NON-POSSESSION AS ONE-TENTH OF THE LAW: RIGHT TO REFUSE OR DUTY TO DEAL IN MOLECULAR MONOPOLIES

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An unresolved tension exists in American jurisprudence between intellectual property and antitrust law. A patent authorizes limited rights of exclusivity to transact on an invention in an attempt to incentivize investment in and disclosure of the creation. Sherman Act Section 2 antitrust liability attaches when a firm possesses market power that it willfully maintains through exclusionary conduct to an overwhelming anticompetitive effect. Put simply, while patent law is dedicated to the preservation of monopolies, antitrust law is concerned with their destruction.

Agency guidelines have attempted to resolve this tension by pursuing joint goals of innovation and consumer welfare. In practice, enforcement has enhanced the primacy of patents through permissive appellate precedent, including a ruling that patents do not necessarily confer market power and licensing schemes are presumptively procompetitive. Antitrust law correspondingly affords a firm acting unilaterally the traditionally presumed right to refuse to deal with competitors. However, under certain circumstances, a firm may be compelled, through a judicially defined equitable duty, to deal with a competitor when its refusal to deal is based on anticompetitive justifications.

Circuits are split as to when a duty to deal arises in an intellectual property case. The Federal Circuit takes the position that a patent holder has a near absolute right to refuse to deal. The Ninth Circuit imposes a duty to deal when evidence of a pretextual justification rebuts the procompetitive presumption of a licensing scheme. Using Myriad *as a case study, this article investigates when the holder of legitimately*

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acquired intellectual property may be exposed to liability based on anticompetitive uses of market power. Ultimately, biotechnology markets are optimized when the right to refuse to deal is qualified and a duty to deal in molecular monopolies is imposed.

INTRODUCTION

Controversy over proprietary ownership of the BRCA1 and BRCA2 ("BRCA1/2") gene sequences has brought the medico-legal community into the public eye. A woman who tests positive for BRCA1/2 mutations has a significantly heightened risk for breast and ovarian cancer. The isolation of these sequences in the 1990s and the subsequent development of diagnostic testing methods and clinical therapies were monumental discoveries. The rise in availability of genetic sequencing signaled to the public that science's promise of personalized medicine might at last be fulfilled. Despite these achievements, one remaining obstacle is that a single company, Myriad Genetics, Inc., ("Myriad") holds certain legal rights associated with these gene sequences. Moreover, Myriad's intellectual property strategy is predicated on a no-license policy coupled with aggressive litigation against alleged infringers—researchers, clinicians, and diagnosticians alike. Myriad's BRCA1/2 tests are reportedly more expensive than its competitors' tests by a factor of four. Some claim that Myriad's BRCA1/2 tests have not kept pace with scientific development, because its patents allow it to bypass competitive pressures. Myriad counters these accusations by contending that it invested in an uncertain market based on the potential for supracompetitive returns. Myriad's control of BRCA1/2 through its

remaining 515 patents has not been invalidated, but the normative question remains: Does Myriad possess legal property to which it has no ethical right?

Myriad's patents were lawfully acquired and thus, from the perspective of intellectual property law, enforcement of Myriad's exclusivity grant must also be lawful. However, antitrust laws are implicated when market power is used to harm the competitive process. Tasked with maintaining the free enterprise structure of the American economy, antitrust law broadly seeks to close current and future avenues for anticompetitive conduct. Among the equitable powers of antitrust is the ability to require compulsory licensing between competitors. A court can also impose a duty to deal on a firm or designate an underlying facility as an essential market input.

This intersection of patents and antitrust is a highly fertile ground of jurisprudence peppered with seeds of legal reasoning spanning nearly three decades. However, its growth has been stunted by ambiguous judicial rulings. The question of whether and when a legitimate patent holder has a right to refuse or a duty to deal has not been decisively answered. The Ninth Circuit has ruled that refusals to deal in intellectual property are subject to antitrust scrutiny, but reasoned that refusals to license a patent are presumptively procompetitive. However, presumption implies a mere starting point for the allocation of legal burdens. Such a presumption can be rebutted by evidence that the proffered business justifications were a pretext for anticompetitive conduct. Conversely, the Federal Circuit has ruled that refusals to deal in intellectual property are entitled to antitrust immunity, assuming the patent was procured and preserved legitimately. The Supreme Court declined to hear this very issue in 2001, preferring to allow the appellate courts to flesh out the nuances of the discussion. Since then, the Federal Circuit has been exclusively applying its own substantive law in cases where patents and antitrust claims interface. Lower courts and parties, in anticipation of inevitable appeals, responded by treating the duty to deal doctrine as a non-starter. Similarly, the Supreme Court deferred on addressing the essential facilities doctrine in 1996, finding satisfactory grounds to decide the case at hand on other questions of law. Now is a prime time for the Supreme Court to clarify these pieces of jurisprudence. The application of either the duty to deal doctrine or the essential facilities doctrine could effectively provide open market access to the BRCA1/2 gene sequences.

The first section of this note discusses the theoretical framework for patents and antitrust, which serves as the backdrop for the circuit split. That section explores the structure and function of both the patent and antitrust regimes, concluding with an investigation into their shared history of monopoly regulation. The second section illuminates some key

features of the biotechnology industry. Particular significance is given to market conditions that affect incentives relating to patents and antitrust. Then, the note describes the intertwined history of Myriad's inception and development of the isolated BRCA1/2 genetic sequences and discusses Myriad's lawsuit. The third section outlines the antitrust doctrines involved in the circuit split, beginning with common law precedent on the right to refuse and duty to deal, and concluding with the leading cases defining the positions of both the Ninth Circuit and the Federal Circuit. The last section discusses the duty to deal and essential facilities doctrines as resolutions for the BRCA1/2 debate.

The controversy over Myriad's BRCA1/2 genetic patents demonstrates that certain economic goods—particularly those with an absence of non-infringing, substitutable material—serve as essential facilities. These required inputs present elements of real scarcity—a scarcity which cannot be innovated around—and thus mirror natural monopolies. Under these circumstances, an absolute right to refuse to unilaterally deal will result in deleterious effects on competition and ultimately will harm consumer welfare. Qualifying the right to refuse, in accordance with the duty to deal doctrine or the essential facilities doctrine, preserves necessary intellectual property incentives while maintaining the competitive structure of the marketplace. A qualified right to refuse to deal in the molecular inputs of intellectual property monopolies creates the best incentive structure to compete in biotechnology markets.

I. THEORETICAL FRAMEWORK

The tension between intellectual property law and antitrust law is based on the central discussion of how monopolies should be regulated. Generally, intellectual property laws allow an inventor to wholly control their invention, in accordance with the theory that long-term innovation counterbalances the short-term harm consumers face. Patent rights create a limited monopoly in a good, which allows inventors to access capital markets in exchange for facilitating and disclosing the invention process. Antitrust laws disrupt dominance of the competitive process, viewing certain acts commenced by firms of sufficient size as harmful for consumers. Remedies are broad under antitrust jurisprudence, giving judges latitude to prevent specific acts or to divest an entire company. The coevolution of these regimes indicates that their aims are far more complex than their monikers—agents of monopoly production and destruction—would suggest. Antitrust and intellectual property laws share the twin objectives of preserving innovation and safeguarding consumer welfare. This common ground serves as the analytical backdrop for resolving the antitrust scrutiny and immunity circuit split.

A. Patent Regime

Intellectual property is a commercially valuable, intangible product of the mind. Intellectual property consists primarily of trademark, copyright, and patent rights. However, it also includes lesser-used rights such as trade secrets, the rights to publicity, moral rights, and rights against unfair competition.[1] Many such rights are constitutionally grounded.[2]

A patent is an official document granting the inventor a suite of legal rights to exclude others from transacting on the invention.[3] Under the current American patent regime, an inventor who has legitimately acquired a patent may legally bar non-licensed parties from making, using, selling, offering to sell, or importing the invention for a period of twenty years.[4] Patents are not passive rights that automatically attach, but rather active rights that require the holder to acquire formal approval from the United States Patent and Trademark Office ("USPTO").[5] A patent examiner must verify that the patent application has met the requirements of novelty, non-obviousness, full disclosure, sufficient utility, being a patentable subject matter, and having been filed before the statutory bars.[6] Once the USPTO has issued the patent, the holder possesses a negative right to bar others from engaging in production, but not necessarily a positive right to produce.[7]

A patent holder enforces its patent rights through an infringement action.[8] An alleged infringer may present a defense of non-infringement or patent invalidity.[9] If the latter defense is successful, the holder's patent is terminated.[10] The court can issue a preliminary injunction if the plaintiff demonstrates a likelihood of success on the merits, a likelihood of suffering irreparable harm absent an injunction, that the balance of equity is in the plaintiff's favor, and that the injunction is in the public interest.[11] Injunctions at the early stages of litigation are opportunities for

1. *Intellectual Property*, BLACK'S LAW DICTIONARY (10th ed. 2014).

2. U.S. CONST. art. I, § 8, cl. 8 ("Congress shall have power to . . . promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

3. *Patent*, BLACK'S LAW DICTIONARY (10th ed. 2014).

4. 35 U.S.C. § 154(a) (2012).

5. *General Information Concerning Patents*, U.S. PATENT & TRADEMARK OFFICE (Oct. 2014), http://www.uspto.gov/patents-getting-started/general-information-concerning-patents.

6. 35 U.S.C. §§ 101, 102(a)–(b), 103, 112 (2012).

7. Richard H. Shear & Thomas E. Kelley, *A Researcher's Guide to Patents*, 132 PLANT PHYSIOLOGY 1127, 1128 (2003).

8. 35 U.S.C. § 271 (2012).

9. *General Information Concerning Patents*, *supra* note 5.

10. *See, e.g.*, Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1928–29 (2015).

11. 35 U.S.C. § 283 (2012); Univ. of Utah Research Found. v. Ambry Genetics Corp. (*In re* BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.), 3 F. Supp. 3d 1213, 1248 (D. Utah 2014).

the respective parties to test the proverbial legal waters and find out which competing interpretation is most lukewarm. The presiding court may also award damages for the infringing acts.[12]

Intellectual property rights are an attempt to create an incentive structure analogous to that of tangible property.[13] Strong property protections reduce uncertainty in the market and allow individuals to secure their investments.[14] Under this utility theory of wealth maximization, scarce goods are allocated to their optimal use.[15] Unlike their physical property counterparts, intangible goods are arguably subjected to inherent underproduction pressures, based on their fundamental non-rivalrous and non-excludable nature.[16] One cannot fence in an idea, and the consumption of an idea does not result in a zero-sum resource trade-off. Competitors in this type of market are rational to free ride on the innovations of industry leaders, resulting in an economy of copying rather than creation.[17] Regulation intervenes in this socially undesirable scenario.

Microeconomic analysis demonstrates that intangible goods are marked by a high fixed cost in their development but a low variable cost in their production.[18] These natural monopolies are less efficient when perfectly competitive and correspondingly more efficient when concentrated.[19] The law of intangible property establishes a limited monopoly for the inventor in her invention to offset this inherent risk of underproduction.[20] Patent grants are the legal-regulatory system's attempt to restructure the intangible goods market as if it functioned like the market for tangible goods.[21]

12. 35 U.S.C. § 284 (2012).

13. *See* Doug Schoen, *Intellectual Property Rights Matter*, FORBES (Sept. 24, 2013, 9:47 AM), http://www.forbes.com/sites/dougschoen/2013/09/24/intellectual-property-rights/.

14. Peter Boettke, *The Role of Private Property in a Free Society*, VA. INST. (Apr. 2005), http://www.virginiainstitute.org/viewpoint/2005_04_2.html.

15. Richard A. Posner, *Utilitarianism, Economics, and Legal Theory*, 8 J. LEGAL STUD. 103, 105 (1979).

16. Bart Verspagen, *University Research, Intellectual Property Rights and European Innovation Systems*, EINDHOVEN CENTRE FOR INNOVATION STUDIES 4 (Eindhoven Centre for Innovation Studies, Working Paper No. 06.05, 2006), http://cms.tm.tue.nl/Ecis/Files/papers/wp2006/wp0605.pdf.

17. AM. BAR ASS'N, INTELLECTUAL PROPERTY AND ANTITRUST HANDBOOK 127–29 (2007).

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

19. William J. Baumol, *On the Proper Cost Tests for Natural Monopoly in a Multiproduct Industry*, 67 AM. ECON. REV. 809, 810 (1977); RUBEN LEE, RUNNING THE WORLD'S MARKETS: THE GOVERNANCE OF FINANCIAL INFRASTRUCTURE 19 (2011).

