

## PRAGMATIC PATENT ADJUDICATION

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*The Federal Circuit was created in large part to introduce stability and predictability into the patent law. By many accounts, it is failing to do so. Moreover, current patent doctrine does not adequately incorporate the patent system's broader utilitarian purpose. Recent decisions on the patentability of diagnostic and therapeutic methods illustrate the fundamental flaws in the Federal Circuit's jurisprudence. Doctrinal incoherence over medical methods is not simply an isolated glitch in the patent law. Rather, it serves as a case study of a larger problem with the court's approach to questions of patent scope. By maintaining a façade of adjudicative rule formalism while tacitly manipulating its rules to approximate policy goals, the court creates doctrinal confusion and perpetuates empirical uncertainty about the patent law's practical effects.*

*The Article proposes a pragmatic alternative whereby the Federal Circuit candidly asks the fundamental factual questions driving disagreements over the extent to which an inventor should be able to assert patent rights in after-arising technologies. It suggests that we focus not just on the substantive content of the patent law, but also on the process by which the law develops. By prompting litigants to directly address contextual issues surrounding patent disputes, pragmatic adjudication may serve an information-eliciting function and shed light on longstanding theoretical debates. The Article explains why the patentable subject matter doctrine is the best place to house this policy-based analysis. It identifies queries specifically pertinent to recent and ongoing cases involving diagnostic and therapeutic methods, and advocates that the Federal Circuit raise similar empirical questions with respect to other inventions whose patentability is contested, such as software and business methods.*

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“What is new in juristic thought today is chiefly the candor of its processes. Much that was once unavowed and kept beneath the surface is now avowed and open. From time immemorial lawyers have felt the impulse to pare down the old rules when in conflict with the present needs. The difference is that even when they yielded to the impulse, it was their habit in greater measure than today to disguise what they were doing, to disguise the innovation even from themselves, and to announce in all sincerity that it was all as it had been before.”<sup>1</sup>

“If you don’t know where you are going, any road will get you there.”<sup>2</sup>

## **I. Introduction**

This Article addresses two separate but related puzzles in the patent law. First, why, despite widespread consensus on the patent system’s utilitarian goals, is there such disagreement among patent scholars over how best to allocate proprietary rights to

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<sup>1</sup> Benjamin Cardozo, *Jurisprudence*, in SELECTED WRITINGS OF BENJAMIN CARDOZO: THE CHOICE OF TYCO BRAHE 7, 37 (1947).

<sup>2</sup> Lewis Carroll (1832-1898).

achieve those ends? Second, why is the Federal Circuit so reluctant to openly mold the patent law to meet the needs of innovation policy?<sup>3</sup> At first blush, these puzzles may seem unrelated. One puzzle occupies the theoretical patent literature while the other manifests itself in the practice of patent adjudication. Yet the Article asserts that the two puzzles are very much connected, as they both stem from a lack of empirical data about the patent system's specific practical effects. Rather than ignoring this problem, the Federal Circuit should directly confront it. In so doing, the court could help both to rationalize the patent doctrine and to inform longstanding scholarly debates.

There is near universal agreement among courts and commentators that the purpose of the patent law is to further technological innovation.<sup>4</sup> The patent law is a government creation with a clear constitutional objective to “promote the Progress of Science and useful Arts.”<sup>5</sup> Despite general accord on the patent system's utilitarian purpose, patent scholars differ sharply over how best to fashion the law to achieve this goal.<sup>6</sup> A number of insightful, well-reasoned, and markedly divergent patent theories have been advanced. Some commentators advocate granting broad patent rights to upstream inventors, whereas others favor allocating a larger portion of proprietary rights to subsequent innovators who develop and market commercial end products.<sup>7</sup> One camp argues that patent exclusivity best encourages research and development (“R&D”), while another asserts that competition, not monopoly, best drives innovation.<sup>8</sup> Some postulate that broad upstream patent rights discourage licensing transactions by creating “hold up” problems, while others suggest that they encourage transactions by mitigating the risks of misappropriation and spillovers.<sup>9</sup> Which of these theories are correct? Probably each of

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<sup>3</sup> This is perplexing given the fact that the Federal Circuit is a specialist court with the authority to shape the patent system, and the patent law is an unequivocally instrumentalist legal regime. See Parts I & II, *infra*.

<sup>4</sup> Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 597-99 (2002); see also Part IIA, *infra*.

<sup>5</sup> U.S. Const., Art. I, §8, cl. 8; Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, GEO. WASH. L. REV. 1, 3 (2008) (“Article I, Section 8, Clause 8 is unique among the Constitution's grants of power in articulating a purpose, and that purpose sounds in innovation.”).

<sup>6</sup> See Part IIA, *infra*.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

them accurately depicts how patents operate with respect to particular industries and technologies. What is missing in the theoretical literature is a comprehensive understanding of which theory prevails in specific contexts. Academic patent scholarship may be experiencing what Adrian Vermeule has generally observed as a “stalemate of empirical intuitions.”<sup>10</sup>

Notably absent from this theoretical debate is the Federal Circuit, the specialist court with exclusive jurisdiction over patent appeals.<sup>11</sup> The Federal Circuit was created by Congress in 1982 in response to a perceived need to bring consistency to patent law and to restore incentives for technological innovation.<sup>12</sup> Since its inception, the Federal Circuit has framed its primary objective as maintaining predictability and stability in the patent law. In furtherance of this goal, it has adopted an approach to patent adjudication which favors acontextual rules-based line drawing.<sup>13</sup> The court has repeatedly eschewed taking a prominent role in patent policy engineering.<sup>14</sup> Although the patent bar is generally pleased with the Federal Circuit’s performance, “legal scholars, economists, the Federal Trade Commission, the National Academies, and even some in the patent industries have expressed concern that there are now too many patents, that they cover too much economic activity, that patent quality is declining, and that the high cost of patent litigation is chilling innovation.”<sup>15</sup> Doctrinal confusion suggests that the Federal

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<sup>10</sup> ADRIAN VERMUELE, *JUDGING UNDER UNCERTAINTY: AN INSTITUTIONAL THEORY OF LEGAL INTERPRETATION* 153 (2006) (“[I]n academic discussion the discovery that disagreements are empirical is often taken to end the conversation. Thus academics must frequently rest content with what we may call *the stalemate of empirical intuitions*.”).

<sup>11</sup> Alan Devlin & Neel Sukhateme, *Self-Realizing Inventions and the Utilitarian Foundation of Patent Law*, 51 WM. AND MARY L. REV. 897, 901 (2009) (“A remarkable asymmetry exists between the economic foundation of patent law and the doctrine that animates this theoretical underpinning.”).

<sup>12</sup> THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT: A HISTORY 1982-1990 12 (Marion T. Bennett ed., 2002); Rochelle Cooper Dreyfuss, *The Federal Circuit as an Institution: What Ought We Expect?*, 43 LOY. L.A. L. REV. 827 (2010) (noting that the Federal Circuit was established for two main reasons: (1) to clear overcrowded dockets of the regional circuits by siphoning off patent appeals; and (2) to introduce uniformity and stability into the patent law); S. REP. NO. 275-97, at 5 (1981) (“The creation of the Court of Appeals for the Federal Circuit will produce desirable uniformity in [patent] law.”).

<sup>13</sup> See Part IIIA, *infra*.

<sup>14</sup> See p. 2, Part IIIA, *infra*.

<sup>15</sup> Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn From the Supreme Court – and Vice Versa*, 59 AM. U. L. REV. 787, 796 (2010).

Circuit has failed to produce the legal stability and uniformity that it intended to create.<sup>16</sup> Moreover, the court has allowed the patent doctrine to become unmoored from the law's overarching social purpose. In the last decade, the Supreme Court has granted certiorari to hear an unprecedented number of Federal Circuit decisions.<sup>17</sup> The Supreme Court's uncharacteristic involvement in patent matters suggests that it too is dissatisfied with the Federal Circuit's performance.<sup>18</sup>

The Article proceeds as follows. Part II reviews the theoretical debate on the optimal scope of patent protection for upstream discoveries that pave the way for follow-on innovation. It shows how application of the patentable subject matter ("PSM") doctrine and the enablement and written description requirements (collectively, "the disclosure requirements") determines the extent to which an upstream inventor may assert patent rights in after-arising technologies. This Part explains why these forward-looking doctrines unavoidably implicate the theoretical debate over patent scope and

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<sup>16</sup> See, e.g., Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1621 (2007) (remarking that [t]he court's high rate of reversal of district courts demonstrates that, despite the circuit's uniform national jurisdiction, 'the promises of pre-trial predictability and expedient patent litigation seem to remain a tantalizing dream' (citing Christian A. Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 BERKELEY TECH. L.J. 1075, 1100 (2001)); Jeffrey A. Lefstin, *The Measure of the Doubt: Dissent, Indeterminacy, and Interpretation at the Federal Circuit*, 58 HASTINGS L.J. 1025, 1026 (2007) (observing that "commentators, practitioners, trial judges, and even some judges of the Federal Circuit themselves seem united in their view that uncertainty and unpredictability are the order of the day"); Glynn S. Lunney, Jr., *Patent Law, the Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 SUP. CT. ECON. REV. 1, 76 (2003) (asserting that empirical data "suggests that the Federal Circuit and its doctrinal changes have brought less certainty and predictability to patent enforcement"); Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 40-41 (2005) (noting "key areas of uncertainty" in Federal Circuit doctrine, including claim construction, the doctrine of equivalents, and the written description requirement); see also Part IIIB, *infra*.

<sup>17</sup> Dreyfuss, *supra* note 1, at 829-30. Examples include *In re Bilski*, 130 S. Ct. 3218 (2010) (patentable subject matter); *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (standing to challenge a patent); *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (nonobviousness); *eBay Inc. v. MercExchange*, 547 U.S. 388 (2006) (injunctive relief); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) (statutory research exemption); and *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) (prosecution history estoppel).

<sup>18</sup> Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787 (2008); Rebecca S. Eisenberg, Commentary, *The Supreme Court and the Federal Circuit: Visitation and Custody of Patent Law*, 106 MICH. L. REV. FIRST IMPRESSIONS 28, 28 (2007), <http://www.michiganlawreview.org/firstimpressions/vol106/eisenberg.pdf> ("The increasing propensity of the Supreme Court to grant review in patent cases suggests that it is concerned about how good a job the Federal Circuit is doing.").

timing. It demonstrates why such issues are crucial when assessing the permissible bounds of method claims not circumscribed by a particular embodiment. Part III summarizes and critiques the Federal Circuit's approach to questions of patent scope. It argues that the core problem with the Federal Circuit's jurisprudence is its failure to openly acknowledge the limitations of *ex ante* rules as applied to varied, complex, and shifting scientific and economic conditions. The court formulates seemingly bright-line rules but then contorts them to reach intuitively desirable outcomes in specific cases. By adopting this strategy of "feigned formalism", the court creates doctrinal confusion and perpetuates uncertainty about the patent law's impact on incentives to create, develop, and commercialize innovative technologies. This Part uses recent Federal Circuit opinions on the patentability of medical methods as an illustrative case study of the pitfalls of feigned formalism.

Part IV proposes a pragmatic adjudicative approach whereby the Federal Circuit candidly acknowledges the fundamental empirical questions underlying patent scope disputes. By prompting litigants to directly address the market and regulatory context in which patenting takes place, pragmatic adjudication may serve an information-eliciting function, and consequently better inform both the court and scholars about the patent law's practical effects. This Part explains why the PSM doctrine is the best tool to tailor patent scope. It considers questions of political economy and relative institutional competence to support the argument that the Federal Circuit is better able than either Congress or the Patent and Trademark Office ("PTO") to take the lead in patent tailoring. Finally, it applies the proposed adjudicative model to recent and ongoing cases involving diagnostic and therapeutic methods. Part V concludes with an inquiry into whether a radical change in judicial structure is necessary to actualize pragmatic patent adjudication.

## II. Intractable Questions of Patent Scope

### A. *The Theoretical Debate: “Stalemate of Empirical Intuitions”*

Information possesses the classic characteristics of a public good. It is both nonexcludable (once the information is made publicly available, its creator cannot prevent others from using it) and nonrivalrous (one person’s use of the information does not reduce the ability of others to use it).<sup>19</sup> Absent patent protection, an inventor’s inability to profit from her work might discourage her from expending the time, money, and effort to create and disseminate the invention. Intellectual property rights solve the public goods problem by permitting prices to rise above marginal costs.<sup>20</sup> Proprietary rights provide both ex ante incentives to invent and ex post incentives to develop and commercialize patented inventions.<sup>21</sup>

There is virtually unanimous consensus in the academic literature that the patent law exists to further utilitarian goals.<sup>22</sup> The Supreme Court has repeatedly confirmed the

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<sup>19</sup> Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 994 (1997) (stating that information is a quintessential public good, because it can be consumed by many people without depletion, and it is difficult to exclude those who use it without compensating the creator).

<sup>20</sup> *Id.* at 996.

<sup>21</sup> Mark A. Lemley, *Ex Ante versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 131-32 (2004). For the argument that patent law’s grant of property rights facilitates commercialization, see F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 710 (2001) (arguing that property rights prevent others from free riding on the patentee’s investments in commercial testing, manufacturing, advertising, and distribution); see also F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 333-34 (2006) (arguing that property rights enforced by strong property rules produce two beneficial effects: a “beacon” effect (multiple complementary users are drawn together) and a “bargain” effect (such users are able to bargain more efficiently)). The late Federal Circuit Judge Giles Rich advocated the commercialization theory of patents. See Giles S. Rich, *The Relation Between Patent Practice and the Anti-Monopoly Laws*, 24 J. Pat. Off. Soc’y 159, 177-81 (1942)(arguing that promoting the commercialization of inventions is the most important function of patent law).

<sup>22</sup> See, e.g., ROBERT P. MERGES & JANE C. GINSBURG, *FOUNDATIONS OF INTELLECTUAL PROPERTY* 21 (2004) (noting that the “utilitarian” view of intellectual property is widely held to be the intellectual foundation for U.S. intellectual property law”); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1597 (2002) (“While there have been a few theories of patent law based in moral right, reward, or distributive justice, they are hard to take seriously as explanations for the actual scope of patent law”); Alan Devlin & Neel Sukhateme, *Self-Realizing Inventions and the Utilitarian Foundation of Patent Law*, 51 WM. AND MARY L. REV. 897, 912 (2009) (concluding that the utilitarian case for patent has proved “compelling”); Jonathan S. Masur, *Regulating Patents*, Sup. Ct. Rev. 6 (forthcoming 2011), available at <http://ssrn.com/abstract=1709222> (“[T]he case for an economic approach is as strong for patent law as it is in nearly any other legal domain.”).

patent system's utilitarian foundation.<sup>23</sup> Ideally, exclusive rights should only be granted if their social costs – restricted output, higher prices, and dynamic inefficiencies – are outweighed by the benefits that accrue from encouraging innovation, such that the patent grant results in a net increase in social welfare.<sup>24</sup> The desirability of patent protection is a function of both the cost of R&D and the extent to which the inventor can appropriate returns from her invention through means other than the patent system.<sup>25</sup> A key determinative factor is the ease with which the commercial product(s) covered by the patent can be imitated by competitors.<sup>26</sup> In some cases, trademark and trade secret protection may be sufficient to promote investment in innovation in the absence of a patent.<sup>27</sup> The need for patent protection also depends on the existence of alternative incentives to invent, including both ex ante incentives such as federal research grants and ex post incentives such as prestige, promotion, and tenure.<sup>28</sup> Ex post incentives to make fundamental discoveries may also include opportunities to patent inventions further downstream in the product development pipeline. Additionally, market-specific features

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<sup>23</sup> See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (referring to the constitutional command that Congress promote the progress of science and the useful arts and stating that “[t]he patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts” (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974)); see also *Graham v. John Deere Co.*, 383 U.S. 1, 8-9 (1966) (noting that Thomas Jefferson rejected a “natural-rights theory in intellectual property rights” and recognized that a patent monopoly “was a reward, and inducement, to bring forth new knowledge”); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (citing *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974)) (stating that the purposes of the patent system are (1) to foster and reward invention; (2) to promote disclosure in order to stimulate new innovation and to enable the public to practice the invention upon patent expiration; and (3) to assure that the public can freely use ideas in the public domain).

<sup>24</sup> Alan Devlin & Neel Sukhateme, *supra* note \_\_, at 901 (noting that a patent can only be justified on utilitarian grounds when it is necessary to incentivize the creation and dissemination of inventions whose social value is greater than the associated deadweight loss).

<sup>25</sup> Burk & Lemley, *supra* note \_\_, at 1586-87.

<sup>26</sup> *Id.*

<sup>27</sup> Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L. J. 1361, 1417 (2009).

<sup>28</sup> See Burk & Lemley, *Policy Levers*, *supra* note \_\_, at 1586-87 (delineating non-patent incentives to innovate); Henry E. Smith, *Institutions and Indirectness in Intellectual Property*, 157 U. PA. L. REV. 2083(2008-2009) (“[T]he nonrival nature of information is a count against intellectual property in comparison with rewards, kudos, lead times, and other alternatives to appropriating the returns from inventive and other creative activity.”); Michael W. Carroll, *supra* note \_\_, at 1409 (noting that in some cases nonpecuniary rewards such as prestige and tenure may spur inventive efforts even in the absence of proprietary rights).



such as first-mover advantage and network effects may operate independently from the patent system to shape innovation incentives.<sup>29</sup>

Edmund Kitch's prospect theory of intellectual property posits that foundational discoveries should receive expansive patent protection.<sup>30</sup> Prospect theory is premised on two putative advantages of broad upstream patents: (1) they will induce owners to invest in development without fear that competitors will appropriate their work;<sup>31</sup> and (2) they will allow owners to coordinate development and avoid wasteful duplicative efforts.<sup>32</sup> Kitch's second premise – that inventors and developers will engage in efficient licensing transactions to bring innovative products to market – rests on Coasean assumptions of perfect information, perfect rationality, and minimal transaction costs.<sup>33</sup> John Duffy has expanded upon Kitch's theory, noting that the earlier a patent is filed, the earlier the claimed invention enters the public domain.<sup>34</sup>

Kenneth Arrow's theory of competitive innovation argues against prospect theory in asserting that competition, not monopoly, best spurs innovation.<sup>35</sup> On this view, patent rights should be narrowly confined to specific embodiments of an invention and should not give the patentee monopoly control over the relevant market.<sup>36</sup> Robert Merges and Richard Nelson build upon this principle and offer a model which focuses on cumulative innovation, in which a final product is derived from a series of sequential steps. Merges and Nelson challenge the notion that coordinated, centralized development by a single rights holder will give rise to a socially optimal level of innovation. They contend that a

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<sup>29</sup> Michael W. Carroll, *supra* note \_\_, at 1414.

<sup>30</sup> See Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977). Kitch's theory builds upon the work of economist Joseph Schumpeter, who argued that monopolists are best able to coordinate innovation. See JOSEPH SCHUMPTER, *CAPITALISM, SOCIALISM, AND DEMOCRACY* 106 (6<sup>th</sup> ed. 1987).

<sup>31</sup> *Id.* at 276-77.

<sup>32</sup> *Id.* at 279.

<sup>33</sup> Lemley, *supra* note \_\_, at 133.

<sup>34</sup> John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 444, 475-80 (2004). Michael Abramowicz critiqued Duffy's theory by noting that early filing increases the likelihood that the patented technology will be underdeveloped. Michael Abramowicz, *The Danger of Undeveloped Patent Prospects*, 92 CORNELL L. REV. 1065, 1089 (2007).

<sup>35</sup> See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *The Rate and Direction of Inventive Activity* 609, 619-20 (Nat'l Bureau of Econ. Research ed., 1962).

<sup>36</sup> Burk & Lemley, *supra* note \_\_, at 1604-05.

rational owner of a broad upstream patent will typically underdevelop many of the potential improvements subsumed by that right. Moreover, coordinated development may not be feasible in light of the steep transaction costs associated with technology licensing.<sup>37</sup> Their theory disputes prospect theorists' presumption that rivalry is wastefully duplicative and posits that rights should be allocated between initial inventors and subsequent improvers.<sup>38</sup>

Other patent scholars have noted that such divided entitlements may give rise to an "anticommons" whereby high transaction costs and strategic behavior prevent the aggregation of the necessary rights to develop and commercialize new products.<sup>39</sup> Upstream inventors holding powerful property rights may discourage or "holdup" efforts by others to bring socially valuable technologies to market.<sup>40</sup> Holdup problems may be significant where the improver contributes greatly and the initial inventor contributes comparatively little to the value of the resulting end product.<sup>41</sup> If the parties cannot expect to complete efficient transactions, the availability of broad upstream rights may produce socially undesirable rent-dissipating patent races, as rational actors will overinvest in pioneering discoveries and underinvest in follow-on development.<sup>42</sup> Holdup concerns have prompted some scholars to advocate using alternatives to

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<sup>37</sup> See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 872-75 (1990).

