing for breast and ovarian cancers in the United States.¹⁹⁰ Myriad's present monopoly status allows it to charge a high premium (approximately \$3120 per patient) for its less-than-optimal *BRC A* testing services.¹⁹¹ Furthermore, Myriad does not offer patients the specialized genetic counseling services that were previously available through its competitors.¹⁹² A court is thus likely to conclude that (1) Myriad's present monopoly status was not obtained through competition on the merits, and (2) Myriad's refusals to deal unjustifiably harm the competitive process by frustrating consumer preferences and erecting barriers to competition.¹⁹³

Furthermore, the categorical deference to the rights of the patent owner is inappropriate in the present case given the inextricable links between gene sequences and lifesaving inventions that promote public health. Accurate gene diagnostic testing is extremely beneficial to consumers because it can help patients identify their risk for certain diseases prior to the appearance of symptoms and facilitates informed medical decision making. Although rare, there are cases where courts have even refused to enforce infringed patents because of overriding public health concerns.¹⁹⁴ A classic case is *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found.*, where the patent owner refused to license its process of irradiating foodstuffs to increase vitamin D content in margarine.¹⁹⁵ Increasing vitamin D was helpful in the treatment of rickets and making increased vitamin D available in a low-cost item like margarine made it accessible to the poor. The court concluded that the patent owner's refusal to license its process justified the denial of the

187. PARTHASARATHY, *supra* note 26, at 93–95.

188. *Id.*

189. *Id.* at 115–19; Cho et al., *supra* note 19, at 3–8.

190. PARTHASARATHY, *supra* note 26, at 116.

191. Benowitz, *supra* note 129, at 80–81; Cook-Deegan et al., *supra* note 23, at S16–17; Walsh et al., *supra* note 129, at 1380; see Gad et al., *supra* note 130, at 388–92.

192. PARTHASARATHY, *supra* note 26, at 119.

193. See *supra* Part IIA.4 for a complete discussion of why Myriad lacks any procompetitive legitimate business justifications for its refusal to license the *BRC A* gene patents.

194. *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934) (refusing to enjoin infringement because doing so “would close the sewage plant, leaving the entire community without any means for the disposal of raw sewage other than running it into Lake Michigan, thereby polluting its waters and endangering the health and lives of that and other adjoining communities”); see also *Vitamin Technologists, Inc. v. Wis. Alumni Res. Found.*, 146 F.2d 941, 944–45 (9th Cir. 1945).

195. *Vitamin Technologists, Inc.*, 146 F.2d at 954.

patent holder's request for injunctive relief.¹⁹⁶ Likewise, refusals to deal involving patented gene sequences should be subject to antitrust liability as a matter of public policy.

III. ANTITRUST LAW PROVIDES REMEDIES THAT PROMOTE INNOVATION AND COMPETITION

To the extent that EFD and refusal to deal claims deter patent owners from engaging in anticompetitive conduct, antitrust law may provide plaintiffs with necessary injunctive relief in the form of compulsory licensing. The Supreme Court has acknowledged that compulsory patent licensing is a recognized antitrust remedy,¹⁹⁷ albeit a rarely implemented one. The use of compulsory licensing as an antitrust remedy is justified when necessary to prevent against the continued monopolization in a market and can thus be viewed as akin to essential facility doctrine or refusal to deal law. Compulsory licensing is an appropriate remedy in the context of gene patents because it restores competition in the biomedical industry by allowing competitors in downstream gene based technology markets (particularly the gene diagnostic market) access to the defendant's upstream patented gene sequences at reasonable rates. Nondiscriminatory access to gene sequences would lower barriers to entry for new competitors and increase technological output in gene diagnostics, gene therapy, and personalized medicine. The use of compulsory licensing in this case is even more compelling given the close links between gene patents and public health concerns.

CONCLUSION

Broad gene patents impede innovation and stymie market competition in the genetic diagnostic markets. This impediment can be attributed to (1) the nature of the gene diagnostic market where a patent owner typically has exclusive rights to both the gene and a genetic testing method for the patented gene and (2) the fact that existing gene patents are almost impossible to invalidate under current patent law.¹⁹⁸ These conditions provide a patent holder with strong incentives to refuse to license its gene patents to competitors who specialize in genetic testing. In addition to impairing the gene diagnostic market, such anticompetitive conduct

196. *Id.* at 954–56.

197. *Besser Mfg. v. United States*, 343 U.S. 444, 447 (1952) (“[C]ompulsory patent licensing is a well-recognized remedy where patent abuses are proved in antitrust actions and it is required for effective relief.”); *see also* *United States v. Glaxo Grp.*, 410 U.S. 52, 64 (1973).

198. The Federal Circuit recently upheld the validity of the *B.R.C.A* gene patents and explained that the patentability of isolated gene sequences was not affected by the Supreme Court's decision in *Mayo Collaborative Services, Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1326–29 (Fed. Cir. 2012) (“While *Mayo* and earlier decisions concerning method claim patentability provide valuable insights and illuminate broad, foundational principles, the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers* set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules.”).

poses a serious threat to advances in gene therapy and personalized medicine as the lines between diagnostics and therapy become increasingly blurred¹⁹⁹ and the field of medical genetics shifts from single gene analysis to full genome analysis.²⁰⁰ Antitrust law offers a well-tailored solution to most of the dilemmas posed by gene patents through the application of EFD or under the more general refusal to deal theory. These proposed solutions deter patent owners from engaging in anticompetitive conduct without eliminating the economic incentives associated with gene patents. Furthermore, antitrust law can provide plaintiffs with nondiscriminatory access to indispensable research tools, thereby facilitating the advancement of cutting-edge gene-based technologies.

199. Filip De Corte, *Licensing in the Medical Sector*, in GENE PATENTS AND PUBLIC HEALTH, *supra* note 14, at 87, 97. “The industry is moving towards an era where diagnostics and pharmaceuticals will go even closer hand in hand. A world can be envisaged where the diagnostic tool is actually part of the package of the drug. Or . . . the drug is part of the package of the diagnostic tool.” *Id.*

200. COMM. ON INTELLECTUAL PROP. RIGHTS IN GENOMIC AND PROTEIN RESEARCH AND INNOVATION, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH 42–43 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006).