20. R. Hewitt Pate, Acting Assistant Att'y Gen., Dep't of Justice, Address Before the American Intellectual Property Law Association 2003 Mid-Winter Institute (Jan. 24, 2003), https://www.justice.gov/atr/public/speeches/200701.htm.

21. *See, e.g.*, JEFFREY M. PERLOFF, MICROECONOMICS 394 (6th ed. 2012) (outlining utilities as the archetypical natural monopoly, where it is inefficient for many firms to invest large capital achieving a network grid only to serve a handful of customers than it is for a

A desire to encourage innovation is the economic philosophy driving intellectual property law in general, and patent law specifically.[22] A patent's grant of exclusivity effectively prioritizes dynamic efficiency (maximizing output over time) over static efficiency (maximizing output at a given time).[23] The resulting economy is characterized by large interbrand competition (competition between product lines), but small intrabrand competition (competition within product lines).[24]

The disclosure requirement is an especially useful theoretical construct serving the goal of innovation. This element obliges the patent applicant to describe the invention in detail sufficient to enable a person having ordinary skill in the art ("PHOSITA") to replicate and operate the invention.[25] Independent from the incentive to produce the invention, the disclosure requirement encourages dissemination of knowledge and prevents wasteful innovative efforts.[26] An inventor is encouraged to release the invention as quickly as possible, facilitating subsequent and cumulative innovations.[27] The relationship between innovation and disclosure best reflects the patent system's global desire to balance the rights of individuals with the public interest.[28]

B. Antitrust Regime

Liability under Section 2 of the Sherman Act requires a concurrent finding of monopolistic power and exclusionary conduct.[29] Without monopoly power, a firm charging supracompetitive prices will be disciplined by vertical and horizontal market forces.[30] Without the requirement of monopolistic conduct, the antitrust laws would devolve into a system of "big is bad," indiscriminately punishing procompetitive and anticompetitive firms alike.[31]

A product and geographic market is determined by measuring cross-elasticity of demand using a small but significant non-transitory increase

concentrated group of firms to share a network and compete in services).

22. *See* Mazer v. Stein, 347 U.S. 201, 219 (1954).

23. POSNER, *supra* note 18, at 38; WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 20–21 (2003).

24. AM. BAR ASS'N, *supra* note 17, at 93.

25. Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 902 (2004); Corinne Langinier & GianCarlo Moschini, *The Economics of Patents: An Overview* 3 (Center for Agricultural and Rural Development, Working Paper 02-WP 293, 2002), http://ageconsearch.umn.edu/bitstream/18374/1/wp020293.pdf.

26. Langinier & Moschini, *supra* note 25, at 5.

27. *See id.* at 10–13.

28. *See* LANDES & POSNER, *supra* note 23, at 13–14.

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

30. *See* Telex Corp. v. Int'l Bus. Machs. Corp., 510 F.2d 894, 913, 917 (10th Cir. 1975) (describing how economic forces react and respond to anticompetitive game theory moves).

31. *See* United States v. Aluminum Co. of Am., 148 F.2d 416, 430 (2d Cir. 1945).

in price ("SSNIP") analysis. If prices can be increased by a hypothetical monopolist by 5% for six months without resulting in considerable consumer shifts, that product or geography will be deemed an independent market.[32] A firm possesses monopoly power in a relevant product and geographic market if it has a market share of roughly 60–70% or if the firm is able to durably raise prices and restrict output in accordance with a SSNIP analysis.[33] This is a mixed analytical and empirical inquiry.

With the exception of a few inherently (*per se*) illegal acts, a firm's conduct will be found to be exclusionary when the anticompetitive effects on consumers and the competitive process outweigh the procompetitive effects.[34] Use of market power to raise prices above, or lower output below, the market equilibrium price point grants a firm monopolistic rents while sacrificing consumer and producer surplus.[35] This ability of a monopolistic firm to impose deadweight loss on the economic system as a whole is the primary concern for antitrust enforcement authorities.[36]

The federal government ordinarily brings antitrust suits either through the Department of Justice's Antitrust Division ("DOJ") or the Federal Trade Commission's Bureau of Competition ("FTC"). The DOJ has authority to enforce the Sherman Act and the FTC's authority under Section 5 of the Federal Trade Commission Act is coextensive in its reach.[37] Despite this overlapping jurisdiction, the FTC typically regulates the pharmaceutical industry in non-criminal cases (criminal antirust cases are within exclusive DOJ jurisdiction).[38] A state's attorney general can also file a suit on behalf of its citizens (*parens patriae*) under the Sherman Act.[39] Private citizens may bring their own actions under the Clayton Act, but only if they survive the high threshold for demonstrating standing, causation, and the presence of an antitrust

32. United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 400, 422 (1956).

33. Syufy Enters. v. Am. Multi-Cinema, Inc., 793 F.2d 990, 995-96 (9th Cir. 1986); Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc., 784 F.2d 1325, 1335–36 (7th Cir. 1986); *E.I. du Pont*, 351 U.S. at 422.

34. *See* United States v. Microsoft Corp., 253 F.3d 34, 59 (D.C. Cir. 2001) (indicating the focus of anticompetitive conduct); *but see* Olympia Equip. Leasing Co. v. W. Union Tel., 797 F.2d 370, 379 (7th Cir. 1986) (excluding harms to competitors as a focus of anticompetitive conduct).

35. KEVIN S. MARSHALL, THE ECONOMICS OF ANTITRUST INJURY AND FIRM-SPECIFIC DAMAGES 48 (2008).

36. Christopher R. Leslie, *Antitrust Damages and Deadweight Loss*, 51 ANTITRUST BULL. 521, 527, 529 (2006).

37. KEITH N. HYLTON, ANTITRUST LAW: ECONOMIC THEORY AND COMMON LAW EVOLUTION 47–48 (2003); 15 U.S.C. § 45 (2012).

38. ROBERT F. LEIBENLUFT ET AL., *United States*, *in* PHARMACEUTICAL ANTITRUST 188 (Marleen Van Kerckhove ed., 2014).

39. AM. BAR ASS'N SECTION OF ANTITRUST LAW, STATE ANTITRUST ENFORCEMENT HANDBOOK 13 (2d ed. 2008).

injury.[40] A monopolistic firm will typically defend a Section 2 antitrust suit by either broadening the market definition to dilute its market power or by defending the procompetitive effects of its conduct as outweighing the anticompetitive effects on the market.[41] A victorious plaintiff is entitled to treble damages and reimbursement for the cost of the suit.[42] The equitable reach for an antitrust judgment can range from an injunction to divestiture, as the presiding court will attempt to close all present and future avenues for anticompetitive conduct.[43]

Antitrust enforcement is primarily concerned with limiting anticompetitive uses of market power.[44] The evolving jurisprudential discipline has deemed social, political, and moral dimensions to be outside the scope of enforcement, leaving the preservation of economic efficiency as the principal theme justifying antitrust intervention.[45] Despite the totalizing language of Section 2, modern enforcement targets only those exercises of monopoly power that have been found to be unreasonable.[46] Structuring an economy based on liberty and revealed preference, the antitrust laws have been hailed as the "Magna Carta of free enterprise."[47]

C. Pendular Coevolution

Although patent authority originated with the 1787 U.S. Constitution, the 1790 Patent Act established the first statutory grant of exclusive rights lasting for the duration of fourteen years.[48] One hundred

40. *See* Ill. Brick Co. v. Illinois, 431 U.S. 720, 748 (1977); Blue Shield of Va. v. McCready, 457 U.S. 465, 470 (1982); Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977).

41. United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 389–405 (1956); United States v. Microsoft Corp., 253 F.3d 34, 59–60 (D.C. Cir. 2001).

42. 15 U.S.C. § 15(a) (2012).

43. *See* 15 U.S.C. § 16 (2012); United States v. Grinnell Corp., 384 U.S. 563, 577 (1966); Int'l Salt Co. v. United States, 332 U.S. 392, 400 (1947).

44. *See* RICHARD A. POSNER, ANTITRUST LAW 2 (2nd ed. 2001).

45. *See generally* Joshua D. Wright & Douglas H. Ginsburg, *The Goals of Antitrust: Welfare Trumps Choice*, 81 FORDHAM L. REV. 2405 (2013).

46. *Compare* 15 U.S.C. § 2 (2012), *with* United States v. Am. Tobacco Co., 221 U.S. 106, 178 (1911) (representing a shift in antitrust jurisprudence away from the literal textual construction of the statute and towards a functional constructive reading-in of unreasonableness).

47. United States v. Topco Assocs., Inc., 405 U.S. 596, 610 (1972); *see also* N. Pac. Ry. Co. v. United States, 356 U.S. 1, 4 (1958) ("the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while [preserving] our democratic political and social institutions"); Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978) ("The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.").

48. *See* P. J. Federico, *Operation of the Patent Act of 1790*, 85 J. PAT. & TRADEMARK

years later, the Sherman Antitrust Act of 1890 passed with overwhelming support from consumers and small businesses.[49] Despite being, in part, a response to collusion within major American steel and oil industries, early Sherman Act enforcement did not subject patents to antitrust scrutiny because it stood to reason that the very object of a patent is to establish a legal monopoly.[50] This approach of absolute judicial deference, in the face of "substantial overreaching by intellectual property owners," continued until the 1920s.[51] The 1890s–1920s could be summarized as an era of *absolute patent primacy*. During this period, antitrust was still in its infancy and courts were cautious about encroaching on longstanding property privileges.

Antitrust law did not truly begin to question the legitimacy of a patentee's monopoly until the early twentieth century, as demonstrated by the 1917 Supreme Court case, *Motion Picture Patents Co. v. Universal Film Manufacturing Co*.[52] In that case, a patented film projector was sold with an additional restriction that the invention could only be used with approved films.[53] The Court concluded that the function of scoping a patent claim was to provide bounds for the intellectual property, and tying the patented product to an unpatented product would effectively circumvent this process.[54] Although the antitrust laws were not directly implicated, the injury analysis of an overextended patent monopoly signaled the beginning of antitrust scrutiny of intellectual property protections.

In the 1942 case, *Morton Salt Co. v. G.S. Suppiger Co.*, the Supreme Court held that equity courts will be unavailable for holders who misuse their patents to create unlawful monopolies in the restraint of commerce.[55] The issue of whether an infringement cause of action was available prevented the court from determining whether the patentee violated the Clayton Act.[56] However, denial of relief was grounded on the basis that it is against public policy to aid the maintenance of an unlawful monopoly.[57] This marked the pendulum's swing away from patent deference, towards a sophisticated economic analysis of a monopolist's use of market power.

OFF. SOC'Y 33 (2003).

49. *See* THE POLITICAL ECONOMY OF THE SHERMAN ACT: THE FIRST ONE HUNDRED YEARS 3–8 (E. Thomas Sullivan ed., 1991).

50. E. Bement & Sons v. Nat'l Harrow Co., 186 U.S. 70, 91 (1902).

51. HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW 1-16.1 (Supp. 2013).

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

53. *Id.* at 506–08.

54. *Id.* at 511–19.

55. Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 488, 491–94 (1942).

56. *Id.* at 494.

57. *Id.* at 493.

The shift from antitrust immunity to antitrust scrutiny between the 1920s and 1970s is best demonstrated by two Supreme Court cases: *Automatic Radio Man v. Hazeltine Research* (1950) and *Zenith Radio Corp. v. Hazeltine Research* (1969).[58] These cases, almost twenty years apart, involving the same defendant and nearly identical conduct, indicated a greater application of antitrust doctrine to patent law. In both cases, Hazeltine granted blanket licenses to its enormous pool of radio patents and charged, as a royalty, a percentage price of the radios that the licensee sold.[59] This percentage price was fixed, and did not adjust in accordance with how many Hazeltine patents were accessed.[60] The Supreme Court upheld the former licensing agreement as voluntary and invalidated the latter as an involuntary package licensing deal, a division considered hard to maintain by some scholars.[61] One thing is clear: by the 1970s antitrust law was being used to limit unlawful extensions of patent-granted monopoly power. Over 80% of patents litigated at this time were found to be invalid and the increasing dominance of antitrust laws resulted in stringent patent review.[62] The period between the 1920s and 1980s could be known as an era of *virtual antitrust primacy*, where the monopoly-enabling regulatory regimes clashed in a manner that disfavored strong patent protections and courts often found antitrust liability.