<sup>38</sup> *Id.* at 876-79.

<sup>39</sup> See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998) (identifying anticommons problems in genomic research); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 192-94 (2001) (asserting that upstream biotechnology patents could trigger bargaining breakdown and impede innovation). See also Burk & Lemley, *supra* note \_\_, at 1613 (noting that there are two possible ways to solve anticommons problems: (1) grant fewer upstream patents or (2) consolidate patent property ownership via vertical integration).

<sup>40</sup> See Lemley, *supra* note \_\_, at 1055-58 (noting that uncertainty over the value of an upstream discovery and the threat of strategic behavior may prevent the inventor and developer from agreeing to an efficient licensing transaction); Clarisa Long, *Proprietary Rights and Why Initial Allocations Matter*, 49 EMORY L.J. 823, 831-36 (2000) (arguing that uncertainty in valuation of patents on basic research tools is likely to thwart efficient licensing); James Bessen, *Holdup and Licensing of Cumulative Innovations with Private Information*, 82 ECONOMICS LETTERS 321-26 (2004) (showing that ex ante licensing does not eliminate the holdup problem in cumulative innovation when development costs of follow-on innovators are private information).

<sup>41</sup> Merges & Nelson, *supra* note \_\_, at 865-66. See also Cooter, Marks & Mnookin, *Bargaining in the Shadow of the Law: A Testable Model of Strategic Behavior*, 11 J. LEGAL STUD. 225, 226 (1982).

<sup>42</sup> Lemley, *supra* note \_\_, at 1064.

intellectual property, such as rewards and prizes, to encourage innovation.<sup>43</sup> A related theory posits the problem of “patent thickets”, in which multiple broad patents are awarded to various parties laying claim to the same technological ground.<sup>44</sup> If transaction costs are too high to “clear” the thicket via cross-licensing of the overlapping rights, innovation may be impeded. The patent thicket concept suggests that patent rights ought to be sufficiently narrow to avoid the creation of overlapping rights.<sup>45</sup>

An emerging area of scholarship goes beyond incentive theories<sup>46</sup> in recognizing the value of patents as contractual bargaining chips. Academic writings incorporating a transaction cost economics (TCE) framework add a new dimension to the ongoing debate over the proper scope of patent protection for upstream inventions. Paul Heald asserts that, in addition to creating ex ante and ex post incentives to innovate, patent rights may add value by facilitating technology transfer transactions that may not otherwise occur.<sup>47</sup> He notes the fact that property rights – unlike contracts – can be asserted against third parties, which makes financing, long-term planning, and collaboration easier.<sup>48</sup> Robert Merges observes that patent rights can facilitate contracting by resolving the Arrow Information Paradox.<sup>49</sup> He also theorizes that property rights can mitigate problems of asset specificity and opportunism associated with contractual interactions.<sup>50</sup> Henry Smith explains that the benefits of modularity accruing from intellectual property rights must be

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<sup>43</sup> See, e.g., Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003). For application of the argument to the drug discovery context, see Joseph Stiglitz, *Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations*, 333 BRIT. MED. J. 1279 (2006); James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519, 1528-34 (2007).

<sup>44</sup> See Carl Shapiro, *Navigating the Patent Thicket: Cross Licensing, Patent Pools, and Standard Setting*, in INNOVATION POLICY AND THE ECONOMY 199, 121 (Adam B. Jaffe et al. eds., 2001).

<sup>45</sup> Burk & Lemley, *supra* note \_\_, at 1614.

<sup>46</sup> For a review of the patent literature on incentive theories and a collection of sources, see DONALD S. CHISUM, CRAIG ALLEN NARD, HERBERT F. SCHWARTZ, PAULINE NEWMAN & F. SCOTT KIEFF, *PRINCIPLES OF PATENT LAW* 58-90 (2d. ed. 2001).

<sup>47</sup> See Paul J. Heald, *A Transaction Costs Theory of Patent Law*, 66 OHIO ST. L. J. 473 (2005) (arguing that a patent regime lowers transaction costs relative to a trade secrecy regime).

<sup>48</sup> *Id.*

<sup>49</sup> Robert P. Merges, *A Transactional View of Property Rights* (2005), available at <http://escholarship.org/uc/item/178400jf>. Kenneth Arrow famously observed that the “fundamental paradox” of information is that “its value for the purchaser is not known until he has the information, but then he has in effect acquired it without cost.” KENNETH J. ARROW, *ESSAYS IN THE THEORY OF RISK-BEARING* 152 (1971).

<sup>50</sup> Merges, *A Transactional View of Property Rights*, *supra* note \_\_.

balanced with the costs of foreclosing socially beneficial interactions when assessing the optimal scope of patent protection in any given context.<sup>51</sup>

Despite substantial discussion and debate among practitioners and scholars over optimal patent scope, evidence to confirm or refute the various patent theories remains elusive. Few commentators contest the notion that there is a causal link between patent rights, investment in R&D, and market productivity. Yet there is scant empirical support for this fundamental assumption.<sup>52</sup> Rigorous testing of alternative patent theories is hampered by a lack of comprehensive data on patents' economic effects in specific contexts. This information gap has created uncertainty with respect to the patent system's optimal form and operation.<sup>53</sup> Both advocates and critics of strong patent rights tend to rely on anecdotal evidence to support their positions. For example, skeptics of prospect theory point to evidence of innovative stagnation in the incandescent lighting field following the grant of an exceptionally broad patent to Thomas Edison for his light bulb.<sup>54</sup> Several scholars have acknowledged this problem, and candidly admit that the principles that they elucidate and espouse await verification.<sup>55</sup> Without a clear idea about how well competing theories accurately describe and predict the patent law's impact in

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<sup>51</sup> Smith, *supra* note \_\_, at 2111-16.

<sup>52</sup> Liza Vertinsky, *Comparing Alternative Institutional Paths to Patent Reform*, 61 ALA. L. REV. 501, 511 (2010).

<sup>53</sup> See, e.g., Matthew Sag & Kurt Rohde, *Patent Reform and Differential Impact*, 8 MINN. J. L. SCI. & TECH. 1, 50 (2007) (noting the "empirical uncertainty surrounding optimal patent scope"); Adam Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process* ii (Nat'l Bureau of Econ. Research, Working Paper No. 7280, 1999) ("[D]espite...the wide availability of detailed data relating to patenting, robust conclusions regarding the empirical consequences for technological innovation of changes in patent policy are few."). See also David McGowan, *Copyright Nonconsequentialism*, 69 MO. L. REV. 1, 67-68 (2004) (delineating the argument, with respect to copyright law, that scholars lack the necessary data to empirically measure the marginal effects of different policies).

<sup>54</sup> Tim Wu, *Intellectual Property, Innovation, and Decentralized Decisions*, 92 VA. L. REV. 123, 125-26 (2006).

<sup>55</sup> See, e.g., F. Scott Kieff, *supra* note \_\_, at 411 (fn. 291) ("Elimination of IP may not even be bad; in fact, the commercialization theory would embrace the decision if it turned out the commercialization benefits were outweighed by the costs of the system. The analysis offered here suggests reasons why that is not expected to be the case. *The ultimate question, however, is an empirical one and is not answered here* (emphasis added)); Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 301 (2007) ("Spillovers aren't always bad, and more property rights aren't always good. Only if we understand when and why each can enhance social welfare can we hope to design legal rules that do more good than harm."); Henry E. Smith, *Intellectual Property As Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742, 1818 (2007) ("The *central empirical question* in both property and intellectual property is when – and how easily – to overcome the basic presumption in favor of exclusion").

the world, the academic debate seems to have reached what Adrian Vermeule has coined a “stalemate of empirical intuitions.”<sup>56</sup>

**B. Patentability Requirements and After-Arising Technologies**

Inventors need not actually reduce their inventions to practice in order to obtain patent protection. Constructive reduction to practice by filing an application containing prophetic examples is sufficient if the description of the invention enables the person having ordinary skill in the art (“PHOSITA”) to practice the invention.<sup>57</sup> A patentee may claim a broad idea that goes beyond the specific embodiment(s) taught in the specification.<sup>58</sup> Each patented invention has a “footprint” which delineates the extent to which it reaches back into inventions that existed before and reaches forward to claim inventions yet to be created.<sup>59</sup> A patent may be objectionable because it seeks to cover too much of the existing technological landscape, too many subsequent technologies, or both. In other words, patentability must be assessed by reference both to a claim’s breadth (i.e., what is the range of currently foreseeable commercial products that the patentee seeks to claim?) and its depth (i.e., how far out into the unforeseeable future does patent coverage extend?).<sup>60</sup>

The Patent Act delineates five main patentability requirements: the claimed invention must constitute patentable subject matter (“PSM”)<sup>61</sup>; possess utility<sup>62</sup>,

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<sup>56</sup> See *supra* note \_\_. See also Cass R. Sunstein, *Must Formalism Be Defended Empirically?*, 66 U. CHI. L. REV. 636, 669 (1999) (“The broadest lesson has to do with the relevance of empirical claims to many topics in legal theory, and the great difficulty of doing the latter without attending to the former.”).

<sup>57</sup> Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 143-44 (2008).

<sup>58</sup> Robin C. Feldman, *The Inventor’s Contribution*, 2005 UCLA J.L. & TECH. 6, ¶160 (2005) (“A patent holder need only identify a single use and a single embodiment for the product to receive rights to a wide range of embodiments and all uses.”). See also Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 480 (2003) (noting that patents track inventions, not product markets).

<sup>59</sup> Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 3 (2005).

<sup>60</sup> See Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083, 1086 (2009) (stating that a claim’s breadth describes the range of products encompassed by the claim at the time of filing, while the claim’s depth describes the expansion of the claim set over time as claim scope reaches an increasing array of newly discovered after-arising technologies).

<sup>61</sup> 35 U.S.C. § 101 (2000).

<sup>62</sup> *Id.*

novelty<sup>63</sup>, and nonobviousness<sup>64</sup>, and be supported by an adequate disclosure.<sup>65</sup> Section 101 of the Patent Act states that patents may be obtained for any “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>66</sup> A claim falling within one of these statutory categories may nonetheless be patent-ineligible if it encompasses one of three judicially-created exceptions: products of nature, natural phenomena, and abstract ideas.<sup>67</sup> However, the useful application of fundamental principles towards specific ends may qualify for patent protection.<sup>68</sup> The PSM doctrine thus performs two distinct functions: (1) it categorically excludes certain types of discoveries; and (2) it limits the scope of patent claims. The courts have construed §112’s disclosure provision to contain two separate requirements: the specification must enable the PHOSITA to make and use the invention (the enablement requirement), and it must adequately describe the invention so as to show to the PHOSITA that the patentee possessed the invention at the time of filing the patent application (the written description requirement).<sup>69</sup> Although they are treated as distinct patentability criteria, the disclosure requirements are conceptually linked both to each other and to the PSM doctrine.<sup>70</sup> Unlike the other patentability requirements,<sup>71</sup> the enablement, written description, and PSM doctrines are forward-looking in that they deal with the proper scope of patent

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<sup>63</sup> 35 U.S.C. §102 (2006).

<sup>64</sup> 35 U.S.C. §103 (2006).

<sup>65</sup> 35 U.S.C. §112 (2006).

<sup>66</sup> 35 U.S.C. § 101 (2000).

<sup>67</sup> Long-standing Supreme Court precedent holds that abstract ideas, scientific and mathematical principles, and law or products of nature constitute unpatentable subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing *Parker v. Flook*, 437 U.S. 584 (1978)); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852).

<sup>68</sup> See Kieff, *supra* note \_\_, at 745.

<sup>69</sup> Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 *BERKELEY TECH. L.J.* 1155, 1174 (2002). Before 1997, the written description requirement was generally thought to apply only to claims added after the original filing date, so as to prevent the late claiming of new matter. However, in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), the Federal Circuit held that the written description requirement, like enablement, is applicable to all claims.

<sup>70</sup> See Michael Risch, *Everything is Patentable*, 75 *TENN. L. REV.* 591, 598-606 (2008) (offering examples of PSM cases that could be reframed through the lens of other patentability doctrines, such as novelty, utility, and adequate disclosure).

<sup>71</sup> The utility requirement assesses the invention standing alone, without need to consider related past, present or future technologies. The novelty and nonobviousness doctrines operate retrospectively, comparing the claimed invention to the existing prior art to assess patentability.

protection in light of what potentially lies ahead. These three requirements operate prospectively to restrict the reach of patent claims that seek to encompass future technologies.<sup>72</sup>

The patent law must grapple with the question of whether the footprint of a patented invention should include after-arising technologies that are unknown at the time the patent is filed. This question confronts the “levels of abstraction” problem in the patent law.<sup>73</sup> For example, if an inventor devises a method of curing AIDS by means of a particular machine, should she be able to claim all cures for AIDS that may ever be discovered, only the specific method of curing AIDS through use of that particular apparatus, or something in between?<sup>74</sup> The level of abstraction at which an inventor may obtain patent protection has significant consequences for both the inventor’s incentives and the rights of end users. The higher the level of abstraction that may be claimed, the greater the incentive to invent patentable technologies. The downside is that monopoly pricing will produce deadweight losses as some users are priced out of the market.<sup>75</sup> Moreover, broad upstream patents may discourage follow-on innovation.<sup>76</sup> In theory, the permissible level of abstraction of a patent claim should correspond to the inventor’s contribution to the value of the commercial end products falling under the claim’s

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<sup>72</sup> Kevin Emerson Collins, *supra* note \_\_, at 1086 (noting that the disclosure requirements are forward-looking doctrines); Kevin Emerson Collins, *An Initial Comment on Ariad: Written Description and the Baseline of Patent Protection for After-Arising Technology*, 2010 PATENTLY-O PATENT L. J. 64 (noting that the “abstract ideas” exception to PSM operates to restrict the reach of patent claims into after-arising technology). There is much debate in the academic literature as to whether the disclosure and written description requirements are and should be distinct requirements as applied to originally filed claims. See, e.g., Christopher M. Holman, *Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and its Progeny in the Courts and PTO*, 17 ALB. J.L. SCI. & TECH. 1, 61-69 (2007) (analyzing the Federal Circuit’s treatment of the claims at issue in *University of Rochester v. G.D. Searle*, 358 F.3d 916 (Fed. Cir. 2004) and *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005) and concluding that the enablement and written description requirements are essentially redundant and should be viewed as a merged “written description” patentability criterion).

<sup>73</sup> T.J. Chiang, *The Levels of Abstraction Problem in Patent Law*, Northwestern University Law Review, forthcoming, George Mason Law and Economics Research Paper Series 09-33, available at <http://ssrn.com/abstract/id=1434465>.

<sup>74</sup> *Id.* at 4.

<sup>75</sup> See Dan L. Burk & Mark A. Lemley, *Quantum Patent Mechanics*, 9 LEWIS & CLARK L. REV. 29, 51 (2005) (arguing that there is no right level of abstraction to apply to claims when making infringement determinations).

<sup>76</sup> See Part IIA, *infra*.

coverage.<sup>77</sup> In reality, however, we often do not know and cannot predict the inventor's proportionate contribution at the time the patent application is filed.

An invention may be novel, useful, and non-obvious at multiple levels of abstraction. Hence these patentability criteria offer no guidance on the extent to which an upstream patent should read on after-arising technologies.<sup>78</sup> The work of resolving this problem must be performed by the judicially-created exceptions to PSM and/or the disclosure requirements.<sup>79</sup> Unlike backward-looking determinations of patent scope which assess the invention by reference to the prior art, application of forward-looking patentability doctrines is inherently indeterminate so long as we allow inventors to claim more than the specific embodiments that they have disclosed how to make and use. The normative question underpinning both the PSM doctrine and the disclosure requirements is the extent to which the inventor should receive patent protection for later developed technologies. This is a difficult question to answer, as it may be socially desirable to allow different inventions to be patented at different levels of abstraction.<sup>80</sup>

Forward-looking patent scope determinations are particularly thorny when assessing the permissible bounds of method claims that are not circumscribed by a particular embodiment. The famous patent case involving Samuel Morse's telegraphy patent is illustrative of this conundrum.<sup>81</sup> Claim 8 in Morse's patent application is a classic example of how a broad method claim can capture a sweeping range of after-arising commercial end products, as it essentially claimed all methods of communicating

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<sup>77</sup> Chiang, *supra* note \_\_, at 9.

<sup>78</sup> Chiang, *The Levels of Abstraction Problem*, *supra* note \_\_, at 27.

<sup>79</sup> See John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609, 645-46 (2009) (speculating as to why the prohibitions on undue abstraction and the patenting of natural phenomena are currently perceived as interpretations of §101 when their "more obvious textual home" is § 112).

<sup>80</sup> See Mark A. Lemley, Michael Risch, Ted M. Sichelman, and R. Polk Wagner, *Life after Bilski*, Stanford Law Review, Forthcoming; Stanford Public Law Working Paper No. 1725009; San Diego Legal Studies Paper No. 11-046. Available at SSRN: <http://ssrn.com/abstract=1725009> (noting that claims that are categorically excluded by §101 – claims that do not constitute a process, machine, manufacture, or composition of matter – are rare and can be dealt with fairly easily, and that the more difficult cases are those involving claims that fall within one of the statutory categories but nonetheless raise policy questions about whether they should be granted patent protection).

<sup>81</sup> 56 U.S. (15 How.) 62 (1854).



at a distance using electromagnetic waves.<sup>82</sup> But since Morse had not disclosed, let alone envisioned, all such methods, the Supreme Court ruled the claim invalid.<sup>83</sup> The Court was concerned about impeding future technological progress:

For aught that we now know, some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. . . . But yet if it is covered by this patent, the inventor could not use it, nor the public have the benefit of it, without the permission of the patentee. . . . In fine, [Morse] claims an exclusive right to use a manner and process which *he has not described and indeed had not invented*. . . . The court is of the opinion that the claim is too broad, and not warranted by law.<sup>84</sup>

Although the *Morse* decision is considered by some to be a PSM case<sup>85</sup>, the Court's opinion sounds very much like modern-day justifications for the written description requirement. The conceptual link between the forward-looking doctrines is further underscored by the fact that many commentators view it as an enablement case.<sup>86</sup>

Contemporary disputes over the patentability of diagnostic and therapeutic methods raise analogous questions about the inventor's permissible reach into after-arising technologies. These issues have come to the fore in the wake of rapid scientific advances in biomedical research in recent decades. The discovery that a particular

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<sup>82</sup> *Id.* at 112.

<sup>83</sup> *Id.* at 119-20.

<sup>84</sup> 56 U.S. (15 How.) 62, 113 (1853) (emphasis added).

<sup>85</sup> Chiang, *The Rules and Standards of Patentable Subject-Matter*, *supra* note \_\_, at 35 (noting that the *Morse* decision has generally been interpreted to establish the principle that laws of nature and abstract ideas are not patentable). See also Peter S. Menell, *Forty Years of Wandering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Ground Patent Law Interpretation and Return Patent Law to its Technology Mooring*, *Stanford Law Review* (forthcoming 2011), available at <http://ssrn.com/abstract=1722422> (stating that the Supreme Court applied the "fundamental principles" exception to PSM in allowing Samuel F.B. Morse's claims to specific uses of electromagnetism in telegraphy, but invalidating a broad claim to the use of electro-magnetism "however developed for marking or printing intelligible characters, signs, or letters, at any distances").

<sup>86</sup> See, e.g., CRAIG ALLEN NARD, *THE LAW OF PATENTS* 51 (2007) (including *Morse* in the section on enablement); Chiang, *The Rules and Standards of Patentable Subject-Matter*, *supra* note \_\_, at 43 (stating that the abstract ideas doctrine is largely redundant with enablement and that *Morse* is often taught in law school patent courses as an enablement case); Mark A. Lemley, et al, *Life after Bilski*, *supra* note \_\_ (noting that although *Morse* is generally regarded as an enablement case, the reasoning behind the Supreme Court's invalidation of Morse's eighth claim goes beyond the traditional concern about enabling practitioners to make and use known embodiments without "undue experimentation.").

biological molecule correlates with a particular condition or disease may spur the development of numerous potential commercial products. For example, genetic discoveries are used to develop, *inter alia*, diagnostic tests which assess disease susceptibility; diagnostic tests which tailor treatment options to a patient's unique genetic profile; and therapeutics targeting genes or gene products implicated in disease pathways.<sup>87</sup> Questions of patent scope are of great importance to the biotechnology industry, because biological molecules and processes are unique and cannot be readily substituted by competitors in the same way that other components of pioneering inventions may be.<sup>88</sup>

Claims to compositions of matter are typically considered stronger than method claims. But this truism does not necessarily hold for upstream biotechnology patents which claim not only the gene or protein itself but also the method of targeting that molecule. In this case, the method claim may be of greatest value, because it captures a potentially infinite range of therapeutic products.<sup>89</sup> Claims to methods of targeting the function of intracellular molecules or cell signaling pathways are much broader than claims to methods of using a particular therapeutic product for a particular clinical indication.<sup>90</sup> While the latter type of therapeutic claim is relatively uncontroversial,<sup>91</sup> the patentability of the former is hotly contested.<sup>92</sup>

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<sup>87</sup> Rochelle Dreyfuss, *The Patentability of Genetic Diagnostics in U.S. Law and Policy*, NYU School of Law Public Law & Legal Theory Research Paper Series, Working Paper No. 10-68, Law & Economics Research Paper Series Working Paper No. 10-44 (September 2010), available at <http://ssrn.com/abstract=1678123>, at 4-6.