This transition reached a climax when the DOJ released a list that became known as the "Nine No-Nos" of patent licensing.[63] The Nine No-Nos were certain practices that DOJ officials said they would consider presumptively unlawful.[64] These *per se* enforcement guidelines greatly abated the prominence of intellectual property protections, and were criticized as being economically baseless and ignorant to the procompetitive innovation incentives patents provided.[65] The

58. *Compare* Automatic Radio Mfg. Co. v. Hazeltine Research, Inc., 339 U.S. 827, 834 (1950), *with* Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135–40 (1969).

59. *See* cases cited *supra* note 58.

60. *Id.*

61. *Compare* Kenneth J. Burchfiel, *Patent Misuse and Antitrust Reform: "Blessed Be the Tie?"*, 4 HARV. J.L. & TECH. 1, 8 (1991) (supporting this distinction of compelled conditioning), *with* HOVENKAMP ET AL., *supra* note 51, at 3–24 (opposing this division as artificial and untenable).

62. Carter-Wallace, Inc. v. Davis-Edwards Pharm. Co., 443 F.2d 867, 872 (1971); ERNEST GELLHORN ET AL., ANTITRUST LAW AND ECONOMICS IN A NUTSHELL 477–78 (5th ed. 2004).

63. Richard Gilbert & Carl Shapiro, *Antitrust Issues in the Licensing of Intellectual Property: The Nine No-No's Meet the Nineties*, BROOKINGS PAPERS ON ECON. ACTIVITY, MICROECONOMICS, 1997, at 283, 284–85, n.6.

64. *Id.* at 285–86.

65. Timothy J. Muris, Former Chairman, Fed. Trade Comm'n, Remarks Before the American Bar Association Antitrust Section Fall Forum: Competition and Intellectual Property Policy: The Way Ahead (Nov. 15, 2001), http://www.ftc.gov/public-statements/2001/11/competition-and-intellectual-property-policy-way-ahead.

"overzealous" antitrust examination of patents in the 1970s mirrored the absolute superiority of patent law over antitrust doctrine at the beginning of the 1900s.[66]

Chicago-School Economics played a central role in rebalancing intellectual property and antitrust doctrine during the mid-1970s. This school of scholars lamented the technological stagnation of the decade, and espoused the dynamic innovative incentives that patents create. These market-literate lawyers and economists defended the efficiencies of market power, and are responsible for the "updated economic framework" which guides contemporary antitrust enforcement.[67]

The status quo of federal antitrust enforcement was jointly established by the DOJ and the FTC in the 1995 *Antitrust Guidelines for the Licensing of Intellectual Property* and reaffirmed in the 2007 *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition*.[68] These guidelines stress the complementary nature of the intellectual property and antitrust laws, proclaiming their joint goals as innovation and consumer welfare. In harmonizing these regimes, the enforcement guidelines state that intellectual property is to be treated as physical property for the purpose of antitrust analysis. In treating intellectual property no different than other forms of property, mere possession of a patent would not necessarily confer market power, as market power remains a prima facie element of Section 2 liability. Market power must be accompanied by exclusionary conduct which, in a rule of reason analysis, results in greater anticompetitive effects on balance than the presumed procompetitive justifications. Exceptions to the rule of reason are classic *per se* violations.[69]

If the 1790s–1920s could be understood as an era of *absolute patent primacy*, and the 1920s–1980s as an era of *virtual antitrust primacy*, the 1980s–2010s would be understood as an era of *analytical patent*

66. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 18 (2003), http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf [hereinafter THE PROPER BALANCE].

67. *Id.* at 22. By 1981 the DOJ had renounced the strict approach of the "Nine No-Nos" and the courts replaced the immutable *per se* analysis of patent licensing agreements with the flexible rule of reason. *See* Muris, *supra* note 65; United States v. Studiengesellschaft Kohle, 670 F.2d 1122 (D.C. Cir. 1981).

68. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995), http://www.justice.gov/atr/public/guidelines/0558.pdf; DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (2007), http://www.usdoj.gov/atr/public/hearings/ip/222655.pdf [hereinafter 2007 ANTITRUST GUIDELINES].

69. 2007 ANTITRUST GUIDELINES, *supra* note 68, at 10 (including horizontal price-fixing and market divisions).

primacy. This term is meant to denote that the courts routinely favor patent justifications, despite engaging in technical economic analysis. The presumed procompetitive nature of patents involves a shift in the burdens of proof favoring intellectual property holders. The circuit split between the Ninth Circuit and the Federal Circuit addresses this point, specifically whether the procompetitive presumption can be rebutted.

A defining historical moment for patent law was the establishment of the Court of Appeals for the Federal Circuit in 1982, with its exclusive jurisdiction over all appeals "relating to patents," and the explicit central mission of strengthening the patent system by providing investment-inducing stability.[70] While regional circuit law typically governs the elements of an antitrust claim, the particular question of whether and to what extent a patentee's behavior is subject to antitrust liability is adjudicated by the Federal Circuit's substantive law.[71] By extension, interlocutory appeals for preliminary injunctions,[72] which involve the potential suspension of a patent right, are governed under Federal Circuit jurisprudence.[73] Since its inception, the Federal Circuit has upheld more patents than have been upheld in any era since the 1920s.[74] The legislature did not explicitly or implicitly grant the Federal Circuit exclusive jurisdiction over the intersection of antitrust and patent law.[75] Some scholars have analogized the creation of "Federal Circuit antitrust law" through the operation of a statutory patent mandate, as the fox guarding the henhouse.[76]

70. *See* Federal Courts Improvement Act, Pub. L. No. 97-164, 96 Stat. 25 (1986) (codified as amended at 28 U.S.C. § 1295); *see also* 28 U.S.C. § 1338(a) (2012); Christianson v. Colt Indus. Operating Corp., 486 U.S. 800 (1988) (interpreting exclusive jurisdiction to include any cause of action arising under patent law or when the rights to relief substantially depend on a patent law question); PHILLIP E. AREEDA & HERBERT HOVENKAMP, *The Federal Circuit: Jurisdiction and Choice of Law in Antitrust Suits Involving Patents*, *in* ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 713 (rev. May 2015) (explaining how, in practice, the Federal Circuit jurisdiction covers enforcement rights under the Patent Act, as well as USPTO and PTAB appeals); BRUCE D. ABRAMSON, THE SECRET CIRCUIT 1, 34 (2007).

71. Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1067–68 (Fed. Cir. 1998).

72. *See, e.g.*, Univ. of Utah Research Found. v. Ambry Genetics Corp. (*In re* BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation), 774 F.3d 755 (Fed. Cir. 2014) (Myriad's appeal of the District Court's denial of its preliminary injunction).

73. Revision Military, Inc. v. Balboa Mfg. Co., 700 F.3d 524 (Fed. Cir. 2012).

74. THE PROPER BALANCE, *supra* note 66, at 20–21.

75. David T. DeZern, Note, *Federal Circuit Antitrust Law and the Legislative History of the Federal Courts Improvement Act of 1982*, 26 REV. LITIG. 457, 458–61 (2007).

76. ABRAMSON, *supra* note 70, at 296–98 ("[does the country] really want a court widely perceived as the champion of patents refereeing potential conflicts between patent law and antitrust law?").

II. BIOTECHNOLOGY CASE STUDY

In the ongoing dialogue of whether, to what degree, and in what manner monopolies should be permitted or prohibited, the biotechnology field serves as a quality and topical case study. The BRCA1/2 controversy has put the life science domain in the public square, with ardent supporters on both sides. One side claims innovation is expensive and the market for capitalization is uncertain. The other claims that natural phenomena cannot be owned and that regulatory barriers to entry are too great. A rigorous discussion of the complexities of the biotechnology industry will allow policymakers to navigate this polemic morass. Patent protections incentivize inventions of diagnostic methods and clinical therapies, but may not be necessary for exploration of the human genome. An investigation into the nature of the industry, the attributes of the market, and the history of gene patents will assist in this endeavor. Finally, a tour through the development of BRCA1/2 sequences and the *Association for Molecular Pathology v. Myriad Genetics, Inc.*, lawsuit sets the stage for the biotechnology case study of the circuit split.

A. Field Exploration

Biotechnology is defined as the manipulation of biological processes to produce useful commodities.[77] Throughout the 1960s and 1970s, the explorations into molecular biology culminated in a "new" biotechnology involving cellular and biomolecular processes.[78] The legal definition of biotechnology now incorporates this molecular scientific branch.[79] In the United States, the biotechnology industry can be divided into agricultural, industrial, medical devices, medical equipment and supplies, pharmaceutical manufacturing, and research.[80] A 2004 study indicates research biotechnology, which consists of companies in the pre-production stage, constitutes over 30% of total biotechnology employment.[81] The biomedical industry employs nearly 65% of the remaining bio-technicians.[82]

Biotechnology's industrial significance is increasing, as seen between 1994 and 2005, when the total value of publically traded

77. *Biotechnology*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/biotechnology (last visited Apr. 16, 2016).

78. DAN ERAMIAN ET AL., BIOTECHNOLOGY INDUS. ORG., BIO 2005-2006 GUIDE TO BIOTECHNOLOGY 1 (2006), http://www.bio-nica.info/biblioteca/BIO2006BiotechGuide.pdf.

79. *Biotechnology*, BLACK'S LAW DICTIONARY (10th ed. 2014).

80. TED EGAN & ELIZABETH JOHNSTON, LIFE SCIENCES IN SAN DIEGO COUNTY: THE INDUSTRY, CENTERS, OCCUPATIONS, AND EDUCATION 1 (2007), http://biotechwork.org/pages/FileStream.aspx?mode=Stream&fileId=e4ee9a56-a205-45c9-9bae-fb171c7a5419.

81. *Id.* at 4.

82. *Id.*

biotechnology companies in the United States increased from $45 billion to $311 billion.[83] The number of biotechnology patents granted annually between 1990 and 2002 increased from 1,765 to 7,763.[84] Biomedical drug and vaccine approvals increased from two in 1982 to forty in 2004.[85] One study asserts that 60% of pharmaceutical inventions owe their existence to the patent regime.[86] For fiscal year 2011, the biotechnology industry had a capital estimate of $92 million.[87] Biotechnology patents play an incontrovertibly prominent and vibrant role in the United States economy.[88]

The biomedical industry is notorious for its exorbitantly costly and protracted timetable for research and development. Gene sequencing must go through several processes, such as isolation, utilization, trials, and regulatory compliance with a timeline ranging from eight to sixteen years.[89] Myriad's research into the BRCA1/2 genes is estimated to have cost the company over $500 million in research and development expenses.[90] Myriad's patents on testing for BRCA1/2 mutations earned the firm $405.5 million in 2012, accounting for 80% of their annual fiscal revenue.[91] The uncertain and resource-intensive process versus the absolute ability to control foundational inputs underlie the gene patents debate.

Gene sequences are a unique good, compared to other patentable subject matter, because there is a complete absence of non-infringing substitutable material.[92] Gene sequences cannot be designed around and thus function as a market "bottleneck."[93] In this sense, the economic

83. ERAMIAN ET AL., *supra* note 78, at 4.

84. *Id.* at 5.

85. *Id.*

86. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32.2 MGMT. SCI. 173, 174–75 (1986).

87. *Natural Justice*, ECONOMIST (Apr. 18, 2013), http://www.economist.com/news/science-and-technology/21576377-americas-supreme-court-rule-patenting-genes-natural-justice.

88. *See* Thomas A. Hemphill, *The Biotechnology Sector and US Gene Patents: Legal Challenges to Intellectual Property Rights and the Impact on Basic Research and Development*, 39 SCI. & PUB. POL'Y 815, 816 (2012).

89. *See* CLAUDE BARFIELD & JOHN E. CALFEE, BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS 15–21 (2007) (outlining unique research and development costs to biotechnology innovations); *see also* ERAMIAN ET AL., *supra* note 78, at 6.

90. Nancie Petrucelli et al., *BRCA1 and BRCA2 Hereditary Breast and Ovarian Cancer*, GENEREVIEWS, http://www.ncbi.nlm.nih.gov/books/NBK1247/ (last updated Sept. 26, 2013); Francie Diep, *Should Companies Be Able to Patent Genes?*, POPULAR SCI. (Apr. 15, 2013), http://www.popsci.com/science/article/2013-04/should-companies-be-able-patent-genes.