<sup>88</sup> *Id.* at 8 (noting that it may not be easy to invent around broad medical method claims because these inventions are "hostage to biology").

<sup>89</sup> The parameters of a product claim are defined by the invention's structural characteristics. A product generally cannot be claimed by reference to its function alone. The PTO will only allow product claims based on functional information if it is combined with structural information about the product's genus. Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 14 (2005). In contrast, there is no structural limitation imposed on claimed methods of targeting a gene or biochemical pathway. See Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083 (2009) (noting that "functional claim language – at least when not construed as part of a means-plus-function limitation – often serves as a red flag of a claim's potential depth").

<sup>90</sup> The patents at issue in *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955 (Fed. Cir. 2001), exemplify the distinction between these two types of therapeutic claims. The court held that Lilly's own prior patent on a method of treating anxiety with Prozac inherently anticipated its subsequent broader claim on a method of blocking serotonin uptake. Serotonin is a biological compound implicated in anxiety and depression, and Prozac operates by inhibiting the cellular reuptake of serotonin.

<sup>91</sup> See Christopher M. Holman, *Bilski: Assessing the Impact of a Newly Invigorated Patent-Eligibility Doctrine on the Pharmaceutical Industry and the Future of Personalized Medicine* (June 23, 2009), Current Topics in Medicinal

Diagnostic claims also raise difficult questions of permissible patent scope.<sup>93</sup> Claims to specific methods of assaying for a particular disease biomarker<sup>94</sup> are undoubtedly patentable. However, the patentability of broad claims to methods of correlating assay results with a condition or disease is a subject of intense debate.<sup>95</sup> The methods at issue in *Laboratory Corporation of America Holdings, DBA Labcorp., v. Metabolite Laboratories, Inc.*<sup>96</sup> illustrate the distinction between controversial and noncontroversial diagnostic claims. Metabolite's patent contained narrow claims to a specific method of assaying for homocysteine in a patient's blood, as well as broader claims to correlating homocysteine levels with vitamin B deficiency. This broader claim covered any diagnostic test developed to assess whether a patient has elevated homocysteine. Labcorp undisputedly did not infringe the narrow claims to particular assay methods, thus the resolution of the case turned on whether Metabolite's patent protection extended to the broad claim to the correlation between homocysteine and vitamin deficiency.<sup>97</sup>

Until recently, courts relied primarily on the enablement and written description requirements to limit the reach of broad upstream claims.<sup>98</sup> The Supreme Court

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Chemistry, forthcoming. available at <http://ssrn.com/abstract=1424493> (noting that all biological inventions implicate natural phenomena, but that drugs and methods of using drugs to treat illness are undoubtedly patentable even though they typically interact with natural body processes).

<sup>92</sup> *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) and *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1366 (Fed. Cir. 2010) (en banc) are prominent examples of disputes involving this type of therapeutic method claim. See Parts IIIB and IVC, *infra*.

<sup>93</sup> Although the questions may be similar the answers may be different. It may be optimal, from a utilitarian perspective, to allow patents covering therapeutic methods at a higher level of abstraction than patents covering diagnostic methods. See Part IVC, *infra*.

<sup>94</sup> A biomarker is a protein or other substance that can be detected or measured in the blood and whose concentration correlates with the risk or progression of a disease, or with a patient's response to a given treatment. See Matthew Herder, *Patents & The Progress of Personalized Medicine: Biomarkers Research as Lens*, 18 Ann. Health L. 187 (2009) (stating that biomarkers have a wide range of clinical applications, including disease prevention, diagnosis, prognosis, prediction of therapeutic response, and measurement of therapeutic efficacy and toxicity).

<sup>95</sup> Recent high-profile cases considering the patentability of such methods include *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1354 (Fed. Cir. 2010), and *Ass'n for Molecular Pathology v. United States PTO*, 2010 U.S. Dist. LEXIS 35418,104 (S.D.N.Y. 2010). See Parts IIIB and IVC, *infra*.

<sup>96</sup> 548 U.S. 124 (2006).

<sup>97</sup> *Id.* at 128-30 (Breyer, J., dissenting).

<sup>98</sup> Christopher M. Holman, *supra* note\_, at 15 (stating that the test for whether a claim preempts substantially all uses of a fundamental principle provides a means for courts to use the PSM doctrine to limit patent scope, but that

resurrected the PSM doctrine when it granted certiorari in *Lapcorp*. Although the Court ultimately dismissed the case as improvidently granted,<sup>99</sup> a vigorous dissent by Justices Breyer, Stevens, and Souter<sup>100</sup> alerted patent challengers to the potential for using the doctrine to cabin the scope of claims.<sup>101</sup> Patent scholars have also taken a fresh look at the merits of using judicially-created exceptions to PSM as a means of allocating incentives between upstream inventors and downstream developers.<sup>102</sup> Nonetheless, the Federal Circuit seems reluctant to adopt a more expansive approach to the PSM doctrine. In *In re Bilski*<sup>103</sup>, the Supreme Court overruled the Federal Circuit's determination that PSM should be assessed by means of a sole, exclusive test which asks whether a claimed method either (1) is tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing (the "machine or transformation" test, or "MOT" test).<sup>104</sup> The Court concluded that the MOT test was merely a "useful and important clue" to patentability, and that the ultimate test for patentability is whether or not the claimed invention preempts all uses of a fundamental principle.<sup>105</sup> Despite the Supreme Court's ruling, the Federal Circuit has continued to rely heavily on the MOT test to assess PSM.<sup>106</sup>

The Federal Circuit's insistence on limiting the PSM inquiry to the MOT test reflects its general adherence to rules-based patent adjudication. An open-ended query into whether a claimed invention preempts all uses of a fundamental principle does not

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until recently this function was accomplished by application of other patentability doctrines, particularly the enablement and written description requirements).

<sup>99</sup> 548 U.S. 124 (2006).

<sup>100</sup> *Id.* at 125-39.

<sup>101</sup> Christopher M. Holman, *supra* note \_\_, at 10.

<sup>102</sup> *See, e.g.*, Mark A. Lemley, et al., *Life After Bilski*, *supra* note \_\_, at 1-2 (arguing that the abstract ideas exception to PSM should be used as a scope-defining doctrine).

<sup>103</sup> 130 S. Ct. 3218 (2010).

<sup>104</sup> *Id.*

<sup>105</sup> *Id.* at 3221.

<sup>106</sup> *See, e.g.*, *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010) (on remand, noting that the Supreme Court in *Bilski* did not invalidate the MOT but merely held that it was not the definitive test for assessing preemption, and holding that the asserted method claims constitute PSM because they satisfy the transformative prong of the MOT test); *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1278 (Fed. Cir. 2010) ("While the Supreme Court in *Bilski* made clear that our machine-or-transformation test is not the exclusive test for patentability, it also made clear that the test is 'a useful and important clue'...We therefore understand the Supreme Court to have rejected the exclusive nature of our test, but not necessarily the wisdom behind it.").

yield readily predictable conclusions, because it turns on how broadly the court defines the “fundamental principle” at issue. For example, is the relevant fundamental principle in *Labcorp* the general idea that blood homocysteine levels correlate with vitamin B6 deficiency, or the more specific idea of assaying the level of homocysteine in a patient’s blood in order to diagnose vitamin B6 deficiency? The way in which the fundamental principle is articulated may be outcome-determinative, since a more broadly defined concept is less likely to be found preempted than one that is more narrowly construed. The inherent indeterminacy of the preemption inquiry may explain why the Federal Circuit continues to latch on to the MOT test as the means for assessing PSM.<sup>107</sup> The court understandably seeks to achieve stability and predictability in the patent law through the use of bright-line rules. However, as explained in Part III below, the Federal Circuit fails to acknowledge the limitations of ex ante rulemaking under conditions of empirical uncertainty. Instead it maintains a façade of adjudicative rule formalism and manipulates its rules to produce intuitively desirable outcomes in specific cases, thereby perpetuating uncertainty and creating doctrinal confusion.

### III. The Pitfalls of Feigned Formalism

#### A. *Crystals or Mud in the Patent Law?*

Patent scholars observe a propensity for formalism in the Federal Circuit’s patent jurisprudence.<sup>108</sup> The court depicts the patent law as an ordered system founded upon a few abstract, discrete categories and higher principles.<sup>109</sup> It perceives each of the

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<sup>107</sup> Timo Minben & Robert M. Schwartz, *US Patent Eligibility in the Wake of Bilski v. Kappos: “Business as Usual” in an Age of New Technologies*, Biotechnology Law Report, Forthcoming, Vol. 29, issue 6 (part I) and Vol. 30, issue 1 (part II), available at <http://ssrn.com/abstract=1682574> (observing that most determinations of patent eligibility for biotechnology inventions will turn on the “natural phenomena” exception, but that the Supreme Court has offered very little guidance as to what constitutes an unpatentable natural phenomenon).

<sup>108</sup> See, e.g., John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 773-74 (2003) (“Where the Federal Circuit once resolved issues based upon ‘all the facts and circumstances,’ it now applies a discrete list of factors. Where the court once employed standards, it now employs rules...In short, the Federal Circuit has embraced an increasingly formal jurisprudence.”).

<sup>109</sup> Jeffrey A. Lefstin, *supra* note \_\_, at 1144. See also ADRIAN VERMEULE, *JUDGING UNDER UNCERTAINTY: AN INSTITUTIONAL THEORY OF LEGAL INTERPRETATION* 72 (2006) (explaining that, in one sense of formalism, the adjudicator justifies the outcome by reference to conceptualist or essentialist reasoning, for example ruling on a matter of constitutional law based on a distinction between “manufacturing” and “commerce” or between “legislative” and “executive” power).

statutory requirements as a distinct silo and rigidly adheres to the notion that each substantive doctrine operates separately and independently from the others.<sup>110</sup> The court also prefers the certainty of rules over the indeterminacy of standards.<sup>111</sup> Its approach is not textualism – it is not mechanistically applying a statutory rule.<sup>112</sup> Rather, the Federal Circuit aims to develop its own judicially-created rules with which to apply vague statutory patentability criteria. A distinctive feature of formalism is the notion that a legal rule is itself the reason for decision, rather than the means for fulfilling an underlying social purpose.<sup>113</sup> The Federal Circuit’s MOT test exemplifies this aspect of formalism. The rule’s narrow focus on physicality allows it to be applied without considering its purpose, which is to limit the scope of patent protection for foundational discoveries so as to encourage follow-on development.

The Federal Circuit’s preference for rules coincides with its clear disinclination to engage in explicit policy analysis.<sup>114</sup> While the court routinely recites policy

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<sup>110</sup> See Kevin Emerson Collins, *An Initial Comment on Ariad: Written Description and the Baseline of Patent Protection for After-Arising Technology*, 2010 PATENTLY-O PATENT L. J. 65 (“[P]atent litigation and scholarship are frequently conducted within distinct doctrinal silos. Courts and manuscripts take on disclosure issues (section 112, paragraph 1), functional claiming issues (section 112, paragraph 6), or utility issues (section 101) in isolation, assuming that each doctrine maps onto a distinct normative problem...”); Lefstin, *supra* note \_\_, at 1144-47 (noting the Federal Circuit’s formalist conception of the patent system as a whole).

<sup>111</sup> See John R. Thomas, *supra* note \_\_, at 778-92 (offering five examples of the trend towards adjudicative rule formalism in the Federal Circuit’s patent jurisprudence: (1) the on-sale bar; (2) the public dedication doctrine; (3) the “strict bar” approach to prosecution history estoppels struck down by the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki*, 535 U.S. 722 (2002); (4) the court’s simple, permissive rule governing subject matter eligibility set forth in *State Street Bank v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998); and the court’s teaching, suggestion, or motivation (TSM) test for nonobviousness); see also Rai, *supra* note \_\_, at 1113-14 (arguing that the Federal Circuit’s *Festo* opinion suggests that adjudicative rule formalism and not simply pro-patent bias drives the court’s decisionmaking). See also Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885 (2003) (generally noting this sense of formalism).

<sup>112</sup> See Arti K. Rai, *Engaging Facts and Policy: A Multi-institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1103 (2003) (noting the distinction between formalism and textualism, and explaining that where a statute clearly adopts a standard, the formalist jurist must go beyond the statutory text to craft a bright-line rule).

<sup>113</sup> *Id.* at 536-37.

<sup>114</sup> See, e.g., *In Re Fisher*, 421 F.3d 1365, 1378 (Fed. Cir. 2005) (“public policy considerations...are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law”); Alan D. Lourie, *A View from the Court*, 75 PAT. TRADEMARK & COPYRIGHT J. 22 (2007) (“[N]ot once have we had a discussion as to what direction the law should take...We have just applied precedent as best we could determine it to the cases that have come before us.”). See also Rochelle Cooper Dreyfuss, *In Search of Institutional Identity*, *supra* note \_\_, at 809 (“[T]he Federal Circuit tends to favor a kind of formalism that is more characteristic of legal thinking in the nineteenth century than in the

justifications for the statutory patentability requirements, it rarely identifies policy reasons for its own decisions.<sup>115</sup> The Federal Circuit’s unwillingness to take an overt role in setting patent policy has sparked a great deal of criticism from patent commentators, including former Chief Judge Michel,<sup>116</sup> who fear that the court’s adherence to bright-line rules may unmoor the patent law from the goals of innovation policy.<sup>117</sup> Dan Burk and Mark Lemley temper this charge by arguing that the court implicitly directs patent policy through selective application of its patentability rules, which they refer to as “policy levers.”<sup>118</sup> Their observation suggests that the Federal Circuit’s approach is really one of feigned formalism, and that “once stripped of its formalist gloss,” patent law actually operates to incorporate a wide range of judicial discretion.<sup>119</sup> One commentator asserts that this practice is socially desirable, because it ensures against absurd results that may arise if the court actually adhered to strict formalism.<sup>120</sup> But feigned formalism arguably is even worse than true formalism, because it negates the key benefits that bright-line

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twenty-first. Thus, opinions rarely provide insight into the goals the court sees the law as achieving; ‘policy discussions’ take the form of incantations of standard justifications of statutory terms.”); Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, GEO. WASH. L. REV. 1, 18 (2008) (noting that the Federal Circuit generally declines to engage in explicit policy analysis despite the patent statute’s open-ended language).

<sup>115</sup> Rochelle Cooper Dreyfuss, *The Federal Circuit as an Institution*, *supra* note \_\_, at 834. In the Federal Circuit’s *Bilski* opinion, only Judge Mayer, in dissent, explicitly considered the patent system’s core utilitarian goals. See *Bilski*, 545 F.3d at 1005-06 (Mayer, J., dissenting).

<sup>116</sup> Craig Allen Nard & John F. Duffy, *Rethinking Patent Law’s Uniformity Principle*, 101 NW. U. L. REV. 1619, 1622 (2007) (citing Hon. Paul R. Michel, Keynote Presentation, Berkeley Center for Law & Technology Conference on Patent System Reform, Mar. 1, 2002 (transcribed by Gerald T. Peters)) (noting that Chief Judge Michel remarked, “We just keep replicating the old results based on the old precedents, whether they have kept pace with changes in business, changes in technology, or changes of a different sort...”).

<sup>117</sup> See, e.g., John R. Thomas, *supra* note \_\_, at 774-75 (“We can imagine a patent law as dynamic as the innovative industries it is said to support, but an orientation towards rules threatens to make the patent law hidebound and unresponsive to changing conditions.”); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, *supra* note \_\_, at 1037 (arguing that the Federal Circuit “adopt[s] bright-line rules that are insensitive both to technological fact and to related issues of innovation policy”); Alan Devlin & Neel Sukhateme, *supra* note \_\_, at 908 (“[The Federal Circuit opinion in] *Bilski*, like the patentable subject matter cases that precede it, regrettably falls prey to a judicial aversion to abstraction and ignores the incentive to invent and commercialize principles that motivate patent law.”); Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 803-04 (2008) (arguing that the Federal Circuit’s disinclination to explain the policy rationales driving its decisions makes it difficult to discern when the court is taking the patent law in a new direction and gives rise to appeals built around minute changes in the language of particular holdings).

<sup>118</sup> Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, *supra* note \_\_.

<sup>119</sup> T.J. Chiang, *The Levels of Abstraction Problem in Patent Law*, *supra* note \_\_, at 28.

<sup>120</sup> *Id.* at 29.

rules have to offer – predictability and stability.<sup>121</sup> It also belies the empirical uncertainty about the patent law’s practical effects that makes formulation and application of suitable patentability rules so difficult. Rules work best when they possess three qualities: *transparency* (the rule’s meaning is easily understood); *accessibility* (the rule is easy to apply to concrete situations); and *congruence* with the rule’s underlying policy objectives.<sup>122</sup> The court’s failing is its denial of the impossibility of crafting ex ante patentability rules which simultaneously satisfy each of these criteria in all cases. Rules may serve as useful guideposts, but cannot be exclusively relied upon to regulate complex, heterogeneous, and constantly evolving technologies. By striving both to produce the certitude of bright-line rules and to achieve intuitively appealing outcomes, the Federal Circuit ends up with the worst of both worlds: legal unpredictability and yet a failure to mirror the patent system’s utilitarian purpose in specific contexts.

Carol Rose famously observed that, in property law, we do not choose between hard-edged rules (“crystals”) and fuzzy, ambiguous ones (“mud”). Rather, we tend to oscillate between them.<sup>123</sup> She notes:

The trouble, then, is that an attractively simple legal device draws in too many users, or too complex a set of uses. And that, of course, is where the simple rule becomes a booby trap. It is this booby trap aspect of what seems to be clear, simple rules – the scenario of disproportionate loss by some party – that seems to drive us to muddy up crystal rules with the exceptions and the post hoc discretionary judgments.<sup>124</sup>

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<sup>121</sup> See Carl Tobias, *The White Commission and the Federal Circuit*, 10 CORNELL J. L. & PUB. POL’Y 45, 58 (2000) (citing a 1999 report by the Commission on Structural Alternatives for the Federal Courts of Appeals which found that the Federal Circuit was second only to the Ninth Circuit in the proportion of attorneys who concluded that the law of the circuit was difficult to discern due to conflicting precedents). See also John R. Thomas, *supra* note \_\_, at 796-97 (arguing that predictability and stability should not be the exclusive goals of the patent law, and that, moreover, historical reflection on the Federal Circuit’s decisionmaking casts serious doubt on the notion that adjudicative rule formalism produces legal certainty).

<sup>122</sup> Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65, 67 (1983). See also Frederick Schauer, *Formalism*, 97 YALE L. J. 509, 539 (1988) (explaining that rules cultivate predictability only if the actors governed by the rule are able to easily identify how things will be categorized and the actors’ categorizations accord with the decisionmaker’s categorizations).

<sup>123</sup> Carol M. Rose, *Crystals and Mud in Property Law*, 40 STAN. L. REV. 577, 593 (1988).

<sup>124</sup> *Id.* at 597.



The problem with the Federal Circuit’s jurisprudence is that it obscures the existence of an analogous phenomenon in the patent law.<sup>125</sup> Examination of the court’s application of the canons of claim construction, the disclosure requirements, and the PSM doctrine reveals that the Federal Circuit depicts patent law “mud” as if it were “crystals.”

Claim construction is ostensibly a textualist exercise that disavows judicial discretion and prevents courts from transforming infringement into a matter of judicial whim.<sup>126</sup> Yet the Federal Circuit’s conflicting canons of claim construction have led some courts to construe claims broadly in accord with the literal language of the claim, others to construe claims narrowly to read only on the embodiment described in the specification, and most to adopt a middle position whereby the construed claim scope extends beyond the specific embodiment but falls short of the level of abstraction embodied in the plain meaning of the claim’s language.<sup>127</sup> “Far from creating a determinate and predictable system that secures patentee rights free from the arbitrary whims of judges and PTO bureaucrats, current claim construction...creates precisely the indeterminate free-for-all that formalism seeks to avoid.”<sup>128</sup>

Similar pitfalls are apparent in the Federal Circuit’s adjudication of the disclosure requirements. One line of cases interprets the disclosure provisions to require that the reader of the specification be able to construct the “full-scope” of the claim at the time of patent filing.<sup>129</sup> Faithful application of the full-scope rule for written description and

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<sup>125</sup> See John F. Duffy, *Rules and Standards on the Forefront of Patentability*, *supra* note \_\_, at 614 (“Eventually, rules always fail. This should surprise no one who studies innovation. The unruly process of creative destruction has the power to undermine today’s legal rules every bit as much as it renders obsolete today’s industrial products, processes, and institutions.”).

<sup>126</sup> T.J. Chiang, *The Levels of Abstraction Problem in Patent Law*, *supra* note \_\_, at 12.

<sup>127</sup> *Id.* at 14 (noting that this uncertainty “increases risk, encourages litigation, and disrupts business planning”).

<sup>128</sup> *Id.* at 15. See also Ted Sichelman, *Myths of (Un)Certainty at the Federal Circuit*, 43 *LOU. L. REV.* 1161, 1191-92 (2010) (“[I]n its quest for predictability, the Federal Circuit has adopted a number of ‘canons’ of claim construction, which – while seemingly instantiating a formal regime of transparent rules – are internally contradictory and rest on flawed premises...[I]t appears that typically unstated judicial ideologies influence judges, whether conspicuous or not, to choose one of the competing canons in the cases in which they conflict.”). See *e.g.*, *Schering Corp. v. Amgen, Inc.*, 222 F.3d 1347 (Fed. Cir. 2000) (adopting a strained interpretation of the claim construction doctrine to limit the reach of the patentee’s claims to proteins known as interferons to the existing scientific knowledge at the time the patent was filed).

<sup>129</sup> See, *e.g.*, *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378-80 (Fed. Cir. 2007).

enablement denies the inventor the opportunity to claim after-arising technologies.<sup>130</sup> A second line of cases interprets the disclosure requirements to say that the specification of a single working embodiment is sufficient.<sup>131</sup> Under this “single-embodiment” rule, a broad claim is valid so long as the specification teaches the PHOSITA how to make and use any one embodiment without undue experimentation.<sup>132</sup> Faithful application of the single-embodiment rule allows the patentee to reach into after-arising technologies and grants the patentee a claim of indefinite temporal depth. Other enablement cases adopt a middle-ground approach between the two extremes in requiring that there be a “reasonable correlation” between the disclosure and the claims.<sup>133</sup> Early Federal Circuit decisions applied the single embodiment rule to predictable (e.g., mechanical) arts and applied the full scope rule to unpredictable (e.g., chemical) arts. However, recent case law no longer predictably tracks this dichotomy.<sup>134</sup>

The Federal Circuit has inconsistently applied the disclosure requirements to biotechnology claims. For example, in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*<sup>135</sup>, the court applied the single-embodiment rule to uphold the validity of a broad claim to all “non-naturally occurring” forms of the hormone erythropoietin (EPO), including EPO created by after-arising scientific methods, based on the disclosure of one method of making and using the claimed composition. On the other hand, in *Chiron Corp. v. Genentech Inc.*<sup>136</sup>, the court rejected the patentee’s claim to all monoclonal antibodies that bind to the human breast cancer antigen Her2 based on an application that disclosed

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<sup>130</sup> Taking the point even further, literal application of the “full scope” rule threatens to render worthless every patent in existence, because it allows competitors to avoid infringement by incorporating into embodiments incremental technological changes that are developed after patent filing. See T.J. Chiang, *The Levels of Abstraction Problem in Patent Law*, *supra* note \_\_, at 20.

<sup>131</sup> See, e.g., *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052 (Fed. Cir. 2005). In holding that the enablement requirement is met if the specification enables any mode of making and using the invention, the court reasoned that, “[w]ere it otherwise, claim inventions would not include improved modes of practicing those inventions. Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed, and the inventor would lose the benefit of the patent bargain.” *Id.* at 1071.

<sup>132</sup> Kevin Emerson Collins, *Enabling After-Arising Technology*, *supra* note \_\_, at 1088; T.J. Chiang, *The Levels of Abstraction Problem in Patent Law*, *supra* note \_\_, at 18.

<sup>133</sup> See, e.g., *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).

<sup>134</sup> Kevin Emerson Collins, *Enabling After-Arising Technology*, *supra* note \_\_, at 1088.

<sup>135</sup> 314 F.3d 1313 (Fed. Cir. 2003).

<sup>136</sup> 363 F.3d 1247 (Fed. Cir. 2004).

one such antibody, concluding that claims to embodiments that do not exist in the art at the time of the invention fail to satisfy the written description requirement. Lacking clear guidance from the Federal Circuit with respect to the conflicts in the law on disclosure, courts tend to manipulate the case law by selecting from among the different options the formalist rule that reaches the favored outcome in any given case.<sup>137</sup> The Federal Circuit denies any inconsistency in its application of the disclosure rules,<sup>138</sup> thereby exacerbating doctrinal instability.

Similar confusion abounds in the Federal Circuit's adjudication of the PSM doctrine.<sup>139</sup> "[T]he Federal Circuit and its predecessor court have changed the rules governing patentable subject matter no less than three times in thirty years."<sup>140</sup> When one rule becomes unworkable, the court simply fashions a new rule that better addresses changing conditions. But rather than admitting that a change in the law is necessary, the court asserts that the newly articulated rule is what the law really has been all along. In *State Street Bank v. Signature Financial Group*<sup>141</sup>, the Federal Circuit did not discuss the practical ramifications of its decision to expansively define PSM as any invention that produces a "useful, concrete, and tangible result." The inadequacy of this permissive rule ultimately compelled the court to replace it with the *Bilski*<sup>142</sup> MOT test.<sup>143</sup> Yet the MOT test seems destined to a similar fate. A patentability rule centered on physicality is problematic in an era when many of our most important technological advances – such as

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<sup>137</sup> *Id.* at 28; Kevin Emerson Collins, *Enabling After-Arising Technology*, *supra* note \_\_, at 1088 ("[C]ourts exercise discretion between the full-scope and single-embodiment doctrines to achieve the desired outcome.").

<sup>138</sup> *See Automotive Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1281 (Fed. Cir. 2007) (rejecting argument that there is a "dichotomy in our case law").

<sup>139</sup> *See, e.g.*, Michael Risch, *Everything is Patentable*, *supra* note \_\_, at 591 (noting that PSM jurisprudence is "currently confused and inconsistent").

<sup>140</sup> John F. Duffy, *Rules and Standards on the Forefront of Patentability*, *supra* note \_\_, at 612. *See also id.* at 639 (attributing the longevity of the abstract ideas exception to PSM to the fact that it is a malleable standard).

<sup>141</sup> 149 F.3d 1369 (Fed. Cir. 1998).

<sup>142</sup> 545 F.3d 943 (Fed. Cir. 2008).

<sup>143</sup> *See* p. \_\_ Part IIB, *infra*.

computer software and communications technology – possess few if any physically transformative features.<sup>144</sup>

**B. *Doctrinal Chaos: Medical Methods as Case Study***

Medical methods patents offer an illustrative case study of the problems with the Federal Circuit’s jurisprudence. Such patents impact an industry characterized by cumulative innovation, a diverse array of market participants,<sup>145</sup> and an elaborate regulatory framework which interacts with the patent system to create a complex web of incentives to invent, develop, and commercialize new technologies.<sup>146</sup> The Federal Circuit does not directly address empirical uncertainty about the social desirability of broad upstream patents. Instead it seems to tacitly shunt its empirical intuitions into its application of rules ostensibly concerned only with technological issues. The result is an incoherent body of law that obscures questions about the practical effects of patenting.

The revived PSM doctrine offers the Federal Circuit a new tool to limit the scope of medical methods patents, since both diagnostic and therapeutic claims implicate the “abstract ideas” and “natural phenomena” exceptions to patentability.<sup>147</sup> Yet the court has thus far been reluctant to clarify its application of the MOT test to medical methods claims. The en banc court deliberately sidestepped the test in *Ariad Pharms., Inc. v. Eli*

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<sup>144</sup> Richard S. Gruner, *In Search of the Undiscovered Country: The Challenge of Describing Patentable Subject Matter*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 395, 398 (2007).

<sup>145</sup> See Alexander K. Haas, *The Wellcome Trust’s Disclosures of Gene Sequence Data into the Public Domain & the Potential for Proprietary Rights in the Human Genome*, 16 BERKELEY TECH. L.J. 145, 147 (2001) (explaining that the biomedical industry includes genomics companies, biotechnology companies, and traditional pharmaceutical companies); Rebecca Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 195 (1987) (noting that researchers within academia and industry often work on similar problems and frequently collaborate with one another).

<sup>146</sup> Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, *supra* note \_\_, at 19-21 (explaining how FDA and NIH regulations work in parallel with PTO examination and Federal Circuit patent adjudication to create incentives to create new drugs and biologics).

<sup>147</sup> See Michael Risch, *Everything is Patentable*, *supra* note \_\_, at 627 (“A new use patent claims the natural phenomenon that a medicine has a certain effect on the body (or, as in *Metabolite*, that certain test process results reflect a certain condition), and the patentee is the first to discover the previously unknown effect.”); Eileen Kane, *Patenting Genes and Genetic Methods: What’s at Stake?*, J. OF BUS. AND TECH. LAW 133 (forthcoming), available at <http://ssrn.com/abstract=1747191> (noting that it is possible to imagine medical method claims that would pass the MOT test but nonetheless preempt a natural phenomenon).

*Lilly & Co.*<sup>148</sup> Ariad held patents with broad claims to methods of targeting the intracellular protein Nuclear Factor Kappa B (“NF-κB”), which scientists had implicated in a variety of disease processes, including cancer, AIDS, sepsis, and atherosclerosis. Lilly had discovered and patented two compounds prior to the discovery of NF-κB’s intracellular signaling activity. Lilly did not know at the time that it patented its compounds that they acted at the molecular level by inhibiting NF-κB activity. Lilly developed, marketed, and sold a drug for osteoporosis and another drug to treat severe sepsis prior to being sued by Ariad for patent infringement.<sup>149</sup>

The district court upheld the validity of Ariad’s patents, rejecting Lilly’s argument that claimed methods of reducing intracellular NF-κB, without reference to any specific embodiment, constituted unpatentable subject matter.<sup>150</sup> The district court’s decision turned on a narrow, highly technical dispute over whether there existed within cells a natural process of inhibiting NF-κB activity (i.e., an “autoregulatory loop”). Since Lilly failed to prove that the autoregulatory loop actually existed in nature, the district court concluded that Ariad’s patents did not cover a natural phenomenon.<sup>151</sup> This conclusion begged the question, should the validity of Ariad’s patents hinge on the existence of a clinically insignificant autoregulatory loop? Perhaps recognizing the MOT test’s deficiencies as applied to medical methods, the Federal Circuit avoided the question of whether the claimed methods constituted PSM.<sup>152</sup> It concluded that the patent failed to satisfy the written description requirement because the specification did not disclose a sufficient number of species to receive patent protection for the entire genus of claimed

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<sup>148</sup> 598 F.3d 1336 (Fed. Cir. 2010) (en banc) (reiterating that § 112 of the Patent Act contains a written description requirement that is separate from the enablement requirement, affirming its holding that Ariad’s patents were invalid for failing to satisfy the written description requirement, and declining to address the question of whether the claimed method constitutes PSM). This practice perpetuates the Federal Circuit’s tendency to rely primarily on the disclosure requirements to limit the reach of therapeutic method claims into AAT. *See, e.g.*, *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) (invalidating a patent claiming methods of inhibiting COX-2 activity in a human host for failing to satisfy the written description requirement where the patentees failed to identify a single compound that selectively inhibited the COX-2 enzyme).

<sup>149</sup> 529 F. Supp. 2d 106, 114 (D. Mass. 2007).

<sup>150</sup> 529 F. Supp. 2d 106 (D. Mass. 2007).

<sup>151</sup> *Id.* at 116-20.

<sup>152</sup> 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

embodiments. Although the specification hypothesized three classes of molecules capable of inhibiting NF- $\kappa$ B activity, this disclosure was deemed insufficient to support a generic claim to all molecules with NF- $\kappa$ B -inhibiting activity.<sup>153</sup>

The Federal Circuit bolstered its decision by reference to the patent system's utilitarian purpose, but policy concerns hovered at the margins rather than at the forefront of the court's analysis. The court observed, "Such claims merely recite a description of the problem to be solved while claiming all solutions to it...leaving it to the pharmaceutical industry to complete an unfinished invention."<sup>154</sup> It also noted, "Ariad presents no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. But claims to research plans also impose costs on downstream research, discouraging later invention."<sup>155</sup> Yet the court failed to articulate the legal relevance of such hypothetical evidence. If Ariad had presented empirical data about the impact of broad therapeutic patents on the incentives to discover and develop new drugs, how would that have affected the Federal Circuit's analysis? What if Ariad had gone a bit further in the development process, for instance by synthesizing a molecule that demonstrated NF- $\kappa$ B inhibition *in vitro*? Should it then have been allowed the broad generic claim that it sought? In refusing to directly confront the tension between fostering *ex ante* incentives to create and sustaining *ex post* incentives to develop, the Federal Circuit perpetuated uncertainty about the desirability and availability of patent protection for broad upstream biological discoveries.<sup>156</sup>

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<sup>153</sup> *Id.* at 1349.

<sup>154</sup> *Id.* at 1353. *See also id.* at 1349 (noting that the written description requirement "keeps inventors from claiming beyond their inventions and thus encourages innovation in new technological areas by preserving patent protection for actual inventions").

<sup>155</sup> *Id.*

<sup>156</sup> Judge Newman wrote a separate concurring opinion "because the real issue of this case is too important to be submerged in rhetoric." 598 F.3d 1336, 1358 (Fed. Cir. 2010) (en banc) (Newman, J., concurring). She urged the court to focus on overriding policy concerns rather than quibbling over which statutory clause governs a particular case. *Id.* at 1359. Judge Rader wrote a separate opinion dissenting-in-part and concurring-in-part with the majority's opinion. Rader rejected the majority's conclusion that the Patent Act contains a separate written description requirement and strongly criticized the decision as opening the floodgates for undisciplined judicial policymaking: "As it stands, the court's inadequate description of its written description requirement acts as a

In *Prometheus Labs, Inc. v. Mayo Collaborative Servs.*<sup>157</sup>, the court applied the PSM doctrine but characterized the disputed claims so as to minimize its effect. The court upheld the validity of claims to methods of measuring the blood levels of certain drug metabolites and using that data to optimize treatment of patients suffering from autoimmune diseases. Whereas the district court characterized the claims as describing correlations between metabolite levels and therapeutic efficacy and toxicity,<sup>158</sup> the Federal Circuit characterized the claims as describing methods of treatment. These divergent depictions of the claimed methods flagged very different analytical approaches to their patentability. The district court held them unpatentable for wholly pre-empting a natural phenomenon,<sup>159</sup> but the Federal Circuit reversed in finding that they satisfied the MOT test.<sup>160</sup> Notably, the court announced a bright-line rule that treatment methods are “*always transformative* when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.”<sup>161</sup>

The Federal Circuit’s 2009 decision was vacated and remanded by the Supreme Court in light of its decision in *Bilski*. On remand, the Federal Circuit reaffirmed its holding that Prometheus’s asserted method claims are drawn to PSM.<sup>162</sup> The court noted that the Supreme Court’s opinion did not invalidate the MOT test, but merely held that it was not a definitive test for assessing preemption of a natural phenomenon.<sup>163</sup> The court reiterated its prior analysis that the asserted claims are effectively methods of treatment, satisfy the transformative prong of the MOT test, and hence constitute PSM.<sup>164</sup> The court thus seemed to pay lip service to the Supreme Court’s instruction in *Bilski* to create a more flexible PSM doctrine, but did not substantively change its articulated rules-based

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wildcard on which the court may rely when it faces a patent that it feels is unworthy of protection.” *Id.* at 1366 (Rader, J., concurring-in-part, dissenting-in-part).

<sup>157</sup> 628 F.3d 1347 (Fed. Cir. 2010).

<sup>158</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 2008 U.S. Dist. LEXIS 25062, at 123-27 (S.D. Cal. 2008).

<sup>159</sup> *Id.*

<sup>160</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009).

<sup>161</sup> *Id.* at 1346 (emphasis added).

<sup>162</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010).

<sup>163</sup> *Id.* at 1355.

<sup>164</sup> *Id.* at 1355-56.

framework. Apparently dissatisfied with the Federal Circuit's resolution of the case, the Supreme Court recently granted Mayo's petition for writ of certiorari.<sup>165</sup>

In *King Pharms., Inc. v. Eon Labs, Inc.*<sup>166</sup>, the Federal Circuit suggested that claimed methods of increasing the bioavailability of a muscle relaxant by ingesting the drug with food are PSM. The court invalidated the claims on other grounds, but reiterated the notion that therapeutic claims necessarily constitute PSM because they satisfy the transformative prong of the MOT test.<sup>167</sup> Yet the Federal Circuit took a strikingly different approach to the therapeutic claims at issue in *Classen Immunotherapies, Inc. v. Biogen Idec.*<sup>168</sup> The court affirmed a district court ruling invalidating Classen's patented methods for evaluating and improving the safety of immunization schedules based on a discovered correlation between vaccines and chronic immune-mediating disorders. In an unpublished opinion, it concluded that the methods constituted unpatentable subject matter because they failed to satisfy the MOT test. The Supreme Court vacated the Federal Circuit's *Classen* decision and remanded the case in light of its holding in *Bilski* that the MOT test is a useful, but not exclusive, test for PSM.<sup>169</sup> **[NOTE: still awaiting the Federal Circuit's opinion on remand]**

The divergent outcomes in *Prometheus* and *Classen* suggest that the Federal Circuit is creating a new implicit policy lever based on a distinction between significant and insignificant data-gathering. Where the court aims to uphold the claims, as in *Prometheus*, it concludes that the transformative aspects of the claims constitute significant data-gathering steps and thus satisfy the MOT test. Conversely, where the court aims to invalidate the claims, as in *Classen*, the court concludes that the transformative aspects of the claims merely constitute insignificant data-gathering steps and thus fail to satisfy the MOT test. Rather than explicitly acknowledging its policy-

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<sup>165</sup> 79 U.S.L.W. 3710 (U.S., June 20, 2011) (No. 10-1150).

<sup>166</sup> 616 F.3d 1267 (Fed. Cir. 2010).

<sup>167</sup> *Id.* at 1278 ("We therefore understand the Supreme Court to have rejected the exclusive nature of our test, but not necessarily the wisdom behind it...The present case, however, does not present the proper vehicle for determining whether claims covering medical treatment are eligible for patenting under § 101 because even if claim 21 recites patent eligible subject matter, that subject matter is anticipated [under § 102].").

<sup>168</sup> 304 Fed. Appx. 866 (Fed. Cir. 2008), *rehearing denied by*, 2009 U.S. App. LEXIS 24202 (Fed. Cir. 2009).

<sup>169</sup> 130 S. Ct. 3541 (2010).



laden judgments, the court makes such determinations under the guise of a formalist rule. It provides scant guidance as to how it will employ this new policy lever, exacerbating doctrinal confusion and unpredictability.

The Federal Circuit was able to frame the complex claim in *Prometheus* as a treatment method and thus sidestep the difficult question of whether a claim to a medically significant scientific correlation constitutes PSM. However, the court will be forced to directly confront this issue in its highly anticipated appellate decision in *Ass'n for Molecular Pathology v. United States PTO*.<sup>170</sup> The district court invalidated claims both to isolated and purified BRCA1 and BRCA2 gene sequences and to methods of analyzing those gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer, concluding that they were unpatentable natural phenomena and abstract mental processes.<sup>171</sup> Notably, although the district court's opinion begins with an in-depth overview of the underlying policy concerns involved in the dispute,<sup>172</sup> the holding that the methods claims are unpatentable is grounded squarely on a formalist application of the MOT test.<sup>173</sup> The court never connects back to the practical implications of its ruling because it lacks an adequate hook to connect doctrine to policy. Part IV asserts that the Federal Circuit should bridge this gap by adopting a pragmatic approach to patent tailoring. **[NOTE: still awaiting the Federal Circuit's opinion on appeal]**

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<sup>170</sup> *Ass'n for Molecular Pathology v. United States PTO*, 2010 U.S. Dist. LEXIS 35418, at 53 (S.D.N.Y. 2010), *motion granted by Ass'n for Molecular Pathology v. United States PTO*, 2010 U.S. App. LEXIS 17077 (Fed. Cir., Aug. 16, 2010).