91. Diep, *supra* note 90.

92. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 700 (1998).

93. *See* Lorelei Perez Westin, *Genetic Patents: Gatekeeper to the Promised Cures*, 25 T. JEFFERSON L. REV. 271, 273–81 (2002) (concluding the impossibility of an innovative work-

justifications for gene patents can be deceptively reductionist. In theory, the government grants short-term monopolies to use an invention, in exchange for incentives to discover and disclose the invention to the public sphere.[94] The ability of a firm to secure a patent significantly increases that firm's access to private capital investment markets and spurs innovations.[95]

In practice, the workings of the biotechnology industry are not so simple. Independent of the possibility of a successful lawsuit on the merits, biotechnology firms with high litigation costs often attempt to avoid patent subclasses populated with firms who maintain low litigation costs.[96] Firms enter patent areas in anticipation of surviving litigation. Thus, certain biotechnology patents can serve as a disincentive to research or develop a given field. Another quirk of the biotechnology industry has been dubbed "the tragedy of the anticommons," where multiple patent owners have the right to exclude competitors from accessing essential resources such as genes.[97] Private firms race to patent all underlying inputs, and the resulting transaction costs, strategic behaviors, and cognitive biases prevent optimal social use of the invention.

In the *Myriad* case, where isolated DNA sequences were disqualified as a patentable subject matter, a key factor in the Court's decision was an acknowledgement of the dangers of removing the human genetic code from the public sphere.[98] The function of the genetic code is an example of *real scarcity*, or scarcity which cannot be innovated around. Like the limited number of houses which can occupy a beach or the best seat in the theater, some qualities cannot be replicated. This difficulty of real scarcity, coupled with the transaction costs of seeking out patentees, creates a unique holdout problem where the assents in a blocking patent artificially inflate the positional value of dissenters.[99] These biotechnology patents grant excessive rights to gatekeepers,

around); *see also* PHILLIP E. AREEDA & HERBERT HOVENKAMP, *Intellectual Property Bottlenecks*, *in* ANTITRUST LAW, *supra* note 70, at ¶ 710b (defining bottleneck intellectual property as an item with limited availability but essential for production; broken up by equitable compulsory nonexclusive licenses).

94. Bronwyn H. Hall & Dietmar Harhoff, *Recent Research on the Economics of Patents* at 3 (Nat'l Bureau of Econ. Research, Working Paper No. 17773, 2012), http://www.nber.org/papers/w17773.pdf.

95. *Id.* at 15, 21.

96. Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J.L. & ECON. 463, 489–90 (1995).

97. *See generally* Heller & Eisenberg, *supra* note 92.

98. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116–19 (2013).

99. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, 1 INNOVATION POL'Y AND THE ECON. 119, 124–26 (2001).

resulting in underused resources and stifled innovation.[100] A firm facing a patent thicket of many overlapping patent rights from multiple patentees must face the cost of overcoming a barrage of infringement actions when deciding whether to innovate or bring a product from research to development.[101] This has been the structure of the gene patent marketplace for thirty years, since the USPTO began issuing gene patents in the 1980s. In 2013, the *Myriad Genetics* ruling disrupted this practice.[102]

A genetic patent is a negative exclusion right on the diagnostics, compositions of matter, and functional uses of a gene sequence.[103] The diagnostic dimension is referred to as a disease gene patent, because of its ability to contribute to the characterization of an individual's disease association for purposes of diagnosis or prognosis. For example, Myriad was offering BRCA1/2 diagnostic tests for $4,000 and was attempting to aggressively enforce its patent portfolio against firms selling diagnostic tests for under $1,000.[104] Disease gene patents can also be used to produce clinical therapies, either by the patent-holding firm, or by a licensed partner firm. However, since a disease gene patent covers all methods for testing a specific gene, a refusal to license does not allow any way of innovating around the monopoly.[105] This element of real scarcity is unique, as typically a market will respond by providing product substitutes when costs of acquisition become too high. Myriad exemplified this biotechnology market quirk by refusing to license the BRCA1/2 gene patent to any laboratory.[106]

In 1980, the Supreme Court ruled in *Diamond v. Chakrabarty* that the discovery of an organism as a result of the inventor's handiwork qualifies as a patentable subject matter.[107] Chakrabarty was a genetic engineer for General Electric who developed a bacterium for breaking down crude oil in oil spills.[108] The USPTO denied the patent on the

100. *Id.*

101. *See id.* at 119, 144. This problem is compounded by divergent methodologies in calculating the life of a patent. *See generally* Nicolas van Zeebroeck, *The Puzzle of Patent Value Indicators*, 20 ECON. INNOVATION & NEW TECH. 54 (2010).

102. Diep, *supra* note 90; *see Myriad Genetics,* 133 S. Ct. at 2119–20.

103. *See* Jon F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 COMMUNITY GENETICS 203 (2005).

104. Univ. of Utah Research Found. v. Ambry Genetics Corp. (*In re* BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation), 774 F.3d 755, 758 (Fed. Cir. 2014); Nick Mulcahy, *Myriad Sues 2 Competitors Offering Cheaper BRCA Testing*, MEDSCAPE (July 12, 2013), http://www.medscape.com/viewarticle/807755.

105. Merz & Cho, *supra* note 103.

106. Roxanne Nelson, *Supreme Court to Hear Challenge to BRCA Gene Patents—Again*, MEDSCAPE (Jan. 25, 2013), http://www.medscape.com/viewarticle/778197.

107. Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980).

108. *Id.* at 305.

theory that living things could not be patented.[109] The Supreme Court overruled the USPTO, reasoning that an organism could constitute a "manufacture" with sufficient human-induced innovation.[110]

In 1995, Congress passed the Biotechnology Process Patent Act, explicitly approving genetic patents that were "isolated from the body, purified, and transformed into something useful."[111] Firms raced to the proverbial anticommons to patent these foundational biotechnology inputs. Between 1980 and 2013, some 4,270 patents were filed with claims on human gene sequences, with the result that nearly 20% of identified human genes are under patent protection.[112] The procompetitive justification for this policy was the goal of promoting and controlling innovative diagnostic testing methods and clinical therapies. Indeed, the Federal Circuit had ruled in 1991 that certain parts of erythropoietin and its chemical substituents were valid patents, which extended *Chakrabarty* to explicitly include isolated genetic sequencing.[113] Some scientists have criticized the courts' designation of a gene as a patentable chemical compound, as opposed to its simultaneous function as a nonpatentable physical substance or a collection of biological information.[114] Here, it suffices to say that empirical sciences rarely fit so neatly into legal analytical categories.

B. Notorious BRCA1/2 Sequences

In 1990, researchers led by Mary King at the University of California, Berkeley, located genetic markers for breast cancer on chromosome 17 (BRCA1).[115] The next step was finding the relevant gene of interest on chromosome 17. In 1991, researchers directed by Marc Skolnick formed Myriad Genetics, Inc.[116] Myriad collaborated with the University of Utah's Cancer Registry, which propelled it into sequencing the BRCA1 locus.[117] In 1999, the USPTO approved Myriad's application

109. *Id.* at 306.

110. *Id.* at 309 (stating that an organism may involve "a product of human ingenuity"); *see also* Hemphill, *supra* note 88; *see also* Microorganism Containing Gene for Human Chorionic Somatomammotropin, U.S. Patent No. 4,447,538 (filed Feb. 5, 1982) (issued May 8, 1984).

111. Hemphill, *supra* note 88, at 816.

112. *Id.*

113. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) (reasoning that gene sequences are patentable because "[a] gene is a chemical compound . . . [which] requires that the inventor be able to define it").

114. Sandra S. Park, *Gene Patents and the Public Interest: Litigating* Association for Molecular Pathology v. Myriad Genetics *and Lessons Moving Forward*, 15 N.C. J.L. & TECH. 519, 530–31 (2014).

115. Jeff M. Hall et al., *Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21*, 250 PUBMED 1684, 1684 (1990).

116. E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S44 (2010).

117. *See* Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and*

for a patent that covered all uses of the BRCA1 gene, including various mutations, methods for detecting mutations, and diagnostic testing methods.[118] Myriad acquired a competing BRCA1 patent through a settlement with OncorMed, the company that had licensed King's genetic markers.[119] Myriad then became the sole and unambiguous owner of the isolated BRCA1 sequence. In 1994, a competing group of researchers led by Michael Stratton linked hereditary breast cancer to a gene located on chromosome 13 (BRCA2).[120] The next step was to sequence this gene. Stratton's group published an article in 1995, which claimed to contain the BRCA2 gene sequence.[121] Myriad had filed a patent application the day before Stratton's team released its article, and in 1996, Myriad published an article claiming Stratton's sequence was incomplete.[122] In 1998 the USPTO approved Myriad's patents for the BRCA2 gene sequence, including methods of detecting mutations and determining diagnosis.[123] Myriad began developing BRCA1/2 tests and concurrently sent out cease-and-desist letters to competing labs.

The statistical relationships between female breast and ovarian cancer and the BRCA1/2 gene sequences are decisive. In 2014, the Surveillance, Epidemiology and End Result Program of the National Cancer Institute ("SEER") estimated nearly 22,000 new cases of ovarian cancer, accounting for over 1% of new cancer cases.[124] In the same year, SEER estimated over 230,000 new cases of breast cancer, accounting for 14% of new cancer cases, and making breast cancer the most prevalent type of cancer among women.[125] Women with BRCA1 and BRCA2 mutations are estimated to have a 57% and 49% risk, respectively, of developing breast cancer by 70 years of age.[126] Women with BRCA1/2 mutations are more likely to develop ovarian cancer by a factor of nine to thirty-five.[127]

Application of Commercial BRCA Testing, 10 HEALTH L.J. 123, 123–24 (2002).

118. Gold & Carbone, *supra* note 116, at S5-S6.

119. Eliot Marshall, *The Battle Over BRCA1 Goes to Court; BRCA2 May be Next*, 278 SCI. 1874, 1874 (1997).

120. Richard Wooster et al., *Localization of a Breast Cancer Susceptibility Gene, BRCA2, to Chromosome 13q12-13*, 265 SCI. 2088, 2088 (1994).

121. Richard Wooster et al., *Identification of the Breast Cancer Susceptibility Gene BRCA2*, 378 NATURE 789, 790 (1995).

122. Sean V. Tavtigian et al., *The Complete BRCA2 Gene and Mutations in Chromosome 13q-linked Kindreds*, 12 NATURE GENETICS 333, 333 (1996).

123. Gold & Carbone, *supra* note 116, at S6.

124. *Surveillance, Epidemiology, and End Results Cancer Statistics Fact Sheets: Ovary Cancer*, NAT'L CANCER INST., http://seer.cancer.gov/statfacts/html/ovary.html (last visited Apr. 9, 2016).

125. *Id.*

126. AM. CANCER SOC'Y, BREAST CANCER FACTS & FIGURES 2009-2010, 11, http://www.cancer.org/acs/groups/content/@nho/documents/document/f861009final90809pdf.pdf

127. Robert Cook-Deegan et al., *Impact of Gene Patents and Licensing Practices on*

For Myriad, enforcing its exclusive right to engage in diagnostic testing is a core component of its business model, a component that had originally encouraged its investors' endowments.[128] Myriad began with the backing of the University of Utah's Center for Genetic Epidemiology, receiving its first contribution of $5 million from the National Institute of Health.[129] In 1993, Myriad raised $10 million in private stock offerings, including $1 million in equity from the pharmaceutical company Eli Lilly and Company.[130] Eli Lilly provided another $1.8 million between 1993 and 1996 to search for diagnostic tests and clinical therapies associated with BRCA1/2. As these expectation-infused investments are precisely the *ex ante* aims of the patent regime, it appears inconsistent to criticize the *ex post* enforcement of these rights.[131]

Between 1998 and 2008, public sentiment turned against Myriad and its intellectual property enforcement practices.[132] The anti-Myriad coalition has been recorded as "the first genetic-rights movement in history."[133] A vocal minority espoused the belief that since these genes naturally occur in all people, Myriad's patents constituted an allowance for corporations to own an individual's genetic material as a commodity.[134] Some worry about this ownership resulting in vulnerable parts of society being priced out of their own DNA.[135] A firm who monopolizes an essential facility of research would be able to stunt innovation through a policy of denying competitor licenses. Ultimately, the costs of Myriad's two-gene screening test, coupled with its aggressive patent enforcement scheme led the American Civil Liberties Union ("ACLU") to file suit on behalf of the Association for Molecular Pathology ("AMP").[136]

Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers with Colon Cancers, 12 GENETICS MED. S15, S19 (2010).

128. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 230 (S.D.N.Y. 2010).

129. Gold & Carbone, *supra* note 116, at S5; Bryn Williams-Jones & Janice E. Graham, *Actor-Network Theory: A Tool to Support Ethical Analysis of Commercial Genetic Testing*, 22 NEW GENETICS & SOC'Y 271 (2003).

130. Gold & Carbone, *supra* note 116, at S41.

131. *Schoen*, *supra* note 13 (outlining investment uncertainty as a key goal of the patent regime).

132. Andrew Pollack, *Gene Patent Ruling Raises Questions for Industry*, N.Y. TIMES (Nov. 1, 2010), http://nyti.ms/1SSFdqu.

133. Tamar Lewin, *Move to Patent Cancer Gene Is Called Obstacle to Research*, N.Y. TIMES (May 21, 1996), http://nyti.ms/1SSFaee.

134. Jane Zones, *Taking Our Bodies Back: The Fight Against Gene Patenting*, WOMEN'S HEALTH ACTIVIST, Nov.–Dec. 2010, at 5.

135. *See* Lizzy Ratner, *Our Bodies, Their Cells?*, AM. PROSPECT (June 11, 2013), http://prospect.org/article/our-bodies-their-cells.

136. *See* David B. Agus, *The Outrageous Cost of a Gene Test*, N.Y. TIMES (May 20, 2013), http://nyti.ms/14KY7bG; John Schwartz & Andrew Pollack, *Judge Invalidates Human*

Joined by the Public Patent Foundation, the ACLU filed suit against Myriad for patenting genes as expressed products of nature. The district court invalidated seven patents related to BRCA1/2, calling the isolation of a genomic sequence a "lawyer's trick" to circumvent the non-patentable subject matter of DNA.[137] Setting the DNA in an isolated form neither fundamentally alters the quality of DNA nor the information it encodes. This was the first time a court had invalided a genetic patent.[138] This ruling called into question two thousand human genetic patents, thirty years of jurisprudence, as well as the fundamentals of the American invention protection regime.[139] Myriad immediately appealed and the Federal Circuit reversed.[140] The Federal Circuit reasoned that composition-of-matter claims on gene sequences like BRCA1/2 were patent eligible, requiring a degree of human ingenuity in their isolation. The Supreme Court granted certiorari on the case, vacated the Federal Circuit's decision, and remanded the case for reconsideration in light of the *Mayo* test.[141]

In 2012, the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[142] Prometheus had developed a method for calibrating proper dosing of a thiopurine drug. The invention would determine whether concentrations of certain metabolites in the blood would make it likely that a certain dosage would be either ineffective or cause harm.[143] The Supreme Court found the pathway by which thiopurine is metabolized to be a natural process, and just like the law of gravity, outside the scope of patentable subject matter.[144] The Federal Circuit had ruled that the addition of substantial physical limitations required an element of creation.[145] The Supreme Court viewed these additional elements as insufficient to transform the natural law into a process that was patentable, in part because the nature of this

Gene Patent, N.Y. TIMES (Mar. 29, 2010), http://nyti.ms/1LjR4L6; *see also* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 204–06 (S.D.N.Y. 2010).

137. Ass'n for Molecular Pathology, 702 F. Supp. 2d at 185.

138. *Patents On Breast Cancer Genes Ruled Invalid in ACLU/PubPat Case*, ACLU (Mar. 29, 2010), https://www.aclu.org/free-speech-womens-rights/patents-breast-cancer-genes-ruled-invalid-aclupubpat-case.

139. *Id.*

140. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1380 (Fed. Cir. 2011) (finding the isolated DNA was "markedly different" in its chemical structure from the continuous strand found in nature).

141. Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, Inc. 132 S. Ct. 1794 (2012) (granting petition for writ of certiorari, vacating the judgment of the Federal Circuit, and remanding the case for further consideration).

142. *Mayo,* 132 S. Ct. at 1289.

143. *Id.* at 1294–95.

144. *Id.* at 1298–1301.

145. *Id.* at 1302–1303.

modification was well known by those in the industry.[146] On these grounds, the Supreme Court vacated and remanded *Myriad* to the Federal Circuit.[147] The remand was a signal that the Supreme Court considered "trivial noninventive transformation[s]" insufficient for patent qualification.[148] The *Mayo* test requires a patent to involve an "inventive concept" beyond "well understood, routine, conventional activity previously engaged" by a PHOSITA.[149] The concern was not allowing patents to create ownership of knowledge previously dedicated to the public.[150]

In August 2012, the Federal Circuit reaffirmed its prior ruling in the *Myriad* case under the *Mayo* test, determining that isolated genomic sequences such as BRCA1/2 constituted patentable subject matter, although methods of "comparing" or "analyzing" DNA sequences would not be transformative enough to exceed the abstract mental processes bar.[151] Again, the Federal Circuit found that isolated strands are not naturally occurring. Of concern was the erosion of incentives to invent around and innovate upwards, by "rop[ing] off far-reaching areas of patent eligibility."[152] In November 2012, the Supreme Court granted certiorari on the issue of Myriad's BRCA1/2 patents.[153] The resulting case has become "a watershed moment for the biotechnology industry."[154]

In June 2013, the Supreme Court ruled in *Myriad* that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated."[155] Myriad claimed that its sequences were distinct from those occurring in the natural world, because their isolated forms have been identified, snipped from the genome string, and chemically altered to allow laboratory analysis.[156]

146. *Id.* at 1297 (ruling that applying natural law is unpatentable unless it involves a significant inventive concept).

147. Ass'n for Molecular Pathology v. Myriad Genetics, Inc. 132 S. Ct. 1794 (2012); Dennis Crouch, *Mayo v. Prometheus: Natural Process + Known Elements = Normally No Patent*, PATENTLY-O (Mar. 20, 2012), http://patentlyo.com/patent/2012/03/mayo-v-prometheus-natural-process-known-elements-normally-no-patent.html (applying *Mayo* finding that natural processes plus known elements are not patentable).

148. Andrew Pollack, *Justices Send Back Gene Case*, N.Y. TIMES (Mar. 26, 2012), http://nyti.ms/2689JGG.

149. *Mayo*, 132 S. Ct. at 1294–1300.

150. *Id.* (fearing patents being used to "preempt the use of a natural law").

151. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1337 (Fed. Cir. 2012).

152. *Id.* at 1333.

153. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694, 695 (2012).

154. Thomas J. Engellenner, *United States: Myriad - One Year Later*, MONDAQ (June 23, 2014), http://www.mondaq.com/unitedstates/x/322282/Patent/Myriad+One+Year+Later.

155. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013).

156. Mansfield, *supra* note 86, at 176.

Invalidating five of Myriad's genetic patents, the *Myriad* ruling stands for the proposition that separating a sequence from its surroundings does not itself constitute an innovation.[157] However, this rule does not pertain to cDNA, which is produced in a lab.[158] cDNA is generated DNA, artificially synthesized from messenger ribonucleic acid ("mRNA") transcripts, using an enzyme known as reverse transcriptase.[159] The chief difference between DNA and RNA is the latter constitutes a single strand of nucleic acids while the former is double stranded. Since cDNA is synthesized from a mature mRNA stand, which has already undergone splicing and post-transcriptional modification in the nucleus, its sequence is not identical to the naturally occurring gene that initially coded it. This is precisely why cDNA is used for cloning or as a probe for locating specific genes.[160] Due to the Supreme Court's narrow *Myriad* holding affecting the validity of DNA but not cDNA, Myriad retained 515 of its 520 patents.[161] The Court noted that gene sequences are unique among patentable subject matters because they cannot be designed around.[162] Specifically, there are no available non-infringing substitutes for a gene sequence through which competitors can innovate.[163] This real scarcity nature of the gene sequence product allows the patent holder to obtain an instant monopoly in the relevant market, and a bottleneck effect in subsequent markets. The *Myriad* Court was clearly attuned to the anticompetitive market effects of a legally granted patent on an ineligible subject matter.

On the same day the Supreme Court decided *Myriad*, Ambry Genetics Corp. announced that it would release its own version of the BRCA1/2 test, priced significantly lower than Myriad's test.[164] Consistent with its history of aggressive patent enforcement, Myriad swiftly filed suit alleging patent infringement, and Ambry countersued claiming violation of the antitrust laws.[165] The antitrust claim alleged

157. *See Myriad Genetics*, 133 S. Ct. at 2107.

158. *Id.*

159. ERAMIAN ET AL., *supra* note 78, at 140.

160. *Id.*

161. *Myriad Genetics*, 133 S. Ct. at 2107; Brian Resnick, *Why Is Myriad Genetics Still Filing Patent Suits for Breast-Cancer Tests?*, ATLANTIC (Aug. 8, 2013), http://www.theatlantic.com/politics/archive/2013/08/why-is-myriad-genetics-still-filing-patent-suits-for-breast-cancer-tests/454197/ .

162. *Myriad Genetics*, 133 S. Ct. at 2116–2119.

163. Jolene S. Fernandes, *Duty to Deal: The Antitrust Antidote to the Gene Patent Dilemma*, 3 UC IRVINE L. REV. 431, 433-34 (2013).

164. Imron T. Aly & A. Taylor Corbitt, *Myriad Faces Yet Another Patent Eligibility Battle in Return to the Federal Circuit*, NAT'L L. REV. (Oct. 8, 2014), http://www.natlawreview.com/article/myriad-faces-yet-another-patent-eligibility-battle-return-to-federal-circuit.

165. Univ. of Utah Research Found. v. Ambry Genetics Corp. (*In re* BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation), 774 F.3d 755, 758 (Fed. Cir. 2014); Kevin E. Noonan, *Myriad Moves to Dismiss Ambry's Antitrust Counterclaims on Noerr-*

Myriad was engaging in a *Walker Process*-based sham litigation with knowledge that the patents were invalid.[166] However, Ambry did not allege facts with sufficient particularity,[167] and the antitrust action was dismissed.[168] Without possessing facts evincing sham litigation, fraud on the USPTO, or an objectively baseless claim, the antitrust countersuit could not survive.[169]

Myriad proceeded by filing a preliminary injunction, to both halt the immediate alleged patent infringements during the course of litigation and to test its ability to succeed on the merits of its claim.[170] The District Court applied the four point standard for evaluating whether a preliminary injunction should be applied: (1) whether the patentee has established a likelihood of success on the merits, (2) whether the patentee has established that they will be irreparably harmed if the injunction is not issued, (3) that the balance of the hardships is in the patentee's favor, and (4) that the public interest is not harmed if the court grants the injunction.[171]

The only factor which Myriad was able to demonstrate was the second, "irreparable harm."[172] The court analyzed Ambry as a feasible market entrant to determine damages, in preparation for circumstances that Myriad would succeed on the merits. The court decided the fourth "public interest" factor was in neither party's favor, finding the justification to be too ephemeral to decisively weigh for either party.[173] The third "balance of hardship" factor seemingly swamped the second, where the court ruled that, notwithstanding the grant that Myriad would suffer irreparable harm, the hardship balance tilted in Ambry's favor. Myriad's longstanding exclusive BRCA1/2 monopoly, with its fortunate

Pennington Doctrine, PATENT DOCS (Aug. 28, 2013), http://www.patentdocs.org/2013/08/myriad-moves-to-dismiss-ambrys-antitrust-counterclaims-on-noerr-pennington-doctrine.html.

166. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 175–77 (1965); Kevin E. Noonan, *Defendants' Oppose Myriad's Motion to Dismiss Antitrust Counterclaims*, PATENT DOCS (Oct. 28, 2013), http://www.patentdocs.org/2013/10/defendants-oppose-myriads-motions-to-dismiss-antitrust-counterclaims.html.

167. *See* Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007); Ashcroft v. Iqbal, 556 U.S. 662 (2009) (requiring a party to initially distinguish pled facts accepted as true in the light most favorable to the nonmoving party and filter out legal conclusions that are not accepted as true).

168. Noonan, *supra* note 166; FED. R. CIV. P. 12(b)(6) ("failure to state a claim upon which relief can be granted").

169. Trs. of Univ. of Pa. v. St. Jude Children's Research Hosp., 940 F. Supp. 2d 233, 247 (E.D. Penn. 2013).

170. Univ. of Utah Research Found. v. Ambry Genetics Corp. (*In re* BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.), 3 F. Supp. 3d 1213, 1248–49 (D. Utah 2014).