<sup>171</sup> *Ass'n for Molecular Pathology v. United States PTO*, 2010 U.S. Dist. LEXIS 35418 (S.D.N.Y. 2010).

<sup>172</sup> *Id.* at 53 (noting that the discovery of BRCA1 resulted from research that was supported heavily by federal funding); *Id.* at 71-72 (citing Professors Heller and Eisenberg's well-known article positing that gene patents deter biomedical R&D by creating a genetic "anti-commons"); *Id.* at 104 (quoting from Justice Breyer's dissent in *Labcorp*, in which Breyer observed that "'sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection'").

<sup>173</sup> *Id.* at 149-158,

## IV. A Pragmatic Proposal

### A. *Evidence-Based Patent Law*

Patentability is often phrased as a query into whether an eligible invention is sufficiently novel, useful, nonobvious, and disclosed to deserve patent protection. But if the driver of the patent system is social welfare, the central inquiry should be what scope of patent protection (if any) is required to promote the creation and development of the relevant technology.<sup>174</sup> This Part proposes incorporating the principles of legal pragmatism and pragmatic adjudication into the patent law. Although there is no universally accepted definition of legal pragmatism, its core tenets include instrumentalism, contextualism, and empiricism.<sup>175</sup> Pragmatism has three main characteristics: hostility to metaphysical concepts (e.g., “nature”) as objects of truth; insistence that propositions be assessed by their consequences; and emphasis on human need as a measure of the value of all social endeavors.<sup>176</sup> Legal pragmatism is an offshoot of philosophical pragmatism, which advocates “an extension of the scientific method into all areas of inquiry.”<sup>177</sup>

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<sup>174</sup> See Rochelle Cooper Dreyfuss, *In Search of Institutional Identity*, *supra* note \_\_, at 827 (asserting that, now that the Federal Circuit has matured beyond experimental status and attained legitimacy, it should shift its focus from the short-term objectives of predictability and stability to the broader goal of crafting the patent law to promote technological innovation).

<sup>175</sup> See RICHARD A. POSNER, *OVERCOMING LAW* 19 (1995) (“Pragmatists want the law to be more empirical, more realistic, more attuned to the needs of real people.”); Richard A. Posner, *What Has Pragmatism to Offer Law?*, 63 S. CAL. L. REV. 1653, 1657 (1990) (“The thing that counts is that legal rules be understood in instrumental terms, implying contestability, revisability, and mutability.”); Thomas C. Grey, *What Good Is Legal Pragmatism*, in *PRAGMATISM IN LAW IN LAW AND SOCIETY* 9, 15 (“We pragmatists keep in the back of our minds the reminder that we are thinking to some end – thinking instrumentally. We also keep there a reminder that we are thinking against a background of tacit presupposition of which we can never be fully aware – thinking *contextually*.”).

<sup>176</sup> Richard A. Posner, *What Has Pragmatism to Offer Law?*, *supra* note \_\_, at 1660-61. Pragmatism is related to but distinct from legal realism, the movement that emerged in the 1920s and 1930s as a response to the formalist legal thought that dominated at the time. Realists rejected the notion that law is a comprehensive system of autonomous conceptual propositions and emphasized its instrumental, practical, contextual, and adaptive character. Pierre Schlag, *Formalism and Realism in Ruins (Mapping the Logics of Collapse)*, 95 IOWA L. REV. 195, 199 (2009). The tenets of early twentieth century realism are present in modern day legal pragmatism and related schools of thought such as law and economics, the legal process school, and critical thought. *Id.* at 207-08.

<sup>177</sup> RICHARD A. POSNER, *HOW JUDGES THINK* 231 (2008) (“On a pragmatist view, our ideas, principles, practices and institutions simply are tools for navigating a social and political world that is shot through with indeterminacy.”). See also *Id.* at 233 (explaining that philosophical and legal pragmatism are related but not identical, and noting, “The case for legal pragmatism is based not on philosophical argument but on the needs and character of American law.”).

Pragmatism pervades the American judicial system.<sup>178</sup> It is odd, therefore, that the Federal Circuit seems so reluctant to incorporate its principles into a body of law that is particularly conducive to pragmatic adjudication. In contrast to other substantive areas, the patent law is a nakedly instrumentalist creation whose uncontroverted purpose is to promote technological innovation.<sup>179</sup> “The more homogeneous, and therefore the wider the agreement on what kind of consequences are good and what kind are bad (and how good and how bad), the greater the guidance that pragmatism will provide.”<sup>180</sup> Moreover, the patent system does not exist in a vacuum. The patent law operates as part of a complex web of regulatory and incentive structures that impose costs and bestow benefits on the creators, developers, and users of innovative technologies.<sup>181</sup> Normative questions of patent scope thus turn on “a pragmatic balancing of real-world consequences.”<sup>182</sup>

There is a solid historical basis for pragmatic adjudication of patent scope. The judicially-created exceptions to PSM trace back to the 1852 Supreme Court opinion, *Le Roy v. Tatham*,<sup>183</sup> which was grounded in concerns about the practical effects of overly broad patents.<sup>184</sup> Similarly, the legal framework for assessing nonobviousness set forth

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<sup>178</sup> See Brian Z. Tamanaha, *How an Instrumental View of Law Corrodes the Rule of Law*, 56 DEPAUL L. REV. 469, 490 (2007) (noting that “[j]udicial decisions today routinely cite policy considerations, consider the purposes behind the law, and pay attention to law’s social consequences”); RICHARD A. POSNER, HOW JUDGES THINK, *supra* note \_\_, at 230 (“The word that best describes the average American judge at all levels of our judicial hierarchies and yields the greatest insight into his behavior is ‘pragmatist’...”). The tenets of pragmatism manifest themselves in the teachings and decisions of Oliver Wendell Holmes. See, e.g., Oliver Wendell Holmes, THE COMMON LAW (1881) (announcing in the first sentence that “[t]he life of the law has not been logic; it has been experience”); Oliver Wendell Holmes, *The Path of Law*, 10 HARV. L. REV. 457 (1897); *Southern Pacific Co. v. Jensen*, 244 U.S. 205, 221 (1917) (Holmes, J., dissenting) (“I recognize without hesitation that judges do and must legislate.”).

<sup>179</sup> See Jonathan S. Masur, *Regulating Patents*, Sup. Ct. Rev. 20 (forthcoming 2011), available at <http://ssrn.com/abstract=1709222> (“While contract and tort law may seek to balance a variety of consequentialist and deontological considerations – welfare maximization, efficiency, fairness, distributional justice, etc. – the objectives of patent law are more straightforward.”).

<sup>180</sup> RICHARD A. POSNER, HOW JUDGES THINK, *supra* note \_\_, at 241.

<sup>181</sup> Craig Allen Nard, *Toward a Cautious Approach to Obeisance: The Role of Scholarship in Federal Circuit Patent Law Jurisprudence*, 39 HOUS. L. REV. 667, 668 (2002).

<sup>182</sup> Tun-Jen Chiang, *The Rules and Standards of Patentable Subject-Matter*, WIS. L. REV. 38 (forthcoming), available at [http://ssrn.com/abstract\\_id=1670871](http://ssrn.com/abstract_id=1670871).

<sup>183</sup> 55 U.S. 156 (1852).

<sup>184</sup> *Id.* at 174-75 (“A patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws.”).

by the Supreme Court in the 1966 case, *Graham v. John Deere Co. of Kan. City*<sup>185</sup>, is “a legal question sitting atop a highly fact-intensive contextual analysis.”<sup>186</sup> At least once the Federal Circuit applied this framework to explicitly incorporate R&D costs into its nonobviousness analysis.<sup>187</sup> Another example of pragmatic adjudication is the judicially-created doctrine of equivalents, which is intended to preserve the incentive structure of the patent system by ensuring that competitors cannot easily escape liability by making insubstantial changes to their products so that they do not literally infringe a patentee’s claims. The Federal Circuit’s preference for acontextual bright-line rules has led it to essentially abandon this fact-dependent doctrine.<sup>188</sup> But the time may be ripe for a return to pragmatism. Justices Breyer,<sup>189</sup> Stevens, and Souter<sup>190</sup> argued in dissent from *Labcorp* that overly expansive patent breadth might undermine public health and scientific progress.<sup>191</sup> The *Bilski* Court cautioned that patentability determinations should take into

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<sup>185</sup> 383 U.S. 1 (1966).

<sup>186</sup> Lee Petherbridge, *On the Development of Patent Law*, 43 LOY. L.A. L. REV. 893, 917 (2010). See also Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 815-16 (1988) (explaining that the Supreme Court supplemented a formalist three-part test for nonobviousness with a set of contextual “secondary considerations” to formulate the modern nonobviousness standard, and noting that the Court expressly “authorized courts to look at evidence outside the intrinsic features of the invention and focus on the real world consequences surrounding its origin and commercialization”).

<sup>187</sup> See, e.g., *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985) (fact that patentee spent seven years and millions of dollars to create the invention is evidence of nonobviousness).

<sup>188</sup> See Lee Petherbridge, *On the Development of Patent Law*, 43 LOY. L.A. L. REV. 893, 920-21 (2010).

<sup>189</sup> Justice Breyer’s pragmatic, evidence-based approach to intellectual property law traces back to his seminal piece on the economics of copyright. See Stephen Breyer, *The Uneasy Case for Copyright: A Study of Copyright in Books, Photocopies, and Computer Programs*, 84 HARV. L. REV. 281 (1970) (making an argument against congressional expansion of copyright law based on an analysis of the economics of the book publishing industry). For an overview of Breyer’s arguments in favor of pragmatic adjudication in general, see STEPHEN BREYER, *ACTIVE LIBERTY: INTERPRETING OUR DEMOCRATIC CONSTITUTION* 88, 118-119 (2005) (asserting that pragmatic considerations should guide questions of statutory interpretation, but that judges should not exercise unfettered discretion and must take account of “the legal precedents, rules, standards, practices, and institutional understanding that a decision will affect”).

<sup>190</sup> Although Justices Stevens and Souter have since retired, recent Supreme Court decisions indicate that there is substantial support for pragmatic patent adjudication among the currently sitting justices.

<sup>191</sup> *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 348 U.S. 124, 125-27 (2006) (asserting that the justification for excluding natural laws from patentable subject matter “does not lie in any claim that their discovery is easy, or that they are not useful...Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts’, the constitutional objective of patent and copyright protection.”). See also John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609 (2009) (noting that Justice Breyer’s *LabCorp* opinion implies that patentability determinations should not be based on the social desirability of patents as ends in themselves, “but on *empirical estimation* of the usefulness of patents in achieving other ends (progress)”).

account economic factors, with patents granted only where they will promote, rather than retard, innovation.<sup>192</sup> While not discarding the Federal Circuit's MOT test, the Supreme Court encouraged the Federal Circuit to articulate an adjudicative framework that better reflects the patent system's overarching innovation goals.<sup>193</sup>

Pragmatism requires that the Federal Circuit do explicitly, with the aid of sound contextual evidence, what the courts have been doing implicitly and haphazardly in their selective application of scope-defining patentability doctrines. The various patent theories delineated in the academic literature<sup>194</sup> present a set of hypotheses that should be tested empirically in specific contexts.<sup>195</sup> While rules such as the MOT test may offer a useful analytical starting point, patentability should ultimately turn on straightforward questions about the disputed patent's impact on technological progress. The Federal Circuit can encourage the aggregation and dissemination of the information needed to answer these questions by directly incorporating evidentiary guideposts into its patentability determinations. Pragmatic adjudication can serve an information-eliciting function by creating an incentive for litigants to produce and interpret relevant empirical information. Litigants are presumably rational actors, and will marshal their resources and tailor their arguments according to the cues that they are given in the Federal Circuit's opinions. If, as the court's recent holdings seem to suggest, semantic arguments about an invention's physical nature are outcome-determinative, then litigants will devote their time and energy to such issues. If, on the other hand, the court signals that the actual economic impact of the contested patent is a central legal concern, then both sides will be compelled to fill in gaps in the relevant empirical data.<sup>196</sup>

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<sup>192</sup> See *Bilski*, 130 S. Ct. at 3228-29.

<sup>193</sup> *Id.* at 3231 ("In disapproving an exclusive machine-or-transformation test, we by no means foreclose the Federal Circuit's development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text."). Justice Stevens wrote a separate opinion in which he relied on legal and economic scholarship as well as "common sense" to conclude that business methods should be categorically excluded from patentable subject matter. *Id.* at 3253-57 (2010) (Stevens, J., concurring).

<sup>194</sup> See Part IIA, *supra*.

<sup>195</sup> See Richard A. Posner, *Legal Pragmatism Defended*, 71 U. CHI. L. REV. 683, 684 (2004) (explaining that legal pragmatism rejects decisionmaking based on abstract moral and philosophical principles, but embraces theories that "guide empirical inquiry").

<sup>196</sup> See Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1633 (2007) ("[T]he appellate system relies on the argumentation of lawyers, and lawyers' arguments will be directly

The Federal Circuit’s emphasis should be on increasing judicial candor,<sup>197</sup> asking the right factual questions, and acknowledging when answers to those difficult questions remain unresolved. The court should refrain from depicting patent “mud” as if it were “crystals.” At the same time, it should actively encourage the crystallization of some of the mud by identifying and addressing areas of empirical uncertainty. Critics of pragmatic adjudication argue that pragmatism has the potential to turn judges into “loose legislative canons” and render the law hopelessly indeterminate.<sup>198</sup> But pragmatism’s call for increased judicial candor actually has the potential to curtail judicial discretion. “Judges are less likely to be drunk with power if they realize they are exercising discretion than if they think they are just a transmission belt for decisions made elsewhere and so bear no responsibility for any ugly consequences of those decisions.”<sup>199</sup> A patent doctrine that explicitly acknowledges the Federal Circuit’s policy engineering role will prevent the court from washing its hands of any systemic problems that its opinions engender.

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influenced by the appellate structure and rules of circuit precedent.”). It is preferable to directly encourage litigants to generate and disseminate economic and empirical data, rather than to rely solely on amicus briefs to offer contextual information. See Craig Allen Nard, *Toward a Cautious Approach to Obeisance: The Role of Scholarship in Federal Circuit Patent Law Jurisprudence*, *supra* note \_\_, at 686 (noting that, although amicus briefs filed by third parties have the veneer of objectivity, amici writers may be motivated to distort information to serve their own interests).

<sup>197</sup> See Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn from the Supreme Court – and Vice Versa*, 59 AM. U. L. REV. 787, 802 (2010) (“[T]he Federal Circuit has to act like a teacher: it has to explain what policies it is adopting...In other words, the Federal Circuit must articulate the theory on which it is relying.”). For general arguments in favor of judicial candor, see Scott C. Idleman, *A Prudential Theory of Judicial Candor*, 73 TEX. L. REV. 1307, 1309 (1995) (arguing that it has traditionally been recognized that “candor is an ideal toward which judges should almost always aspire”); GUIDO CALABRESI, *A COMMON LAW FOR THE AGE OF STATUTES* 178-81 (1982) (discussing the benefits of judicial candor); Susan Estrich, *The Justice of Candor*, 74 TEX. L. REV. 1227, 1228 (1996) (“It is precisely because of its underlying political nature that the task of judging...demands both rigor and candor.”). See also Charles E. Clark and David M. Trubek, *The Creative Role of the Judge: Restraint and Freedom in the Common Law Tradition*, 71 YALE L.J. 255, 271(1961) (“There should be a sterner and more forthright exercise of judicial talent to look steadily and with balance to the consequences to be expected from the judicial act and to its effect as a precedent on the growth of the law. Escape from this hard task by reliance on neutrality and certainty to avoid forthrightness is itself a decision, albeit one of negation.”); RICHARD A. POSNER, *HOW JUDGES THINK*, *supra* note \_\_, at 271 (asserting that pragmatism is inescapable and that denying it only has the effect of reducing judicial candor).

<sup>198</sup> RICHARD A. POSNER, *HOW JUDGES THINK*, *supra* note \_\_, at 252.

<sup>199</sup> *Id.* Federal Circuit Judge Plager has acknowledged that claim construction ultimately rests upon the court’s contextual intuitions. See S. Jay Plager, *The Federal Circuit as an Institution: On Uncertainty and Policy Levers*, 43 LOY. L.A. L. REV. 749, 761 (2010) (“However, the judgments may be articulated, however rationalized they may be in terms of the carefully selected canons of claim construction, the outcomes depend on the Federal Circuit’s judgment about the sense of the situation.”).

Ideally, patentability determinations should reflect a careful balance of factors, including the need for patent-induced innovation, the competitiveness of the relevant market, the ease with which an invention’s patentability can be assessed, and the existence of mechanisms outside the patent law for appropriating an invention’s benefits.<sup>200</sup> The Federal Circuit should expressly incorporate contextual factors into its patent scope determinations, including the cost of research and development (R&D), the ratio of R&D costs to imitation costs, technological risk, and the availability of non-patent alternatives for capturing the social value of inventions. Alternative means of capturing value may include government grants and other direct funding sources, non-patent legal means of protecting proprietary rights (e.g., copyright, trademark, and trade secrecy), technical means of protecting information (e.g., encryption), and market-based protections (e.g., first-mover advantage and network effects).<sup>201</sup>

Importantly, the Federal Circuit “must not make the best the enemy of the good.”<sup>202</sup> Since the court will rarely have information to reach the socially optimal result, its aim should be to reach results that are “good enough” approximations.<sup>203</sup> The goal should not be to ascertain optimal patent scope for every invention, but rather to accumulate empirical information with which to move the patent law closer in that direction. Pragmatism’s empirical focus favors an incremental approach, whereby the Federal Circuit decides difficult cases narrowly and then broadens the reach of its decisions as knowledge accumulates. This approach will create the flexibility to adapt the law to new information or changing circumstances without being unduly constrained by principles of stare decisis.<sup>204</sup> The pragmatic response to uncertainty about the

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<sup>200</sup> John R. Thomas, *Formalism at the Federal Circuit*, *supra* note \_\_, at 799.

<sup>201</sup> Peter S. Menell, *A Method for Reforming the Patent System*, 13 MICH. TELECOMM. TECH. L. REV. 487, 494 (2007).

<sup>202</sup> RICHARD A. POSNER, HOW JUDGES THINK, *supra* note \_\_, at 241. *See also* RICHARD A. POSNER, OVERCOMING LAW 396 (1995) (explaining that the goal of legal pragmatism is not to attain some universal “truth” but rather to constantly build upon our wealth of knowledge about the world).

<sup>203</sup> RICHARD A. POSNER, HOW JUDGES THINK, *supra* note \_\_, at 241. *See also* ADRIAN VERMUELE, JUDGING UNDER UNCERTAINTY: AN INSTITUTIONAL THEORY OF LEGAL INTERPRETATION 176-78 (2006) (explaining that satisficing is a response to uncertainty in which a decisionmaker searches for and selects the option that is “good enough” rather than holding out for the possibility that maximizes welfare in the immediate case).

<sup>204</sup> *See id.* at 246-47 (“The broader the ground, the less scope the judges will have for obtaining from future cases additional information bearing on the consequences of the activity, because the decision will be a precedent that until overruled or distinguished will rule new cases within its semantic domain, which may be vast.”).

consequences of ruling one way or another is to maintain the legal status quo, “since the effect of overruling [past decisions] would be to sacrifice [legal] certainty and stability for merely conjectural gain.”<sup>205</sup> Therefore, a pragmatic approach to a novel or difficult patentability case may be to point out the relevant policy questions, lament the paucity of available empirical data to definitively answer those questions, and reluctantly follow the most analogous precedent. The outcome in the immediate case might be the same as that under a non-pragmatic regime, but such a real world-oriented opinion would prompt litigants in future cases to produce and interpret relevant data.<sup>206</sup> Over time, the patent system as a whole would benefit from the aggregation of contextual information with which to guide judicial decisionmaking.

Pragmatic patent adjudication could both enrich the case law and move the academic community beyond its “stalemate of empirical intuitions” by encouraging researchers not only to generate hypotheses but also to test them empirically. With a few notable exceptions,<sup>207</sup> Federal Circuit judges have consciously refrained from referring to the patent literature in their opinions. They defend this practice by asserting that the literature’s preoccupation with abstract modeling offers little practical guidance about how to resolve specific cases.<sup>208</sup> Although empirical research which examines the impact

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<sup>205</sup> Richard A. Posner, *Pragmatic Adjudication*, 18 CARDOZO L. REV. 1, 8 (1996).