171. *Id.*

172. *Id.* at 1249–56.

173. *Id.* at 1275–76.

revenue projections, market strength, product expertise, and brand name recognition were dispositive factors.[174]

The first factor was the most revealing, where the court determined that Myriad was unlikely to succeed on the merits of its claim.[175] Here, the court conducted a truncated assessment of the claim, which would prove revealing for both parties. The court held that despite the theoretical incentives surrounding the gene patent debate, the practical result of Myriad's licensing and patent enforcement strategy has been to "hinder or halt follow-up research, data sharing, patient testing, and the creation of additional and more affordable" BRCA1/2 technologies.[176] The theoretical justification relied upon by the court manifestly prioritizes the art of invention over the labor of discovery.[177] Myriad filed an interlocutory appeal that was affirmed on similar grounds.[178] The antitrust question remains: Are there any viable causes of action for an intellectual property monopolist anticompetitively refusing to license a patent?

III. CIRCUIT SPLIT

Under what circumstances can an inventor be obligated to license her patent to a competitor? If a patent is validly obtained, does the patentee face antitrust scrutiny or enjoy antitrust immunity? Does a competitor have a right to refuse or a duty to deal? These are the central questions that divide the Ninth Circuit and Federal Circuit. The common law *Colgate* doctrine regards the privilege of choosing with whom to transact as a core tenant of the antitrust laws and the free enterprise system those laws are designed to protect. *Aspen Skiing* laid out a qualification to this right to refuse by imposing a duty to deal when there is evidence of anticompetitive malice. *Trinko* narrowed the duty to deal doctrine, giving ideological and pragmatic primacy to a competitor's

174. *Id.* at 1273–75.

175. *Id.* at 1256–1273; *see also* John Conley, *District Court Denies Myriad's Preliminary Injunction Against Ambry*, GENOMICS L. REP. (Mar. 18, 2014), http://www.genomicslawreport.com/index.php/2014/03/18/district-court-denies-myriads-preliminary-injunction-against-ambry/.

176. *Univ. of Utah Research Found.*, 3 F. Supp. 3d at 1276 ("Myriad distorts rather than serves the patent system's goal of public disclosure in exchange for exclusive rights . . . . Myriad has chosen a commercial path that turns much of our patent system policy on its head"); *see also* Brief for Am. Civil Liberties Union et al. as Amici Curiae Supporting Appellee, Univ. of Utah Research Found. v. Ambry Genetics Corp., 3 F. Supp. 3d 1213 (Fed. Cir. 2014) (Nos. 14-1361-1366).

177. Robert Cook-Deegan & Annie Niehaus, *After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents*, 2.4 CURRENT GENETIC MED. REPS. 223 (2014).

178. Conley, *supra* note 175; Univ. of Utah Research Found. v. Ambry Genetics Corp. (*In re* BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation), 774 F.3d 755 (Fed. Cir. 2014).

right to refuse. As these notions pertain to patents, the Ninth Circuit reasons that evidence of pretextual business justifications can rebut the procompetitive presumption of a patent. The Federal Circuit has taken the position that the procompetitive presumption of a patent is near absolute, and this presumption can only be rebutted by evidence that the patent was acquired or maintained fraudulently. The state of Federal Circuit antitrust law influences both the adjudication decisions of lower courts as well as filing decisions by prospective litigants.

A. Common Law Foundations

Because its seminal statute remains unchanged since it was written in the late nineteenth century, antitrust law is almost entirely judge-made. Retreating from the literalism of the Sherman Act drafters by imbuing an implied reasonableness requirement, modern antitrust jurisprudence coheres with empirical economic thinking and American free market principles. Capitalism encourages maximum diversification of products, by which consumers reveal their preference through buying patterns, and this selection process signals to manufacturers which methods should be replicated.[179] This model of *diversification, selection, and reproduction* produces diversification on a higher level of selection. Through this system, society is offered the best quality pencils, haircuts, and clothing. Price wars between competitors fighting for market share result in the lowest consumer prices. It is in this spirit that the right to refuse emerges. The competitive system of horizontal and vertical pressures is ultimately maintained by the arm's length bargaining of market participants such as consumers, retailers, manufacturers, producers, and developers. The logic of using a firm's intent to harm the competitive process as a basis for antitrust injury could be applied to the Myriad scenario, where refusing to license a patent results in the wholescale degradation of the market.[180] The right to refuse is classically given prevalence over the narrowly constructed and imposed duty to deal.

Under what has come to be known as the *Colgate* doctrine, a firm generally has the right to unilaterally determine with whom it conducts business.[181] The 1919 *United States v. Colgate & Co.* case involved a manufacturer attempting to effectuate a price maintenance scheme by refusing to deal with retailers who sold below the suggested price. The Court reasoned that the retailer's ability to switch manufacturers negated

179. *Capitalism*, BLACK'S LAW DICTIONARY (10th ed. 2014).

180. *In re* LIBOR-Based Fin. Instruments Antitrust Litig., 935 F. Supp. 2d 666, 687 (S.D.N.Y. 2013); Sharon E. Foster, *Harm to Competition and the Competitive Process: A Circular Charade in the Libor Antitrust Litigation*, 10 BYU INT'L L. & MGMT. REV. 91 (2014).

181. United States v. Colgate & Co., 250 U.S. 300, 305 (1919).

the harms of vertical price restraints.[182] The theory rests on the maximum facilitation of *transactional permeability*. This system, where buyers and sellers are freely able to switch inputs, pressures each individual firm to offer premium rates and commodities. Through these interactions, firms become price takers to consumer price makers. A critical assumption is that all firms have access to market inputs.[183]

Nearly sixty-five years later, the Supreme Court ruled that this right to refuse to deal is not absolute, but qualified by certain circumstances in which a firm may have an affirmative duty to deal with competitors. The seminal case for this proposition is *Aspen Skiing v. Aspen Highlands Skiing*, where a defendant corporation owned three of the four destination resort ski mountains in Aspen, Colorado and refused to reissue a joint pass with the fourth mountain.[184] The *Aspen Skiing* Court was particularly interested in the fact that the defendant had voluntarily commenced the joint Aspen lift ticket, pursued the profitable joint venture for years, and then ceased the joint action in an attempt to eliminate a competitor.[185] Additionally, the defendant made the crucial mistake of rejecting cash vouchers issued by its competitor as part of a replacement pass, presumably calculating that its monopoly rents would be higher if the fourth mountain went out of business.[186] Refusing to accept the liquidated capital exchange made it difficult for the defendant to argue a procompetitive justification for its refusal to deal.[187] A key issue in *Aspen Skiing* was this imputed motive of the defendant firm.[188]

Nearly twenty years later, the Supreme Court clarified *Aspen Skiing*'s ruling as the outer bounds of Section 2 liability.[189] In *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, Verizon was a telephone service provider who had refused to provide AT&T sufficient access to its systems, as mandated by the Telecommunications Act of 1996.[190] The Court found no "dreams of monopoly" by Verizon and distinguished *Aspen Skiing* by indicating that Verizon had no prior dealings to evidence malicious intent.[191] The Court placed a "high value" on the right to refuse to deal, although it acknowledged that the right was not unqualified.[192] The *Trinko* Court, recognizing the inherent dangers of

182. *Id.* at 304–08.

183. Westin, *supra* note 93, at 281–82.

184. Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 589 (1985).

185. *Id.* at 608–609.

186. *Id.* at 609–611.

187. *Id.* at 610–611

188. *Id.*

189. Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP. (*Trinko*), 540 U.S. 398, 409 (2004).

190. *Id.* at 398.

191. *Id.* at 409.

192. *Id.* at 408 ("[T]he high value that we have placed on the right to refuse to deal with

compelling collusion as contrary to the goals of the antitrust statute, found no Section 2 liability under the duty to deal.[193] Finding sufficient grounds to rule on the matter, the court proceeded to defer addressing the essential facilities doctrine.[194]

The circumstances under which a patent-holding firm has the *Colgate* right to refuse or the *Aspen Skiing* duty to deal with a competitor are uncertain, causing confusion between jurisdictions.[195] In particular, the Ninth Circuit and the Federal Circuit are split as to whether refusals to deal in intellectual property should be subject to antitrust scrutiny, and if so, what role subjective intent should play. In 2001, the Solicitor General urged the Supreme Court not to resolve this issue yet, but rather to allow the dispute to "percolate further in the courts of appeals."[196] The Supreme Court obliged in declining to hear the test case, to allow the appellate courts to flesh out the nuances of this issue. However, the development of substantive Federal Circuit antitrust law in the past two decades has quelled this discussion.[197] A categorical ban on genetic patents would devastate the biotechnology field, which is dependent on investor capital and PHOSITA disclosures to innovate.[198] Additionally, revoking patent protections for gene sequences would cause inventors to shift to trade secret protections.[199] Qualifying a competitor's right to refuse, either by establishing a duty to deal in molecular monopolies, or designating molecular monopolies as essential facilities, preserves innovation incentives and consumer welfare by striking a balance between inventors, the biomedical industry, and the general public.

other firms does not mean that the right is unqualified." (citation omitted)).

193. *Id.* at 407–8 ("Compelling such firms to share the source of their advantage is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, the rival, or both to invest in those economically beneficial facilities. Enforced sharing also requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they are ill suited. Moreover, compelling negotiation between competitors may facilitate the supreme evil of antitrust: collusion. Thus, as a general matter, the Sherman Act 'does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal.'" (citation omitted)).

194. *Id*. at 411 ("We [The Supreme Court] have never recognized such a doctrine . . . and we find no need either to recognize it or to repudiate it here. It suffices for present purposes to note that the indispensable requirement for invoking the doctrine is the unavailability of access to the 'essential facilities' . . . ." (citations omitted)).

195. Telecom Tech. Servs. Inc. v. Rolm Co., 388 F.3d 820, 826 (11th Cir. 2004) ("[T]his question lies at the intersection of intellectual property law and antitrust law and presents a difficult and increasingly important issue.").

196. Brief for the United States as Amicus Curiae Supporting Respondents, CSU, L.L.C. v. Xerox Corp., 2001 WL 34135314 (2001) (No. 00-62).

197. ABRAMSON, *supra* note 70, at 296–98.

198. David C. Hoffman, Note, *A Modest Proposal: Toward Improved Access of Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1022 (2004).

199. Fernandes, *supra* note 163, at 440.

B. Ninth Circuit Antitrust Scrutiny

The crux of the Ninth Circuit's rule is that the presumptively procompetitive status of a lawfully acquired patent can be rebutted by evidence of pretext. Both the Ninth Circuit and Federal Circuit agree that if a patent is acquired unlawfully or if the litigation process is used to restrain trade or preserve a monopoly, antitrust liability can be found on the theory that abusing equity proceedings have economic implications. The Ninth Circuit extends this logic to an anticompetitive use of patent rights. Under this line of jurisprudence, a patent holder may exclude competitors from licensing its product as long as there are not adverse effects on the market process.

In *Data General Corp. v. Grumman Systems Support Corp.*, the First Circuit analyzed whether refusals to deal in intellectual property constituted exclusionary conduct as an anticompetitive abuse of market power.[200] A computer manufacturer competed with a servicer of its parts, and began to refuse to license these essential facilities. The court found that refusals to deal can serve as the basis of antitrust liability, although exclusionary conduct alone was "a presumptively valid business justification for any immediate harm to consumers."[201] A firm has the ability to claim procompetitive justifications such as efficiencies of scale and quality control, although evidence of monopoly maintenance or thwarting new entrants would be viewed as anticompetitive.[202] Ultimately, the court ruled that there was no Section 2 violation, because the plaintiff could not overcome the rebuttable presumption granted to holders of intellectual property.[203]

The subsequent *Kodak* lawsuits (*Eastman Kodak Co. v. Image Technical Services* ["*Kodak I*"][204] and *Image Technical Services v. Eastman Kodak Co.* ["*Kodak II*"][205]) set out the source of Section 2 antitrust liability for the circuit split. Independent service organizations ("ISOs") competed with Kodak in the maintenance and repair of Kodak copiers.[206] Kodak responded by refusing to license parts to ISOs.[207] The

200. Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147 (1st Cir. 1994) *abrogated by* Reed Elsevier, Inc. v. Muchnick, 559 U.S. 154 (2010).

201. *Id.* at 1187; *see also* PHILLIP E. AREEDA & HERBERT HOVENKAMP, *Business Justification*, *in* ANTITRUST LAW, *supra* note 70, at ¶ 658f (indicating business justifications must at least be profitable to the firm, and firms need not operate as public trustees; efficiency is taken from the cost and output decisions of the firm not the market as a whole, i.e. productive not allocative efficiency).

202. *Data Gen. Corp.*, 36 F.3d at 1183 (describing countervailing *benefits* to the competitive process).

203. *Id.* at 1182.

204. Eastman Kodak Co. v. Image Tech. Servs. (*Kodak I*), 504 U.S. 451 (1992).

205. Image Tech. Servs. v. Eastman Kodak Co. (*Kodak II*), 125 F.3d 1195 (9th Cir. 1997).

206. *Kodak I*, 504 U.S. at 455.

207. *Id.*

plaintiff ISOs alleged antitrust violations, claiming monopoly tying and a unilateral refusal to deal.[208] The Supreme Court affirmed its prior rule that "[monopoly] power gained through some natural and legal advantage such as a patent, copyright, or business acumen can give rise to liability if 'a seller exploits his dominant position in one market to expand his empire into the next.'"[209] Although the Supreme Court was analyzing a Section 1 tying claim, the Ninth Circuit interpreted this to mean that "a monopolist who acquires a dominant position in one market through patents and copyrights may violate § 2 if the monopolist exploits that dominant position to enhance a monopoly in another market."[210] Putting aside the issue of discontinuity between Sections 1 and 2, the Ninth Circuit remanded the case in *Kodak II* with instructions to analyze the anticompetitive and procompetitive effects of a refusal to deal in intellectual property.[211]

The *Kodak* cases set out the Ninth Circuit test for applying a duty to deal, namely that a refusal to deal is presumed procompetitive, but that presumption is rebuttable if evidence of pretext is presented.[212] The paradigmatic example was Kodak's policy of allowing consumers to self-service their machines, while claiming that excluding competitors from servicing machines related to the machine's performance and Kodak's brand name.[213] The result of this jurisprudence is that a duty to deal exists when there are no procompetitive reasons not to deal. This ruling affirmed the "untrammeled right" of the patentee, while simultaneously limiting an essential component of that right to exclude from extending natural monopolies into separate markets.[214] In the *Microsoft* case, the D.C. Circuit analogized intellectual property protections to a baseball bat, stating that even if legitimately acquired, it may be improperly used to cause harm.[215]

Protecting consumer welfare is at the heart of this level of antitrust regulation. If patents are awarded primacy through an automatic

208. *Id.* at 459.

209. *Id.* at 479 n.29, *quoting* Times-Picayune Publ'g Co. v. United States, 345 U.S. 594, 611 (1953).

210. *Kodak II*, 125 F.3d at 1216.

211. *Id.* at 1225–26.

212. *Id.* at 1219 (defining evidence of pretext as business justifications "played no part in the decision to act").

213. *Id.* (requiring that "a reasonable trier of fact could conclude that [the {procompetitive} justification] is pretextual" (quoting *Kodak I*, 504 U.S. at 484)).

214. *Id.* at 1215 (citation omitted).

215. United States v. Microsoft Corp., 253 F.3d 34, 63 (D.C. Cir. 2001) ("[The claim that] '[i]f intellectual property rights have been lawfully acquired,' . . . then 'their subsequent exercise cannot give rise to antitrust liability' . . . . is no more correct than the proposition that use of one's personal property, such as a baseball bat, cannot give rise to tort liability . . . 'Intellectual property rights do not confer a privilege to violate the antitrust laws.'" (citation omitted)).

determination of procompetitive justifications, explicit anticompetitive conduct may be immune from antitrust scrutiny through the acquisition of intellectual property rights.[216] The risk here is that patent immunity creates implied antitrust exemptions not statutorily permitted, rather than examining the monopolist's intent as per *Trinko* jurisprudence.[217]

C. Federal Circuit Antitrust Immunity

The crux of the Federal Circuit's rule is that once a patent is legitimately acquired, no antitrust liability can result from its exercise. Exclusion of competitors is an entitlement of the patentee—a right granted by the USPTO after appropriate examinations—and market corrections should only be instituted when the patent authorization is faulty.[218] Proponents of this view claim that patent and antitrust law both deal with monopoly regulation, and thus modify each other accordingly.[219] Protecting entrepreneurial welfare is at the heart of this level of antitrust regulation.

In re Independent Service Organizations Antitrust Litigation ("*Xerox*") sets out the doctrine for intellectual property immunity for antitrust liability, with nearly identical facts to *Data General* and the *Kodak* cases.[220] Xerox, a manufacturer of photocopiers, refused to sell upstream replacement parts to ISOs who competed against Xerox in the downstream market for services.[221] The ISOs argued the Ninth Circuit logic, that a unilateral refusal to deal can unlawfully extend legitimate monopoly power, as granted by the patent, illegitimately into the service market.[222] The *Xerox* Court rejected this reasoning, finding that neither

216. Jeffrey K. MacKie-Mason, *Antitrust Immunity for Refusals to Deal in (Intellectual) Property is a Slippery Slope*, ANTITRUST SOURCE, July 2002, at 8 ("What if Aspen had a patented gear mechanism in its ski lifts?").

217. *Compare* A. Douglas Melamed & Ali M. Stoeppelwerth, *The CSU Case: Facts, Formalism and the Intersection of Antitrust and Intellectual Property Law*, 10 GEO. MASON L. REV. 407, 409–10, 425 (2002), *with* Simon Genevaz, *Against Antitrust 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, 758 (2004).

218. Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 423–24 (1908) (chronicling early cases where patent holders were awarded a "complete monopoly . . . so explicitly given . . . [with] no further explanation").

219. Simpson v. Union Oil Co. of California, 377 U.S. 13, 24 (1964) (rooting the basis for intellectual property's antitrust immunity in the theory that the regimes are "in pari materia" or upon the same subject matter and thus modify each other "pro tanto" or to that extent).

220. *See In re* Independent Serv. Organizations Antitrust Litigation (*Xerox*), 203 F.3d 1322 (Fed. Cir. 2000); Data Gen. Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147 (1st Cir. 1994) *abrogated by* Reed Elsevier, Inc. v. Muchnick, 559 U.S. 154 (2010); Eastman Kodak Co. v. Image Tech. Servs. (*Kodak I*), 504 U.S. 451 (1992); Image Tech. Servs. v. Eastman Kodak Co. (*Kodak II*), 125 F.3d 1195 (9th Cir. 1997).

221. *Xerox*, 203 F.3d at 1324.

222. *Id.* at 1326–27.

patent nor antitrust laws violate each other.[223] Absent illegal tying, fraud on the USPTO, or sham litigation, a "patent holder may . . . exclude others . . . free from liability under the antitrust laws."[224] The Court declined to inquire into the subjective motivations of anticompetitive effects, so long as the patent use did not extend beyond the patent grant.[225] The Federal Circuit interpreted the *Kodak I* footnote as confined to the Section 1 context, construing its meaning as blatantly referring to a "beyond the scope of the patent" claim.[226] Petitioners filed a writ of certiorari with the Supreme Court, but the DOJ Solicitor General urged the Court to allow the circuit courts to resolve the "considerable uncertainty," which led to the Supreme Court declining to hear the issue.[227] As the Federal Circuit is involved both as an advocate in and adjudicator of this circuit split, the discussion will likely not progress further absent a demonstration of Supreme Court wisdom.[228]

Parties and lower courts alike have followed the Federal Circuit's jurisprudence on antitrust immunity for validly acquired and maintained intellectual property in anticipation of the Federal Circuit's exclusive subject matter jurisdiction. This is demonstrated by Ambry suing Myriad solely on *Walker Process*-based sham litigation grounds, as opposed to refusal to deal or essential facility grounds. In *Schor v. Abbott Labs*, the defendant was a pharmaceutical company that manufactured AIDS drugs, which it sold to competitors at an inflated price, causing the price of its competitor's combination therapy to rise accordingly.[229] The defendant's own combination prices benefited from production economies, and lack of transaction costs. The Court ruled that a firm who has a *Colgate* right to refuse necessarily must have a right to dictate terms of sale, which essentially abolished monopoly leveraging claims.[230] The Court opined in dicta that this area of law is prime for a Supreme Court resolution.[231] Due to the Federal Circuit's interpretation of a

223. *Id.* at 1328–29.

224. *Id.* at 1327–28.

225. *Id.* at 1327 (holding that there is "no more reason to inquire into the subjective motivation of Xerox in refusing to sell or license its patented works than we found in evaluating the subjective motivation of a patentee in bringing suit to enforce that same right").

226. Eastman Kodak Co. v. Image Tech. Servs. (*Kodak I*), 504 U.S. 451, 479 n.29 (1992); *Xerox*, 203 F.3d at 1327.

227. Brief for the United States as Amicus Curiae Supporting Respondents, *supra* note 196.

228. *Cf. Xerox*, 203 F.3d at 1324 (indicating that "the patent or copyright holder's unilateral refusal to sell or license its patented invention or copyrighted expression is not unlawful exclusionary conduct under the antitrust laws, even if the refusal to deal impacts competition in more than one market."); ABRAMSON, *supra* note 70, at 296–98.

229. Schor v. Abbott Labs., 378 F. Supp. 2d 850 (N.D. Ill. 2005).

230. *Id.* at 858 ("[A] patentee's exercise of its statutorily-granted market power does not constitute a Sherman Act violation, even if such conduct affects a second market.").

231. *Id.* at 857 ("Applying the refusal to deal case law to the instant case, however, is no easy task. There is no Supreme Court precedent, and a split exists between the Ninth and

patentee's right to refuse, duty to deal claims are unlikely to succeed absent a Supreme Court clarification of the rule. Proponents of the Federal Circuit's jurisprudence claim a patentee's absolute right to refuse and the subsequent monopoly rents are crucial to incentivize innovation and long-term competition.[232] Requiring a duty to deal turns judges into regulators due to the post-trial obligations necessary to enforce such a duty. Additionally, a duty to deal creates incentives for competitors to free ride on the industry leader, debilitating the intellectual property incentives and encouraging an economy of copying rather than creation. Finally, proponents of antitrust immunity for validly acquired intellectual property rights claim the subjective intent test "is based on a false dichotomy," where seekers of intellectual property are supposed to abandon the very incentive that induced them to innovate.[233]

It seems clear that Ambry's choice of antitrust countersuit, based on allegations of *Walker Process*-based sham litigation, was the result of strategic appeal decisions.[234] Had Ambry filed a Section 2 refusal to deal claim, the Federal Circuit would have denied the claim on the basis that a patent confers an absolute monopoly if legitimately acquired. However, if the Supreme Court were to qualify the Federal Circuit's right to refuse jurisprudence by affirming the Ninth Circuit's duty to deal reasoning, Myriad might potentially be liable for a Section 2 refusal to deal violation.

IV. RESOLUTION

Using the biotechnology industry as a case study, there are two potential avenues where a duty to deal can be found. If *Myriad* were to be counterfactually adjudicated under the Ninth Circuit's jurisprudence, Myriad could have its right to refuse qualified. It would have a difficult time articulating its domination of the research market as anything but a willful maintenance of a monopoly. The diagnostic testing and clinical therapy markets appear to be distinct examples of extending one empire into the next. The deteriorating quality and the rising cost of the tests present a clear case for competitive and consumer harm. Myriad's

Federal Circuits regarding whether the monopoly leveraging theory may be applied to patent holders.").

232. *See* Dawson Chemical v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (finding that exclusion rights are the essence of a patent and compulsory licensing should be a "rarity").

233. Melamed & Stoeppelwerth, *supra* note 217, at 426. *Compare* Melamed & Stoeppelwerth, *supra* note 217, at 426 (describing the self-serving nature of intent inquiries); *with* AREEDA & HOVENKAMP, *supra* note 201 (indicating how "legitimate business justification" inquiries serve as objective proxies for subjective intent by contextualizing facts, taking actions out of the proverbial vacuum, and assisting the prediction of future party decisions).

234. Noonan, *supra* note 166.

integration of all aspects of the BRCA1/2 market demonstrates the degree to which its model is inefficient. Furthermore, a horizontal agreement might subject it to a nearly unconditional license.

The Supreme Court could also rule that human genetic sequences are essential facilities. This would not be an exclusionary conduct cause of action, but would require compulsory licensure if the gene sequence was ruled to be not reasonably and practically duplicable. The impact on investment incentives would be minimal, as firms first acquiring this upstream knowledge can still enter downstream markets at a significant temporal first mover advantage.