<sup>206</sup> This approach may help to mitigate the “repeat player disadvantage” identified by Rochelle Cooper Dreyfuss. See Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn From the Supreme Court – and Vice Versa*, *supra* note \_\_, at 805 (observing that a case of first impression may set a precedent which, upon further reflection, is wrong, confusing, or ill suited to unforeseeable future situations, but that attorneys who appear before the Federal Circuit regularly may be reluctant to take up the issue for fear of displeasing the judges and/or tarnishing their reputations).

<sup>207</sup> Judge Newman has cited and discussed patent scholarship in several of her opinions. See, e.g., *Hilton Davis Co. v. Warner-Jenkinson*, 62 F.3d 1512, 1529 (Fed. Cir. 1995) (en banc) (Newman, J., concurring), *rev’d.*, 520 U.S. 17 (1997) (explaining how she has sought to understand how the doctrine of equivalents affects technological innovation and stating, “This path has led me into the thicket of the sociology and economics of patent law, for I have attempted to place the basic question – the role and application of the doctrine of equivalents – into the practical context of the purposes and workings of the patent system, as informed by modern scholarship.”); see also *Johnson & Johnson Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1071-72 (Fed. Cir. 2002) (en banc) (Newman, J., dissenting) (discussing economic and empirical literature).

<sup>208</sup> See, e.g., *Judge Michel Presses for More Data and Rigor in Patent Reform Process*, 63 PAT. TRADEMARK & COPYRIGHT J. (BNA) 429, 430 (Mar. 22, 2002) (“[W]hen the court is asked to reconsider established patent law understandings, [Judge Michel] added, it must rely on the briefs, and those filings rarely contain any ‘data, facts, or hard numbers’ to substantiate the policy arguments being advocated by the litigants.”); S. Jay Plager & Lynne E. Pettigrew, *Rethinking Patent Law’s Uniformity Principle: A Response to Nard and Duffy*, 101 NW. U. L. REV. 1735,



of patents on the innovation practices of firms in various industries does exist,<sup>209</sup> the bulk of academic patent scholarship is highly theoretical.<sup>210</sup> By signaling the legal significance of empirical work, pragmatic patent adjudication may thus create incentives for academics as well as litigants to focus on the patent system's specific practical effects. At the very least, an opinion citing and discussing empirical and economic literature conveys to the affected parties that the court appreciates the consequences of its decisions. It also contributes to "the development of a pragmatic culture – an environment where patent doctrine and policy can constantly be subject to maintenance."<sup>211</sup>

A pragmatic adjudicative regime need not be exclusively rules-based or standards-based.<sup>212</sup> The Federal Circuit should stake out a middle ground between the one extreme in which a court mechanistically applies rules without regard to their

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1752 (2007) (criticizing patent scholars' suggestion that the Federal Circuit engage the secondary patent literature, arguing that "to 'engage' the literature in an opinion is an invitation to flights of dicta, that pervasive curse of the judicial process that adds immeasurably to confusion in the law").

<sup>209</sup> See, e.g., WESLEY M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) 4 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000) (finding that firms in some industries patent to block the development of substitutes by competitors while firms in other industries are more likely to use patent to negotiate licensing deals); Edwin Mansfield, *Unauthorized Use of Intellectual Property: Effects on Investment, Technology Transfer, and Innovation*, in GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 107 (Mitchell B. Wallerstein et al. eds., 1993) (surveying 100 American firms about the importance of intellectual property rights in relation to direct foreign investment); Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 793-95 (Martin Neil Bailly & Clifford Winstron eds., 1987) (analyzing 650 responses to a questionnaire about the effectiveness of alternative means of protecting new inventions).

<sup>210</sup> See Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L. J. 1361, 1434 (2009) ("Subsequent economic analysis of intellectual property law has largely eschewed evidence-based analysis for more abstract modeling."). See also Pierre Schlag, *Formalism and Realism in Ruins (Mapping the Logics of Collapse)*, 95 IOWA L. REV. 195 (2009) (observing academics' general tendency towards abstraction and stating, "In a powerful (and not fully explained) sense, comprehensive formalism remains, for many legal academics, a kind of closet ideal. All this theorizing, modeling, and paradigm-building; all this highly conceptualist work; and all this automatic insistence on elegance, coherence, systematicity, and precision regardless of context suggest the continued hold of the formalist ideal on the American legal-academic imagination").

<sup>211</sup> Craig Allen Nard, *Toward a Cautious Approach to Obeisance: The Role of Scholarship in Federal Circuit Patent Law Jurisprudence*, *supra* note \_\_, at 685.

<sup>212</sup> See Richard A. Posner, *Pragmatic Adjudication*, 18 CARDOZO L. REV. 1, 16 (1996) (noting that pragmatism is "wholly neutral" on whether to apply the law by rules or by standards). For a general overview of the rules versus standards debate, see Louis Kaplow, *Rules versus Standards: An Economic Analysis*, 42 DUKE L.J. 557 (1992); Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65 (1983); Peter H. Schuck, *Legal Complexity: Some Causes, Consequences, and Cures*, 42 DUKE L.J. 1 (1992).

underlying purposes, and the other extreme whereby a court enjoys unfettered discretion to carry out the law's purposes as it sees fit.<sup>213</sup> The argument that a rule should remain tied to the reasons behind its formulation does not lead to the conclusion that rules should be eliminated. Well-crafted rules can help to quickly dispose of core cases and can serve as useful guideposts for difficult boundary cases, illuminating but not dispositive for resolution of the issue.<sup>214</sup> Patent adjudication may work best under a system of “presumptive formalism,” in which the applicable acontextual rule would presumptively govern, but could be rejected if the particular facts of the case suggest that its application would contravene the purpose behind the rule.<sup>215</sup> Indeed, the Supreme Court seemed to instruct the Federal Circuit to adopt this type of approach in its *Bilski* opinion. The Court did not strike down the MOT test, but cautioned the Federal Circuit to apply it as a rule of thumb rather than as a mechanistic exclusive test.<sup>216</sup>

It may be pragmatic for the Federal Circuit to rely on rules when dealing with cases of first impression, but announce its willingness to discard or revise those rules as new information develops.<sup>217</sup> The patentability of DNA sequences offers an illustrative case in point. Under current guidelines, human genes may be patented so long as the

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<sup>213</sup> See Lawrence A. Cunningham, *A Prescription to Retire the Rhetoric of “Principles-Based Systems” in Corporate Law, Securities Regulation, and Accounting*, 60 VAND. L. REV. 1409, 1413 (2007) (noting that regimes governing corporate law, securities regulation, and accounting systems exist on a continuum on the rules/principles axis and cannot be neatly placed into either category).

<sup>214</sup> See Frederick Schauer, *Formalism*, 97 YALE L. J. 509, 537 (1988) (asserting that rules are desirable so long as they are applied as “rules of thumb, useful but intrinsically unweighty indicators of the results likely to be reached by direct application of reasons”). See also Ronald A. Cass, *Judging: Norms and Incentives of Retrospective Decision-Making*, 75 B.U. L. REV. 941, 942 (1995) (noting that, although he rejected the view of the law as a system of formulas for judges to mechanically apply, Oliver Wendell Holmes stressed the importance of anchoring the law within a framework of predictable rules). See also Louis Kaplow, *Rules versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 585-86 (1992) (noting that the desirability of giving content to a rule ex ante as opposed to giving content to a standard ex post depends upon the frequency with which the particular issue arises. Frequency implies homogeneity across the range of cases falling under the legal formulation, while infrequency implies heterogeneity across the range of covered cases).

<sup>215</sup> See Frederick Schauer, *Formalism*, *supra* note \_\_, at 547 (advocating this regime and explaining that it would have the advantages of stability of predictability, but also retain the flexibility necessary to ensure that the law does not deviate from its underlying social goals).

<sup>216</sup> 130 S. Ct. 3218, 3221 (2010).

<sup>217</sup> See Richard A. Posner, *Legal Pragmatism Defended*, 71 U. CHI. L. REV. 683, 683-684 (2004) (explaining that “[t]here are bound to be formalist pockets in a pragmatic system of adjudication, notably decision by rules rather than by standards”).

invention describes a gene that has been isolated and purified from its natural setting.<sup>218</sup> This rule traces back to Learned Hand's 1911 decision in *Parke-Davis & Co. v. H.K. Mulford Co.*<sup>219</sup>, which upheld a patent on adrenaline that had been purified from the adrenal glands of cadavers because, unlike adrenaline in its natural setting, the patented substance had practical therapeutic utility. By signaling its approval of a formalist rule that all useful biological inventions are PSM so long as they are altered from their natural state, the Federal Circuit locked itself into a path that now, in the face of increasing scrutiny from the Supreme Court, it must reexamine. It may have been sensible for the court to reason by analogy to existing therapeutic biological substances when first addressing the patentability of biotechnology, but the court should have remained vigilant to the possibility that new scientific and economic developments might undermine the utility of that analogy.<sup>220</sup> Drawing analogies to the most similar precedents makes sense when there is insufficient information to justify forging a new legal path for a novel invention. But the Federal Circuit must be mindful of the possible negative consequences of continuing to follow this course. It may become apparent over time that the downsides of rigid adherence to precedent outweigh the advantages of stability and predictability. The beneficiaries of the patent law will be better served if the Federal Circuit candidly exercises judicial discretion rather than obscuring judicial policymaking in the guise of formalist reasoning.

Pragmatic patent adjudication would better align the patent law with the law of copyright. Courts considering the levels of abstraction problem in copyright cases refrain from absolutist rules and instead employ a more flexible analysis that takes into account real world economic factors.<sup>221</sup> Pragmatic patent adjudication would also harmonize the

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<sup>218</sup> See Utility Examination Guidelines, 66 Fed. Reg. at 1095.

<sup>219</sup> 189 F. 95 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912).

<sup>220</sup> Application of the "human intervention" doctrine to biotechnological inventions may have been pragmatic in the early days of biotech research, but its utility today is questionable in light of current scientific understandings. See Eileen Kane, *Patent-mediated Standards in Genetic Testing*, 2008 UTAH L. REV. 835, 890-91 (2008) (explaining that, unlike other types of molecules, the commercial utility of genes and proteins stems mainly from their informational content and does not derive from isolation and purification as it does in the classic human intervention cases).

<sup>221</sup> T.J. Chiang, *The Levels of Abstraction Problem in Patent Law*, *supra* note \_\_, at 44-45.

patent law with modern antitrust jurisprudence.<sup>222</sup> The need to reconcile patent with antitrust is particularly pressing given their frequent intersection and the Federal Circuit's 1998 decision that it would no longer apply the antitrust law of the circuit in which a case originates but rather develop and apply its own antitrust law to antitrust questions raised by patent cases.<sup>223</sup> The patent and antitrust regimes represent complementary systems, as both are designed to maximize long-run social welfare by promoting innovation and competition.<sup>224</sup> The Federal Circuit would improve the interoperability of patent and antitrust law<sup>225</sup> by incorporating pragmatic aspects of antitrust decisionmaking into its patent jurisprudence.

Antitrust law encompasses a mix of flexible standards and bright-line rules that enables courts to transparently engage in policy engineering. Empirical questions are resolved through various procedural mechanisms that force parties to produce the key

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<sup>222</sup> See, e.g., *State Oil Co. v. Khan*, 522 U.S. 3, 20-21 (1997) (“[T]he general presumption that legislative changes should be left to Congress has less force with respect to the Sherman Act in light of the accepted view that Congress ‘expected the courts to give shape to the statute’s broad mandate by drawing on common-law tradition.’”).

<sup>223</sup> *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1067 (Fed. Cir. 1998).

<sup>224</sup> U.S. Dep’t of Justice and Fed. Trade Comm’n, Antitrust Guidelines for the Licensing of Intellectual Property § 1.0 (1995) (“The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare.”), <http://www.justice.gov/atr/public/guidelines/0558.htm> (last visited January 25, 2011); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) (“The patent and antitrust laws are complementary, the patent system serving to encourage innovation and the bringing of new products to market by adjusting investment-based risk and the antitrust laws serving to foster industrial competition.”); *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990) (“[T]he aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complementary, as both are aimed at encouraging innovation, industry and competition.”). See also Thomas O. Barnett, *Interoperability Between Antitrust and Intellectual Property*, 14 GEO. MASON L. REV. 859, 860 (2007) (explaining that competition reduces static inefficiency by driving prices toward marginal costs of production, but at the risk of increasing dynamic inefficiency if the drive towards marginal costs occurs too early in the product development timeline, and that this insight suggests that “intellectual property protection is not separate from competition principles, but rather, is an integral part of antitrust policy as a whole”).

<sup>225</sup> See Thomas O. Barnett, *Interoperability Between Antitrust and Intellectual Property*, supra note \_\_, at 870 (asserting that “firms making investment decisions seek clear, predictable rules as to how the intellectual property and antitrust regimes will function together – or interoperate.”). See also 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 (2002) (criticizing the the Federal Circuit’s decision in *In re Independent Service Organization Antitrust Litigation*, 203 F.3d 1322 (Fed. Cir. 2000) (“CSU”), which held that patentees may lawfully refuse to sell or license their patent rights if they do not engage in a *per se* violation of the antitrust laws such as illegal tying or fraud and arguing that the decision runs against the grain of the current trend in antitrust law moving away from adjudicative rule formalism and towards a contextual analysis that applies economic principles to distinguish anticompetitive and precompetitive conduct).

information courts need to fit the law to different factual circumstances. The Sherman Act's sweeping provisions provide courts a great deal of discretion to adapt antitrust policy to changing market conditions and to new economic learning about the competitive process.<sup>226</sup> Some acts, such as price-fixing or bid-rigging, are per se unreasonable restraints of trade because courts have concluded from past experience that they are manifestly anticompetitive and socially undesirable.<sup>227</sup> Other restraints are judged under a loose "rule of reason" standard. Conduct that does not fall into a per se prohibited category must undergo a highly contextual, fact-intensive analysis in order for judges to ascertain whether they are, on balance, anticompetitive or procompetitive. Similarly, the Clayton Act encompasses an amalgam of rules and standards, as it prohibits certain specific activities, such as price discrimination, tying, or certain acquisitions, but only where the effect of the arrangement may be to substantially reduce competition or to create a monopoly.<sup>228</sup> "It is only because the courts (following dominant economic opinion) are confident that the ordinary garden-variety cartel or price-fixing agreement is socially inefficient that there is a *rule* against cartelizing or price fixing...When the judges' confidence in the competitive significance of a challenged practice is sufficiently shaken...they engage in a more freewheeling inquiry [guided by the rule of reason]."<sup>229</sup> Although the Patent Act comprises a more detailed

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<sup>226</sup> Sherman Act § 1, 15 U.S.C. § 1 (2000) ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."); Sherman Act § 2, 15 U.S.C. § 2 (2000) ("Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony."). See also JOHN H. SHENEFIELD & IRWIN M. STELZER, *THE ANTITRUST LAWS* 15-19 (2001) (explaining that when drafting the Sherman Act, Congress did not delineate lists of prohibited activities, but rather chose to proscribe restraints generally, in sweeping provisions to be developed and applied by courts in specific cases).

<sup>227</sup> JOHN H. SHENEFIELD & IRWIN M. STELZER, *THE ANTITRUST LAWS* 16-17(2001) (explaining that most per se rules are not applied as bright-lines, and that "[s]ome practices, while subjected to what courts call per se treatment, nevertheless are evaluated by reference to market circumstances....Others are condemned outright, without any such further analysis. But those latter instances are increasingly rare.").

<sup>228</sup> *Id.* at 21.

<sup>229</sup> RICHARD POSNER, *ANTITRUST LAW* 39-40 (2001). See also *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977) (rejecting application of the Sherman Act to nonprice vertical restraints which rested upon a formalist distinction between sales and consignments and clarifying that adjudication of antitrust cases must center on the challenged activity's demonstrable economic consequences). But see David F. Shores, *Economic Formalism in Antitrust Decisionmaking*, 68 ALB. L. REV. 1053 (2005) (cautioning that recent antitrust case law purporting to

statutory scheme than the antitrust laws,<sup>230</sup> the Federal Circuit retains a significant amount of discretion to carry out its central goal of promoting innovation. The broadly defined statutory requirements, supplemented by longstanding judicially-created doctrines, leave much room for the court to develop an approach to patent adjudication patterned after that of antitrust.

The PSM doctrine is the best doctrinal vehicle to perform explicit policy-based patent tailoring. The appeal of a contextual approach to patent adjudication is that it allows the law to adapt to changes other than scientific advancements which impact the incentives of inventors and developers, such as new regulatory changes or shifting market conditions.<sup>231</sup> Unlike the disclosure requirements, the PSM doctrine is not ostensibly tied by the PHOSITA to strictly technological considerations.<sup>232</sup> Hence use of the PSM doctrine to calibrate the reach of claims into after-arising technology would not risk divergence of patent doctrine with scientific reality.<sup>233</sup> It would also increase transparency by alerting inventors and developers to the basis for the court's decisions. Litigants will not be left to wonder whether a patentability determination reflects the Federal Circuit's (mis)understanding of the relevant state of the art or implicit acknowledgement of economic and market considerations. A more expansive, scope-defining PSM doctrine may obviate the need for a separate written description

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emphasize demonstrable economic effects actually relies on abstract economic theory that has not been empirically tested, and thus manifests economic, as opposed to legal, formalism).

<sup>230</sup> S. Jay Plager & Lynne E. Pettigrew, *Rethinking Patent Law's Uniformity Principle: A Response to Nard and Duffy*, 101 NW. U. L. REV. 1735, 1737 (2007) (asserting that the Federal Circuit's discretion is more limited than is the discretion of courts hearing antitrust cases, because the Patent Act comprises a detailed statutory scheme and the Federal Circuit is constrained by congressional policy choices embedded in the legislation).

<sup>231</sup> For example, if the federal government were to significantly slash its NIH budget or substantially change FDA safety and efficacy requirements, the level of skill in the biopharmaceutical arts would not change, but incentives to invent biotechnologies may be significantly affected.

<sup>232</sup> See Peter S. Menell, *A Method for Reforming the Patent System*, *supra* note \_\_, at 489-90 (noting that doctrines tied to the PHOSITA standard cannot adequately take into account critical variables relevant to optimal patent scope, including the costs of creation and invention, alternative means of appropriating the value of inventions, and network effects).

<sup>233</sup> Claim construction is of limited utility in tailoring patent scope to achieve utilitarian aims so long as the plain meaning of the claim's language is acknowledged. Morse's eighth claim illustrates why we must go beyond claim language if we are to set meaningful limits on the reach into after-arising technologies.

requirement for originally filed claims.<sup>234</sup> It will also allow the court to assess enablement by reference to the embodiment described in the specification, preventing contortion of the enablement doctrine through selective application of the “full scope” rule or “reasonable correlation” test.<sup>235</sup>

Dan Burk and Mark Lemley argue that a touchstone of subject matter eligibility should be whether or not the public is already deriving benefit from a newly discovery substance or property.<sup>236</sup> This is a pragmatic approach in that it centers on the practical implications of patenting. This Article’s proposal goes a step further by asserting that the question of whether a claim wholly preempts a fundamental principle should explicitly turn on the patent’s *net* social benefits. Even if the public is not already deriving benefit from a newly discovered phenomenon, a patent may nonetheless be welfare reducing if it significantly impedes follow-on development.

Importantly, pragmatism favors using the PSM doctrine as a “backstop”<sup>237</sup> that prevents the patenting of inventions that satisfy other statutory patentability criteria but nonetheless should, in the interests of innovation policy, remain in the public domain. The Federal Circuit should first assess whether the claim meets the requirements of novelty, nonobviousness, utility, and adequate disclosure (according to the “single-embodiment” rule). Only if a claim meets each of these criteria should the court proceed with a PSM analysis which grapples with the levels of abstraction problem. This approach would enable the court to employ the “take the best” heuristic, which instructs the decisionmaker to act on a single valid cue and ignore other less reliable forms of

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<sup>234</sup> See Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141 (2008) (explaining that the written description requirement allocates proprietary rights among pioneering inventors and follow-on developers by restricting claim scope to a particular level of abstraction). The written description requirement would still be useful to assess the priority date of claims that are added after the filing date of the original application. The question would be whether the specification adequately describes the subject matter of the after-filed claims such that the patentee possessed the later-claimed invention on the filing date.

<sup>235</sup> See Tun-Jen Chiang, *The Rules and Standards of Patentable Subject-Matter*, *supra* note \_\_, at 44-45 (explaining that, so long as we think that patentees ought to be able to claim some subset of after-arising technologies, enablement is an awkward tool to make determinations of how large that subset should be).

<sup>236</sup> Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM AND MARY L. REV. 371, 407-08 (2005).