A. Ninth Circuit Myriad Counterfactual

The *Kodak* test for antitrust liability in patent refusal to deal cases involves a rebuttable presumption that the refusal to deal is procompetitive.[235] This is accomplished by evincing the extraneousness of the proffered business justifications.[236] Antitrust litigation has become increasingly empirical, and such evidence would require data and studies to prove the claims.[237]

Non-profit research is an area where proving a procompetitive justification for refusing to deal might be difficult due to the lack of revenue trade-off between market players.[238] Myriad asserts that it does not block research licenses for BRCA1/2, but researchers frequently complain about Myriad's aggressive patent enforcement and dissemination of cease-and-desist letters.[239] Although the philosophy of patents eschews intrabrand competition in favor of interbrand competition, the removal of required inputs from the public sphere coupled with the absence of non-infringing substitutable material (i.e. the presence of real scarcity) will tend to degrade competition in both the short and long run.[240] When producers of shoes use their patent to

235. Image Tech. Servs. v. Eastman Kodak Co. (*Kodak II*), 125 F.3d 1195, 1218 (9th Cir. 1997).

236. PHILLIP E. AREEDA & HERBERT HOVENKAMP, *Unilateral Refusals to Deal and "Essential Facility" Doctrine – Intuitive and Historical Rationales Through* Aspen Skiing *and* Trinko, *in* ANTITRUST LAW, *supra* note 70, at ¶ 772 (describing how anticompetitive conduct must derive from, and go beyond, a simple refusal to deal); 35 U.S.C. § 271(d)(4) (2013).

237. *See generally* Jonathan B. Baker & Daniel L. Rubinfeld, *Empirical Methods in Antitrust Litigation: Review and Critique*, 1 AM. L. & ECONS. ASS'N 386 (1999).

238. AREEDA & HOVENKAMP, *supra* note 201 (asserting that *Aspen Skiing* authorizes loss of market share as proof of actions based on legitimate business justifications).

239. *Compare* Gold & Carbone, *supra* note 116, *with* Marcy Darnovsky & Karuna Jaggar, *Who should own DNA? All of Us*, L.A. TIMES (Apr. 12, 2013), http://articles.latimes.com/2013/apr/12/opinion/la-oe-darnovsky-breast-genes-patents-20130412.

240. *See* PHILLIP E. AREEDA & HERBERT HOVENKAMP, *"Arbitrary" Refusal to Deal*, *in* ANTITRUST LAW, *supra* note 70, at ¶ 770 (avoiding the unfavorable "no fault antitrust" of the essential facilities doctrine).

produce bad footwear, they go out of business and their competitors absorb their market assets, because consumers reject their product. In the case of the BRCA1/2 diagnostic tests, Myriad's refusal to license means no competitors can test on those gene sequences. The result is a perfectly inelastic market, in which the consumers are captured, and the product becomes insulated from the upward mobilization pressures of quality and downward mobilization pressures of cost.[241] So while the dereliction in quality from fungible patents may not be a concern for a competitive market, using federal policy to create monopolies on nonfungible goods produces a complete regulatory barrier to entry into the market. An efficiency defense based on quality very well may be pretexual.[242]

Data General analyzes the anticompetitive effects on a relevant market to determine whether a firm's presumptively procompetitive justification for its refusal to deal can be rebutted. Myriad's price for a BRCA1/2 test was four times greater than its competitors.[243] While seeking monopoly rents could be considered procompetitive, utilizing costly methods may not. Lower-cost alternatives have been circulating in Europe since 1995, but have not been implemented by Myriad.[244] The downward effects on quality of the BRCA1/2 testing market are nearly as pronounced as the upward effects are on cost. Myriad's test is known to miss 10–20% of BRCA1/2 gene mutations, and to indicate positive mutations when the results are normal.[245] *Kodak II* provides a pretext foundation for unsubstantiated claims.[246] Myriad would thus be unable to base its procompetitive justifications on manifestly untrue claims of cost or quality control.

Aspen Skiing's qualifications on the refusal to deal can be said to stand for the proposition that an intellectual property license can rarely be revoked without demonstrating an intent to willfully maintain a monopoly.[247] This creates an industry conundrum. If Myriad is not part

241. Darnovsky & Jaggar, *supra* note 239; *see* PHILLIP E. AREEDA & HERBERT HOVENKAMP, *Refusal to License as Antitrust Violation; Equity Alternative*, *in* ANTITRUST LAW, *supra* note 70, at ¶ 709 (indicating the threshold for exclusionary conduct lowered by "locked-in" submarkets); *see generally* Lorain Journal Co. v. United States, 342 U.S. 143 (1951).

242. AREEDA & HOVENKAMP, *supra* note 241 (speculating that essentiality of patent to market competition claims are potentially successful where appeals to public interest fail).

243. Mulcahy, *supra* note 104.

244. 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).

245. Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT'L CANCER INST. 80, 80–81 (2002); Ellen Matloff & Arthur Caplan, *Direct to Confusion: Lessons Learned from Marketing BRCA Testing*, 8 AM. J. BIOETHICS 5, 7 (2008).

246. *See* Image Tech. Servs. v. Eastman Kodak Co. (*Kodak II*), 125 F.3d 1195 (9th Cir. 1997).

247. *See generally* Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985).

of a certain BRCA1/2 clinical therapy market, alleging procompetitive justifications for non-licensing becomes difficult, as there is no revenue trade-off. If Myriad is competing in a certain clinical therapy market, it must either license the BRCA1/2 patent to horizontal partner firms or vertically integrate its R&D. Firms are only as efficient as their strategic investments, meaning if they vertically integrate too much or in ways which they are not skilled, they will have a model of inefficient expenditure.[248] On the other hand, if they horizontally license, they will be subject to *Aspen Skiing*'s near-perpetual rule.[249] Under *Kodak II*, Myriad must be able to maintain its monopoly on BRCA1/2 research, diagnostics, and therapies.[250] A monopolist firm should not be able to bar competitors from transacting in a market in which the monopolist firm has not entered. Once entering a market, a monopolist firm should be encouraged either to efficiently horizontally license or efficiently vertically integrate. Only the *Kodak II* ruling compels a patent holder to responsibly scope its monopolies accordingly to their performance capacities.

The question remains as to what incentives are necessary to produce particular products. There are likely insufficient inherent market incentives for the development of a competitive diagnostic testing and clinical therapies market, but there is likely sufficient inherent market incentive for the exploration of the human genome. Antitrust immunity is appropriate in the former, but inappropriate in the latter. This finding is the factual basis of the analytical precept that upstream molecular markets should belong to the public.

B. Essential Facilities

The common law essential facilities doctrine, if applied to genetic patents as an anticompetitive molecular monopoly, would establish an independent duty for Myriad to deal with competitors. The essential facilities doctrine was established by the canonical Supreme Court cases *United States v. Terminal Railroad Association of St. Louis* and *Otter Tail Power Co. v. United States*.[251] In *Terminal Railroad*, a group of railroad owners possessed the only railway bridge to St. Louis.[252] The Supreme Court ruled that the joint owners of the bridge had denied an

248. PHILLIP E. AREEDA & HERBERT HOVENKAMP, *Unilateral Refusals to Deal and the "Essential Facility" Doctrine: Preliminary Considerations*, *in* ANTITRUST LAW, *supra* note 70, at ¶ 771 (illuminating how the essential facilities doctrine is disfavored when tied to de-integrating an organic vertical arrangement).

249. AREEDA & HOVENKAMP, *supra* note 241.

250. *Kodak II*, 125 F.3d 1195.

251. United States v. Terminal R.R. Ass'n of St. Louis, 224 U.S. 383 (1912); Otter Tail Power Co. v. United States, 410 U.S. 366 (1973).

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

essential facility to their competitors.[253] This input was considered essential because the real scarcity of available land meant it was impossible and impractical for all market participants to build their own bridge. The railway bridge market fit the natural monopoly analysis and was deemed to operate most efficiently under a regulated scheme. In *Otter Tail*, a public utility company owned the only transmission lines into several municipalities.[254] Otter Tail refused to sell electricity to competitors on the wholesale market and also refused to transmit its competitor's electricity over its transmission lines. Affirming the trial court's finding of Section 2 liability, the *Otter Tail* Court extended *Terminal Railroad*'s natural monopoly analysis to craft the modern essential facilities doctrine.[255] The test for an essential facility, laid out by *MCI Communications v. American Telephone & Telegraph Co.*, requires the control of an essential facility by a monopolist, the practical or reasonable inability of a competitor to duplicate the essential facility, the monopolist's denial to license the essential facility to a competitor, and the feasibility of providing the essential facility to the competitor.[256] If applied to human genes, Myriad might be obligated to provide access to the BRCA1/2 sequences.

Myriad controls the upstream BRCA1/2 market, which it refuses to, but feasibly could, license to downstream researchers, diagnosticians, and clinicians. The inquiry turns on whether competitors can reasonably or practically duplicate these essential inputs. Myriad's gene patents serve as "gatekeeper patents" because they are an indispensable input for all subsequent gene-based technologies.[257] Myriad demonstrated this exclusive control by stunting the medical application of this biotechnology. The presence of real scarcity creates natural monopolistic tendencies of the genetic patent market and qualifies human genes (as exemplars of anticompetitive molecular monopolies) as supreme candidates for essential facilities designation.[258] Firms are unlikely to be disincentivized from investing in gene sequence research and development because the firm to arrive first in the marketplace will secure the early mover competitive advantage of being ahead of its

253. *Id.* at 397.

254. *Otter Tail Power Co.*, 410 U.S. at 378–81.

255. AREEDA & HOVENKAMP, *supra* note 236 (describing *Terminal Railroad* and *Otter Tail* as the archetypical cases for essential facilities, because of the real scarcity associated with a natural monopoly in land; in contrast to the *Trinko* essential facility of an artificial telecommunications monopoly).

256. MCI Commc'ns Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1132–3 (7th Cir. 1983) (explaining that satisfying such circumstances imposes a duty on monopolists to make essential facilities available on non-discriminatory terms).

257. Westin, *supra* note 93.

258. Sandeep Vaheesan, Note, *Reviving an Epithet: A New Way Forward for the Essential Facilities Doctrine*, 3 UTAH L. REV. 1, 38-40 (2010).

rivals' commoditizing timeline. Firms will always race to discover these critical inputs, even if they cannot bar their competitors from using them, owing to the persistence of this market edge. Imposing the essential facilities doctrine would alleviate the biomedical anticommons as a deterrent to innovation.[259]

CONCLUSION

All participants in this discussion want more advanced and cheaper medical technology, but the question is how to best achieve those outcomes. The clearest way forward is by providing unrestricted access to the essential facilities. A qualified right for a firm to refuse to deal with competitors, resulting in a narrowly imposed duty to deal in the naturally monopolized molecular good, creates the most efficient incentive structure to compete in biotechnology markets.

The patent regime is concerned with innovation and dynamic efficiency. A duty to deal is unlikely to disincentivize the development of raw genetic inputs, as those who gain initial access will possess an early entrant market advantage. In contrast, the antitrust regime is concerned with consumer welfare and deadweight loss. A firm that is able to restrict output levels below or raises prices above socially optimal levels is deemed to harm the competitive process. By using its remaining patents to prevent clinicians and diagnosticians from interfacing with the BRCA1/2 sequences, Myriad is using a natural monopolistic good to bottleneck downstream markets.

The duty to deal and essential facilities doctrines are prime for Supreme Court elucidation. The Federal Circuit's choice of law decision entails that no more percolation of the duty to deal question will occur. The Supreme Court deferred the essential facilities doctrine on a power transmission lines fact pattern, which is a categorically poor choice for the essential facilities doctrine as compared to the gene sequencing debate. The biotechnology industry is a pillar of the economy, and clarification of these doctrines will do much to benefit the future of patent innovations and investments. After all, a technology is only as valuable as its use.[260] To this end, mandating a duty to deal or declaring human genes essential facilities would be a momentous step in the direction of healthcare access, quality, and cost.

259. Heller & Eisenberg, *supra* note 92.

260. Quyen Nguyen, *Color-Coded Surgery*, TEDTALKS (Oct. 2011), https://www.ted.com/talks/quyen_nguyen_color_coded_surgery ("one of the biggest myths in medicine . . . is the idea that all we need are more medical breakthroughs and then all of our problems will be solved").