<sup>237</sup> See Mark A. Lemley, et al., *Life after Bilski*, *supra* note \_\_ (advocating this approach). See also Tun-Jen Chiang, *The Rules and Standards of Patentable Subject-Matter*, *supra* note \_\_, at 44 (“Ideally, scope delineation should be the *last* exercise performed by a court or the PTO, because it is the most complicated and administratively expensive inquiry”).

evidence.<sup>238</sup> Interestingly, the Federal Circuit took this approach in *Ariad* when it deviated from established custom of treating PSM as a threshold inquiry, sidestepping the PSM question and electing instead to invalidate the claim on written description grounds.

The tailoring functions performed by the PSM doctrine may be supplemented by judicious application of the standard for injunctive relief. The remedy for infringement can create a “safety valve” which mitigates the harmful effects of erroneous validity determinations.<sup>239</sup> Where there is some empirical data to suggest that a particular type of upstream patent may deter innovation, a pragmatic approach may be to uphold the validity of the patent but deny injunctive relief. In this case, the remedy for patent infringement would be limited to compensatory damages. The court may revisit the validity issue at a later time as additional information about the technology develops and more becomes known about the impact of such patents on technological progress.

Pragmatic adjudication arguably would create greater legal predictability than the Federal Circuit’s current practice of feigned formalism.<sup>240</sup> Even if a shift to pragmatism does produce short-term legal instability, it is important to note that patents are inherently uncertain probabilistic rights.<sup>241</sup> Moreover, muddy patent rules may promote efficient licensing transactions by facilitating bargaining and discouraging strategic behavior. Ian

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<sup>238</sup> See ADRIAN VERMUELE, *JUDGING UNDER UNCERTAINTY: AN INSTITUTIONAL THEORY OF LEGAL INTERPRETATION* 180 (2006) (generally explaining the “take the best” heuristic).

<sup>239</sup> See Henry E. Smith, *Institutions and Indirectness in Intellectual Property*, *supra* note \_\_, at 2127 (explaining that injunctive relief can operate as a “safety valve” to reach equitable outcomes in particular situations in which the holdup threat is particularly concerning, forestalling the need for more aggressive legislative or judicial reforms). See also Michael W. Carroll, *Patent Injunctions and the Problem of Uniformity Cost*, 13 MICH. TELECOMM. & TECH. L. REV. 421 (2007) (explaining that flexibility in the standard for injunctive relief should lead to industry-specific patterns in its application because of industry-specific facts relevant to the standard).

<sup>240</sup> See Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L. J. 1361, 1428-29 (2009) (explaining that increased complexity associated with patent tailoring will not necessarily produce greater administrative costs, and that greater complexity may actually reduce licensing and litigation costs if it produces legal terminology with comparatively stable meaning).

<sup>241</sup> See Mark Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPECTIVES 75 (2005) (delineating the numerous uncertainties associated with patent rights); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 395 (2003) (noting that “all real patents are *less strong* than the idealized patent grant usually imagined in economic theory” because what a patent provides is not a right to exclude “but rather a more limited ‘right to try to exclude’ by suing for patent infringement in court”); Kelly Casey Mullally, *Legal (Un)certainly, Legal Process, and Patent Law*, 43 LOY. L.A. L. REV. 1135, 1135-41 (2010) (explaining that, contrary to the general presupposition that private actors favor legal clarity, patent applicants have incentives to introduce uncertainty into their patents by drafting broad claims intended to cover unknown future technologies and to capture all possible infringements).



Ayres and Eric Talley have demonstrated using game theory that muddy rules, in which each party has a probabilistic claim, make parties more willing to negotiate and force parties to reveal information during negotiations.<sup>242</sup> This insight suggests that a certain degree of legal uncertainty about the scope of patent claims is not unduly troubling, as it conforms to inventors' and developers' expectations and may actually increase social welfare.

### **B. Institutional Considerations**

Envisioning a pragmatic approach to patent adjudication raises questions of political economy and relative institutional competence. If we are to develop evidence-based patent law, why should the Federal Circuit, rather than the PTO or Congress, be the entity to do so?<sup>243</sup> Patent reform proposals must be mindful of the “nirvana fallacy,” the phenomenon whereby “an excessively optimistic account of one institution is compared with an excessively pessimistic account of another.”<sup>244</sup> The institutional decision necessarily involves a choice among highly imperfect alternatives.<sup>245</sup> Key factors to consider include relative expertise; responsiveness to public opinion; procedural differences; and political insulation and susceptibility to capture.<sup>246</sup>

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<sup>242</sup> Ian Ayres & Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement to Facilitate Coasean Trade*, 104 YALE L.J. 1027 (1995) (characterizing muddy rules as an example of divided entitlements).

<sup>243</sup> See Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, *supra* note \_\_, at 1400 (noting that intellectual property can be tailored by judicial adjudication, administrative rules and adjudication, or by legislation); ADRIAN VERMUELE, JUDGING UNDER UNCERTAINTY: AN INSTITUTIONAL THEORY OF LEGAL INTERPRETATION 64 (2006) (explaining that “specifying a criterion for a successful interpretive outcome...says nothing at all about which institution is best situated to implement the chosen aim”).

<sup>244</sup> ADRIAN VERMUELE, JUDGING UNDER UNCERTAINTY, *supra* note \_\_, at 40. See also Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1 (1969) (identifying the “nirvana” fallacy and arguing in favor of a comparative institutional approach).

<sup>245</sup> See Arti K. Rai, *Engaging Facts and Policy: A Multi-institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1039 (2003) (“Only by evaluating the relative competence of the various institutions in performing the tasks required by the patent process can we hope to design a system that works reasonably well – or, at a minimum, less imperfectly than the alternatives.”). See generally, Neil K. Komisar, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY 4-6 (1994) (asserting that comparative institutional analysis is essential to addressing public policy questions and that “tasks that strain the abilities of an institution may wisely be assigned to it anyway if the alternatives are even worse”).

<sup>246</sup> Jonathan S. Masur, *Regulating Patents*, SUP. CT. REV. 31-32 (forthcoming 2011), available at <http://ssrn.com/abstract=1709222>. Public choice theory assumes that government actors are influenced by their own personal motives when making decisions that impact social welfare, and thus are subject to capture by powerful special interests. See, e.g., Roger G. Noll, *Economic Perspectives on the Politics of Regulation*, in 2

The PTO is not the best institution to formulate evidence-based patent law, because it lacks substantive rulemaking authority and economic expertise.<sup>247</sup> Absent rulemaking authority, it is not capable of fine-tuning the patent law to keep it abreast with evolving needs. Even if Congress were to grant the agency rulemaking authority, the PTO's capability to competently exercise such authority is questionable.<sup>248</sup> Patent examiners are not lawyers – they merely perform the ministerial function of administering the law created by Congress and the courts.<sup>249</sup> Admittedly, the PTO's policymaking capability would be strengthened if it were granted the authority and resources to tackle the complex economics of patent scope.<sup>250</sup> But a better funded agency would still be hampered by the inherent limitations of ex ante rules as applied to heterogeneous and constantly evolving technologies. It also may be unduly costly to center the focus of patent tailoring on the PTO. Very few patents have real marketplace value – the overwhelming majority are neither licensed nor litigated<sup>251</sup> – so it would be wasteful for the PTO to expend substantial resources performing detailed examinations.<sup>252</sup>

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HANDBOOK OF INDUSTRIAL ORGANIZATION 1253, 1262-63 (Richard Schmalensee & Robert D. Willig eds., 1989) (arguing that public actors will effectuate policies that do not reflect the interests of citizens if adequate monitoring and enforcement mechanisms are not instituted).

<sup>247</sup> Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 47(2008) (explaining that the PTO does not engage in substantive rulemaking and currently lacks the expertise to formulate innovation policy).

<sup>248</sup> See, e.g., Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1132-33 (2003); John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L. J. 727, 742-43 (2002). But see Jonathan S. Masur, *Regulating Patents*, SUP. CT. REV. 46 (forthcoming 2011), available at <http://ssrn.com/abstract=1709222> (arguing that the PTO would do a better job than the Federal Circuit at setting patent policy if given substantive rulemaking authority).

<sup>249</sup> Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WM. & MARY L. REV. 127, 138-140 (2000) (noting that “The PTO and its over three thousand patent examiners serve a narrowly circumscribed role in the private law patent system. The PTO has a ministerial task: to apply a legal standard determined by Congress and the courts to the facts presented to it by the patent applicant.”).

<sup>250</sup> See Jonathan Masur, *Regulating Patents*, *supra* note \_\_ (arguing that the PTO should be granted substantive rulemaking authority).

<sup>251</sup> Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 18-19 (2005).

<sup>252</sup> See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1497 (2001) (“In short, the PTO doesn’t do a very detailed job of examining patents, but we probably don’t want it to. It is ‘rationally ignorant’ of the objective validity of patents, in economics lingo, because it is too costly for the PTO to discover those facts.”).

Moreover, the scope of patent protection for the small fraction of patented inventions that are commercially valuable is best assessed through *ex post* litigation than through *ex ante* agency examination.<sup>253</sup> The Federal Circuit is a better venue than the PTO to elicit the information required to answer empirical questions about patents' practical effects. The court has the advantage of the opportunity to take into account scientific and market developments that occur after a patent has been issued. It may only become apparent with the benefit of time that an upstream inventor has been granted a disproportionately broad patent that threatens to stifle follow-on development.<sup>254</sup> In addition, the court can assess the scope of an upstream invention by reference to a concrete situation involving a specific after-arising technology. Our adversarial judicial system is founded on the premise that those who have the most at stake in the outcome will produce the best research and make the best arguments. "On this view...accused infringers...will do a better job of proving a patent invalid than an examiner ever could."<sup>255</sup> The Federal Circuit may also be less susceptible to capture than the PTO. Agency officials may be influenced by the narrow interests of the patent applicants who supply the bulk of the information used to make patentability determinations.<sup>256</sup> Tenured judges tend to have more secure salaries and budgets than agency officials, and may have

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<sup>253</sup> Dan L. Burk and Mark A. Lemley, *Fence Posts or Sign Posts?: Rethinking Claim Construction*, 157 U. PA. L. REV. 1743, 1782 (2009) (arguing that the "innovations that are worth fighting for sort themselves out over time and [can be] vetted by the institution best able to make an *ex post* determination regarding patent value and scope: the courts."). See also DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 95 (2009)(arguing that the courts are the best institutions for patentability analysis).

<sup>254</sup> See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 845-48 (1990) (noting that it is difficult to resolve issues like the "undue experimentation" facet of the enablement requirement when a patent is filed, because at that point no one knows how the technology will evolve or how much work will be required to develop follow-on innovations); T.J. Chiang, *The Levels of Abstraction Problem in Patent Law*, *supra* note \_\_, at 40-41 ("If – as is almost certainly the case – judges have a difficult time determining optimal scope *after*-the-fact because of the complexity of the inquiry; then it is almost impossible to imagine how Congress or the PTO will have the capability to determine a method of computing optimal scope *before*-the-fact, when less information is available.").

<sup>255</sup> Mark A. Lemley, *Rational Ignorance at the Patent Office*, *supra* note \_\_, at 1522.

<sup>256</sup> See Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, *supra* note \_\_, at 36-37 (noting that agency officials are most susceptible to capture by those interests who disproportionately supply the information upon which agency decisions are made).

a greater desire for prestige than anything else that powerful interest groups may readily provide.<sup>257</sup>

The Federal Circuit is also better equipped than Congress to engage in comprehensive patent tailoring. Legislative discretion is constrained by the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPs”), which prohibits member states from discriminating based on technology in their grant of patent rights.<sup>258</sup> Even if legislative tailoring is legally permissible, it may not be desirable. A statute is too blunt an instrument to capture the context-dependent predictions of patent theory.<sup>259</sup> Because the legislative process is slow, legislatures tend to make substantial changes to the law when they garner the momentum to act. In contrast, judicial lawmaking tends to be more precise because it develops incrementally on a case-by-case basis.<sup>260</sup> Congress may be too sluggish and inflexible to keep pace with fast moving technological change.<sup>261</sup> It also may be more susceptible than the Federal Circuit to capture by rent-seeking special interests.<sup>262</sup>

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<sup>257</sup> *Id.* at 38 (noting that the prevailing view among commentators is that courts are less likely than agencies to be captured). *But see* Jonathan S. Masur, *Regulating Patents*, *supra* note \_\_, at 28 (arguing that there is no reason to believe that the PTO is particularly susceptible to capture, and suggesting that the Federal Circuit may have been captured by private interests).

<sup>258</sup> Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, *supra* note \_\_, at 1634.

<sup>259</sup> *Id.* at 1635 (“Many of the predictions of economic theory are fact-specific – they suggest different factors that should bear on the outcome of particular cases, but that require case-by-case-adjudication that cannot be easily captured in a statute.”).

<sup>260</sup> Shyamkrishna Balganesh, “The Pragmatic Incrementalism of Common Law Intellectual Property” 44 (2010). *Scholarship at Penn Law*. Paper 314, available at [http://lsr.nellco.org/upenn\\_wps/314](http://lsr.nellco.org/upenn_wps/314).

<sup>261</sup> See Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 800-01 (2008) (arguing that Congress is ill-suited to the task of tailoring patent law, because “[t]he complexity, frequency, and pace of [scientific and market] changes far outstrip Congress’s capacity to legislate”; Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900-2000*, 88 CAL. L. REV. 2187, 2190 (2000) (arguing that the intellectual property system works best when the courts have “legislative slack” to adapt the law to new technologies); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, *supra* note \_\_, at 1636-37 (offering as an example the Semiconductor Chip Protection Act designed to protect semiconductor mask works, which has virtually never been used because changes in the way chips are made quickly rendered it obsolete).

<sup>262</sup> See NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES*, *supra* note \_\_, at 124 (explaining that federal judges’ job security, their general disinterest in alternative employment opportunities, and steep penalties associated with financial inducement of judges make judges less susceptible than elected officials to influence peddling); Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, *supra* note \_\_, at 40-42 (arguing that recent attempts at legislative patent reform reflect the problem of congressional capture, because long-term considerations of social welfare tend to be overshadowed by competing short-term interests of patent-dependent life sciences firms and comparatively patent-independent information technology firms); RICHARD A. POSNER, *HOW*

Congress has displayed neither the inclination nor the capacity to tackle difficult questions of patent scope. The language and legislative history of the Patent Act strongly suggest that Congress intended to delegate policymaking authority to the courts.<sup>263</sup> Legislators passed the Patent Act of 1952 with shockingly little idea of the statute's content and meaning.<sup>264</sup> The legislative decision to rely primarily on statutory standards rather than rules reflects an expectation that courts would exercise judicial discretion when determining patentability.<sup>265</sup> Moreover, Congress arguably intended to specifically delegate policymaking authority to the Federal Circuit when it created the court in 1982. By historical standards, a new version of the Patent Act was due when Congress created the Federal Circuit in 1982, and thus Congress's decision to establish the court rather than enact new patent legislation could be seen as a delegation of lawmaking authority to the Federal Circuit.<sup>266</sup> Congress has intervened in patent matters since the Federal Circuit's inception – it has altered the patent term for pharmaceutical patents<sup>267</sup>, carved out experimental use defenses for generic pharmaceutical manufacturers<sup>268</sup>, prohibited enforcing patents on medical procedures against doctors<sup>269</sup>, and created a prior user

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JUDGES THINK, *supra* note \_\_, at 253 (noting that, in contrast to legislators who rely on campaign contributions from powerful interest groups, judges' compensation is not tied to their decisions in particular cases).

<sup>263</sup> See Peter S. Menell, *Forty Years of Wandering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Ground Patent Law Interpretation and Return Patent Law to its Technology Mooring*, Stanford Law Review 21(forthcoming 2011), available at <http://ssrn.com/abstract=1722422> (arguing that when Congress enacted the Patent Act of 1952, it intended for courts to continue the jurisprudential tradition of "drawing upon statutory, constitutional, common sense, and experiential sources and insights [so as to ensure that the patent system evolved] into a workable, dynamic system").

<sup>264</sup> See WILLIAM KINGSTON, *BEYOND INTELLECTUAL PROPERTY: MATCHING INFORMATION PROTECTION TO INNOVATION* 87 (2010) (noting that Federal Circuit Judge Rich, who was a patent attorney at the time and a main drafter of the act, later explained: "The [1952] Patent Act was written basically by patent lawyers...A good 95% of the members [of Congress] never knew that the legislation was under consideration, or that it had passed, let alone what it contained").

<sup>265</sup> Michael W. Carroll, *A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: One for All: The Problem of Uniformity Cost in Intellectual Property*, 55 AM. U. L. REV. 845, 895 (2006). See also Jonathan S. Masur, *Regulating Patents*, *supra* note \_\_, at 13 ("It makes no sense to pretend that Congress somehow managed to embed the proper [patent] rules into the [Patent] Act's terse language in 1952 (and before), and that the courts need merely divine Congress's intent.").

<sup>266</sup> Rochelle Cooper Dreyfuss, *The Federal Circuit as an Institution: What Ought We Expect?*, *supra* note \_\_, at 837 (making this argument).

<sup>267</sup> See 35 U.S.C.155-156 (2000).

<sup>268</sup> See *id.* §271(e) (2000).

<sup>269</sup> See *id.* §287(2000).

defense against business method patents.<sup>270</sup> Yet sporadic legislative efforts to comprehensively overhaul the patent system have yet to lead anywhere.<sup>271</sup>

Admittedly, the Federal Circuit faces practical limitations in its ability to evaluate complex economic data. Yet Congress may be even less suited to this task.<sup>272</sup> The nature of the litigation process provides courts with a comparative advantage over legislatures to contextualize the patent law. Judges, unlike legislators, create the law by reference to concrete sets of facts and need not imagine all of the possible ramifications of their decisions *ex ante*.<sup>273</sup> The Federal Circuit routinely confronts highly technical expert testimony in drawing conclusions about patent validity and infringement, thus empirical data regarding the balance of incentives in industries characterized by cumulative innovation should not pose a unique challenge. Congress may generally be better able than the courts to ascertain public norms and interest group preferences.<sup>274</sup> However, as a specialist court the Federal Circuit has greater capability than generalist courts to appreciate “legislative intentions, interest-group deals, statutory policies, and social and economic consequences” of its decisions.<sup>275</sup> The Federal Circuit will not be unduly burdened if it adopts an incremental approach in which it asks relevant empirical questions, creates incentives for the affected parties to seek answers, and proceeds cautiously as the fund of information accumulates over time.

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<sup>270</sup> *See id.* §273(a)(3) (2000).

<sup>271</sup> Proposed reform bills include the Patent Reform Act of 2005, H.R. 2795, 109<sup>th</sup> Cong. (2005); the Patents Depend on Quality Act of 2006, H.R. 5096, 109<sup>th</sup> Cong. (2006); H.R. 5418, 109<sup>th</sup> Cong. (2006); S. 1145, 110<sup>th</sup> Cong. (2007); S. 3923, 110<sup>th</sup> Cong. (2007); H.R. 1908, 110<sup>th</sup> Cong. (2007); H.R. 1260, 111<sup>th</sup> Cong. (2009), and the Patent Reform Act of 2009, 111<sup>th</sup> Cong. (2009).

<sup>272</sup> *See* James J. White, *Phoebe’s Lament*, 98 MICH. L. REV. 2773 (2000) (discussing the lack of influence empirical work has on legislators). Although the Federal Circuit tends to ignore the uncomfortable problem of imperfect information, other courts have freely acknowledged a similar problem in the copyright context. *See, e.g.,* *Nash v. CBS, Inc.*, 899 F.2d 1537, 1541 (7th Cir. 1990) (“Neither Congress nor the courts has the information that would allow it to determine [optimal copyright scope]. Both institutions must muddle through.”).

<sup>273</sup> Louis Kaplow, *Rules versus Standards: An Economic Analysis*, *supra* note \_\_, at 609 (making this observation).

<sup>274</sup> *See* ADRIAN VERMUELE, *JUDGING UNDER UNCERTAINTY*, *supra* note \_\_, at 65 (explaining that Congress’s greater susceptibility to capture must be weighed against judges’ comparative informational deficits stemming from their insularity).

<sup>275</sup> *Id.* at 74-75 (explaining why a specialist court is generally better able than a generalist court to adopt an anti-formalist adjudicative approach). *See also* Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885, 888 & 922-23 (2003) (noting that anti-formalism may be better suited to specialist judges than to generalist judges).

The Delaware Chancery Court’s corporate law jurisprudence offers an adjudicative model for the Federal Circuit. Like the patent law, corporate law grapples with the challenge of formulating a regulatory scheme that applies to a wide range of private actors amidst constantly evolving economic and market conditions.<sup>276</sup> By wide margins, Delaware is the favored state for incorporation.<sup>277</sup> Several commentators have attributed Delaware’s corporate law preeminence to the excellence of its judiciary.<sup>278</sup> Recognized benefits of Delaware courts’ adjudicative approach include “flexibility, responsiveness, insulation from undue influence, and transparency.”<sup>279</sup> The shared expertise of the specialized court and bar generates a body of corporate law that is attuned to empirical uncertainty<sup>280</sup> and quickly updates to incorporate new information. Delaware courts do not employ an exclusively rules-based or standards-based approach, but rather blend the two strategies together to balance predictability and adaptability.<sup>281</sup>

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<sup>276</sup> See Jill E. Fisch, *The Peculiar Role of the Delaware Courts in the Competition for Corporate Charters*, 68 U. CIN. L. REV. 1061, 1099 (2000) (identifying these challenges with respect to corporate law). The Federal Circuit’s task may be easier than that of the Delaware chancery courts, because, in contrast to the corporate law, there is widespread consensus on the patent law’s ends. See, e.g., William Klein, *Criteria for Good Laws of Business Associations*, 2 BERKELEY BUS. L.J. 13 (2005) (identifying fairness, economic goals, political control and reducing administrative costs as possible goals of the corporate law); Andrew S. Gold, *A Decision Theory Approach to the Business Judgment Rule: Reflections on Disney, Good Faith, and Judicial Uncertainty*, *supra* note \_\_, at 437-40 (noting that there is a wide range of theoretical disagreement over the ends of corporate law).

<sup>277</sup> William J. Carney & George B. Shepherd, *The Mystery of Delaware Law’s Continuing Success*, 2009 U. ILL. L. REV. 1, 3 (2009) (“During the period 1996-2000, 58% of all publicly held firms and 59% of the Fortune 500 Industrial firms were incorporated in Delaware. During the period 1978-2000, 56% of all initial public offerings (“IPOs”) involved Delaware corporations.”).

<sup>278</sup> See, e.g., Bernard S. Black, *Is Corporate Law Trivial?: A Political and Economic Analysis*, 84 NW. U. L. REV. 542, 589-90 (1990) (concluding that judicial expertise is the main reason for Delaware’s dominance in the state competition for corporate charters). See also ROBERTA ROMANO, *THE GENIUS OF AMERICAN CORPORATE LAW* 39-40 (1993); Marcel Kahan & Ehud Kamar, *The Myth of State Competition in Corporate Law*, 55 STAN. L. REV. 679, 708 (2002). But see William J. Carney & George B. Shepherd, *The Mystery of Delaware Law’s Continuing Success*, 2009 U. ILL. L. REV. 1 (2009) (arguing that Delaware corporate law has become increasingly indeterminate because the Delaware Chancery Court has transformed the standards of care, good faith, and loyalty into a convoluted series of mini-rules).

<sup>279</sup> Bernard S. Black, *Is Corporate Law Trivial?: A Political and Economic Analysis*, *supra* note \_\_, at 1064.

<sup>280</sup> See Andrew S. Gold, *A Decision Theory Approach to the Business Judgment Rule: Reflections on Disney, Good Faith, and Judicial Uncertainty*, 66 MD. L. REV. 398 (2007) (arguing that the empirical uncertainty that surrounds debates over the duty of good faith suggests that a rational basis test is appropriate to assess claims of subjective failings or improper motivations).

<sup>281</sup> Lawrence A. Cunningham, *A Prescription to Retire the Rhetoric of “Principles-Based Systems” in Corporate Law, Securities Regulation, and Accounting*, 60 VAND. L. REV. 1409, 1436 (2007) (“Corporate law is a mixture of rules and principles whose application and interaction generates a rich, complex tapestry that diminishes the utility of any such tidy classifications.”); William T. Quillen & Michael Hanrahan, *A Short History of the Delaware Court of*

Although fiduciary duty law rests upon vague concepts such as the “duty of care” and the “duty of loyalty”, several cognizable rules have emerged through the adjudication process.<sup>282</sup> Delaware corporate law is reasonably determinate because it has been developed through a series of richly detailed opinions, or “corporate law sermons.”<sup>283</sup> Delaware judges actively engage with the academic corporate law literature<sup>284</sup> and liberally impart “extrajudicial utterances [that] can be read as attempts to be heard on a critical matter in the absence of a case raising just the right issue and in the absence of the articulation (or articulability) of a governing rule.”<sup>285</sup>

Like the Delaware Chancery Court, the Federal Circuit should transparently engage in policy engineering but tie its decisions to clearly articulated instrumental objectives. It should acknowledge empirical uncertainty and create incentives for litigants to fill in those information gaps. When empirical questions cannot be adequately answered for want of decisive information, the court should pragmatically refrain from upsetting settled expectations and adhere to the presumption of patent validity while signaling a willingness to revisit contested issues in response to future developments.

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*Chancery – 1792-1992*, 18 DEL. J. CORP. L. 819, 820 (1993) (“Delaware’s Court of Chancery has never become so bound by procedural technicalities and restrictive legal doctrines that it has failed the fundamental purpose of an equity court – to provide relief suited to the circumstances when no adequate remedy is available at law.”); Jill E. Fisch, *The Peculiar Role of the Delaware Courts in the Competition for Corporate Charters*, *supra* note (explaining that Delaware chancery courts employ a distinctive process for developing corporate law that in some respects resembles legislation and in other respects resembles the work of an administrative agency).

<sup>282</sup> Lawrence A. Cunningham, *A Prescription to Retire the Rhetoric of “Principles-Based Systems” in Corporate Law, Securities Regulation, and Accounting*, 60 VAND. L. REV. 1409, 1442-44 (2007) (citing as examples the business judgment rule and rules that have emerged from cases involving alleged breaches of the duty of loyalty that do not involve self-interested transactions). *See also* Timothy P. Glynn, *Delaware’s Vantagepoint: The Empire Strikes Back in the Post-Post-Enron Era*, 102 NW. U. L. REV. 91, 97-101 (2008) (“Hence, the Delaware courts are the primary source of both the substance and enforcement of Delaware corporate law. By developing standards through a careful, contextual approach, rather than via broad pronouncements of unbending general rules, the courts assure further litigation over corporate legal norms and their application.”).

<sup>283</sup> Edward B. Rock, *Saints and Sinners: How Does Delaware Corporate Law Work?*, 44 UCLA L. REV. 1009, 1016 (1997).

<sup>284</sup> William J. Carney & George B. Shepherd, *The Mystery of Delaware Law’s Continuing Success*, 2009 U. ILL. L. REV. 1, 43-44 (2009).

<sup>285</sup> Edward B. Rock, *Saints and Sinners: How Does Delaware Corporate Law Work?*, *supra* note \_\_, at 1095.



The Federal Circuit should function as the locus of empirically-driven patent tailoring while promoting a multi-institutional approach to innovation policy.<sup>286</sup> The Supreme Court lacks the time and expertise to tackle the intricacies of patent law, but the Court is well suited to demarcate the relationships between patent law and other substantive areas.<sup>287</sup> Contextual information elicited through the litigation process should also prompt extra-judicial measures (i.e., statutory changes or modifications of PTO regulations) that work in concert with pragmatic patent adjudication to better align the patent law with the patent system's utilitarian purpose. Additionally, technological advances may raise ethical, social and moral issues that may not be conducive to judicial resolution.<sup>288</sup> The Federal Circuit should focus on calibrating incentives to promote technological innovation, leaving it to the legislative and executive branches to further broader social goals. Part IVC, *infra*, illustrates how the proposed approach may be applied to recent and ongoing disputes involving diagnostic and therapeutic method claims.

### **C. Application to Medical Methods**

Patent law shapes biomedical innovation in concert with, *inter alia*, federal research funding policies, food and drug law, and regulation of the health insurance industry.<sup>289</sup> The Federal Circuit should acknowledge these complexities when

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<sup>286</sup>Arti K. Rai, *Patent Law in Perspective: Institute for Intellectual Property & Information Law Symposium: Article: Building a Better Innovation System: Combining Facially Neutral Patent Standards with Therapeutics Regulation*, 45 Hous. L. REV. 1037, 1040 (2008) (arguing that we need to avoid "tunnel vision" in thinking about regulatory systems that promote innovation and recognize that a multi-system approach may be optimal for resolving questions of innovation policy).

<sup>287</sup> Rochelle Cooper Dreyfuss, *The Federal Circuit as an Institution: What Ought We Expect?*, *supra* note \_\_, at 839 (arguing that the Federal Circuit is better able than the Supreme Court to hone the contours of patent scope and strength, but that the Supreme Court is well suited to address overarching issues such as the relationship between patent and antitrust). *See also* Illinois Tool Works Inc. v. Independent Ink, Inc., 547 U.S. 28, 34 & 43-44 (2006) (eliminating a per se presumption of market power in tying arrangements involving patented products and replacing it with a flexible rule-of-reason analysis).

<sup>288</sup> *See* Dana Remus Irwin, *Paradise Lost in the Patent Law? Changing Visions of Technology in the Subject Matter Inquiry*, 60 FLA. L. REV. 775, 819-21 (2008) (making this observation).

<sup>289</sup> *See* Arti K. Rai, *Patent Law in Perspective: Institute for Intellectual Property & Information Law Symposium: Article: Building a Better Innovation System: Combining Facially Neutral Patent Standards with Therapeutics Regulation*, 45 Hous. L. REV. 1037, 1039 (2008) (noting that the FDA and the health insurance industry operate outside the patent system and heavily influence the pharmaceuticals market); Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, *supra* note \_\_, at 19-21 (explaining how the FDA and NIH work in

determining the proper scope of patent protection for diagnostic and therapeutic methods. Objective factors to consider when making claim scope determinations should include financing needs, sources of funding, and regulatory barriers to entry at each stage of the relevant product development life cycle. A related consideration should be the extent to which patent protection on an upstream discovery is perceived by investors to be required for downstream development. For example, surveys of venture capital firms may be utilized to ascertain the effect of upstream patents on the decision to invest in early stage life sciences companies. Such evidence could be used to discern material differences across diagnostic and therapeutic sectors.

Surveys demonstrate that biopharmaceutical companies and investors rely heavily on patent exclusivity.<sup>290</sup> However, there is an important distinction between patents on therapeutic end products and patents on the upstream scientific discoveries that lead to new products. It is uncontroversial that the former are necessary to incentivize development, but it is less clear that the latter promote innovation. Patents on pre-market inventions that explain disease pathways and identify drug targets may actually deter progress by driving up the costs of drug development. Upstream discoveries are often made in university laboratories, who then license the technology to the biopharmaceutical firms who develop and commercialize end products.<sup>291</sup> “These discoveries are like so many siphons at the feeding trough of new drugs, draining away profits in many different directions.”<sup>292</sup> Empirical data comparing the development and commercialization of pharmaceutical products targeting proprietary targets with that of products targeting

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parallel with the PTO and the Federal Circuit to set innovation policy with respect to drugs and biologics); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 290-91 (2003) (arguing that the level of patent protection available for biomedical research should take into account the incentive effects of direct and indirect government financing); John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L. J. 101, 109 (2001) (arguing that patent commentary often overlooks the role of multi-billion dollar public financing of biomedical research).

<sup>290</sup> See, e.g., JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION AT RISK 89 (2008).

<sup>291</sup> Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 480-81 (2003-2004).

<sup>292</sup> *Id.* at 481.

public domain targets would be highly useful in the analysis of the proper scope of patent protection for therapeutic methods.

It is also important to distinguish between therapeutics and diagnostics. The cost of developing a diagnostic test based on a correlation between a biomarker and a clinical condition is much lower than the cost of bringing a new therapeutic to market. Whereas the developers of therapeutics must undergo the arduous FDA approval process, including expensive clinical trials to assess safety and efficacy, the developers of diagnostic tests typically face minimal regulatory hurdles.<sup>293</sup> Many diagnostic tests are developed in-house by clinical laboratories (“home brews”) and need not undergo regulatory review.<sup>294</sup> Empirical data comparing the development and commercialization of diagnostic products incorporating proprietary biomarkers with that of diagnostic products incorporating public domain biomarkers would be useful in the analysis of the proper scope of patent protection for methods of drawing clinical correlations. Pronouncements by the Federal Circuit that such contextual information is directly relevant to patentability will create incentives for litigants to generate these data.<sup>295</sup>

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<sup>293</sup> See SECRETARY’S ADVISORY COMM. ON GENETICS, HEALTH, AND SOCIETY, U.S. DEP’T OF HEALTH & HUM. SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS (2010), available at [http://oba.od.nih.gov/oba/sacghs/reports/SACGHS\\_patents\\_report\\_2010.pdf](http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf) [hereinafter SACGHS Report], at lines 1327-29 (noting that the costs to develop a diagnostic test are under \$10,000). While patents may not be necessary to incentivize development of simple diagnostic tests, they may be needed to promote development of more complicated diagnostic products involving complex associations among numerous biological and environmental phenomena. In his opinion in *Bilski*, Justice Kennedy suggested that the patent law draw a distinction between simple correlations and more complex diagnostics. See 130 S. Ct. 3218, 3227.

<sup>294</sup> See Matthew Herder, *Patents & The Progress of Personalized Medicine: Biomarkers Research as Lens*, 18 ANN. HEALTH L. 187, 200-01 (2009) (explaining that diagnostic tests sold as “test kits” are subject to FDA review and safety, but that all commercially available genetic tests are marketed as “home brews” and thus are not subject to regulatory scrutiny). See also Eileen Kane, *Patent-mediated Standards in Genetic Testing*, 2008 UTAH L. REV. 835, 874 (2008) (explaining that if genetic diagnostic tests become subject to FDA review, researchers engaged in genetic testing may be able to evade infringement liability by invoking the protection of 35 U.S.C. § 271(e), which creates a safe harbor for activities that are “reasonably related” to FDA approval, and noting this fact as an example of the complicated nexus between patent law and food and drug law).

<sup>295</sup> Although information gaps persist, some empirical data and analyses are available. See, e.g., SACGHS Report, *supra* note \_ (drawing the following conclusions about the effects of patents on genetic testing: (1) patents do not accelerate inventive activity; (2) the availability of patents is not necessary to promote disclosure of genetic discoveries; (3) patents have some positive effects on investment in commercial test kits which must be approved by the FDA; but (4) the development of in-house laboratory tests which do not require FDA approval does not hinge on patent rights); Heidi Williams, *Intellectual property rights and innovation: Evidence from the human genome*, NBER Working Paper, 2010 (comparing product development stemming from gene sequences temporarily subject to proprietary rights held by the private firm Celera with gene sequences discovered by the

The result in *Ariad v. Lilly*<sup>296</sup> would not change were the Federal Circuit to re-decide the case under the proposed framework. Since the patentee did not specifically describe a compound capable of inhibiting NF-κB activity, the court would invalidate the claims for lack of adequate disclosure without need to resort to the PSM doctrine. However, under the proposed approach the court would explicitly acknowledge the levels of abstraction problem and signal its willingness to consider contextual factors when deciding future cases involving slightly different fact patterns. The court's opinion might explain that the PSM doctrine would come into play were a patentee in Ariad's position to disclose one or more specific compounds capable of performing the claimed function. It would further acknowledge that the MOT test, while a useful rule of thumb when determining PSM in other contexts, offer little practical guidance with respect to medical method claims. Finally, the opinion would note that there is no indication that the discovery of the NF-κB pathway in any way spurred the development of the allegedly infringing drugs,<sup>297</sup> and flag for future litigants empirical uncertainty as to whether patents on disease pathways promote or impede biopharmaceutical innovation.

The Federal Circuit should take a similar approach to the therapeutic method claims at issue in *Classen v. Biogen Idec*.<sup>298</sup> The court should base its opinion not on an awkward application of the MOT test, but rather on an analysis of the need for patents to incentivize the discovery and implementation of safer immunization schedules. In its review of *Prometheus v. Mayo*,<sup>299</sup> the Supreme Court should instruct the Federal Circuit to discard its formalist conclusion that the claims are therapeutic and thus per se constitute PSM. Similarly, the Federal Circuit should directly confront the limitations of

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Human Genome Project and immediately transferred into the public domain and offering an empirical analysis which suggests that Celera's proprietary rights led to reductions in product development outcomes on the order of 30 percent).

<sup>296</sup> 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

<sup>297</sup> 529 F. Supp. 2d 106, 114 (D. Mass. 2007). The facts of this case are notably similar to those in *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004), where the alleged infringers brought drugs to market even though they did not have patents on the target itself or methods of inhibiting the targeted enzyme.

<sup>298</sup> See 130 S. Ct. 3541 (2010) (vacating the Federal Circuit's decision and remanding the case in light of its holding in *Bilski* that the MOT is a useful, but not exclusive, test for PSM).

<sup>299</sup> 628 F.3d 1347 (Fed. Cir. 2010), cert. granted, 79 U.S.L.W. 3710 (U.S., June 20, 2011) (No. 10-1150).

its MOT test in its review of the district court decision in *AMP v. PTO*.<sup>300</sup> Patentability should turn on whether broad proprietary rights are necessary to encourage the discovery of gene/disease correlations and the development of commercial diagnostic tests. If there is insufficient data to overcome the presumption of patent validity, the court should uphold the patent but encourage litigants to revisit the issue in future cases.

Pragmatic patent adjudication should work in tandem with other institutional efforts to calibrate the scope and strength of proprietary rights in biological discoveries. Non-judicial interventions to address public health needs may include legislative initiatives, such as research exemptions or general exemptions to infringement of certain patents; targeted administrative actions such as compulsory licensing; or the use of march-in rights by the NIH for patents arising from federal funding.<sup>301</sup> As an illustration, in 1996 Congress granted medical practitioners statutory immunity from liability for infringing patents on medical methods while performing any “medical activity.”<sup>302</sup> Importantly, the statute merely shields a class of potential defendants from liability and does not in any way restrict PSM. This example demonstrates the benefits of a multi-institutional approach to tailoring. Congress was able to address the concerns of a narrow interest group (doctors seeking protection from infringement liability) without radically transforming the patent doctrine and creating far-reaching unintended consequences for the biomedical industry.

The Federal Circuit should apply the proposed model to all claims which raise normative questions of patent scope. Medical and surgical procedures arguably best track cumulative innovation theory, since the pioneering procedure typically is refined with follow-on improvements as physicians gain experience with the technique in the course of treating patients. This argues against broad upstream patents and perhaps

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<sup>300</sup> 2010 U.S. Dist. LEXIS 35418 (S.D.N.Y. 2010).

<sup>301</sup> Eileen Kane, *Patent-mediated Standards in Genetic Testing*, 2008 UTAH L. REV. 835 (2008) (noting possible field-wide solutions). See also SACGHS Report, *supra* note \_\_, at lines 2495-3504 (recommending the following statutory changes: A. The creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes; and B. The creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research).

<sup>302</sup> 35 U.S.C. §287(c) (2006).

against patents at all. Possible cases in which patents on medical and surgical procedures may be desirable are those involving breakthrough techniques that require a substantial investment of time and money to develop. Nuanced contextual analysis could elicit the data necessary to confirm these empirical intuitions. An analogous approach could be taken to the patentability of inventions in other technological fields, such as those involving software or business methods. Software research, like medical research, is characterized by substantial government funding and cumulative innovation. The software industry also manifests network effects and possesses a wide range of non-patent means of appropriating value.<sup>303</sup> In many cases, inventors of novel business methods may be able to rely on trade secret protection and/or first mover advantages to profit from their innovations.<sup>304</sup> The Federal Circuit should explicitly incorporate such practical considerations into its patentability determinations.

## V. Conclusion

Heightened Supreme Court scrutiny compels the Federal Circuit to rethink its patent jurisprudence. Yet commentators express skepticism that the court will heed the call for a more expansive, contextual adjudicative approach.<sup>305</sup> The National Academies' 2004 study on patent reform recommended that the Federal Circuit guard against the hazards of insularity by staying informed about relevant legal and economic scholarship, encouraging the submission of amicus briefs, and fostering dialogue with other courts.<sup>306</sup> Yet given Federal Circuit judges' stated reluctance to change course,<sup>307</sup> perhaps a

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<sup>303</sup> Peter S. Menell, *A Method for Reforming the Patent System*, *supra* note \_\_, at 495.

<sup>304</sup> *See, e.g.*, R. Levin et al., *Appropriating the Returns from Industrial Research and Development*, in 3 *Brookings Papers on Econ. Activity* 794-95 (1987); Burk & Lemley, *Policy Levers in Patent Law*, *supra* note \_\_, at 1618 (discussing various first mover advantages, such as branding and network effects).

<sup>305</sup> *See, e.g.*, Rebecca S. Eisenberg, *Commentary, The Supreme Court and the Federal Circuit: Visitation and Custody of Patent Law*, 106 *MICH. L. REV. FIRST IMPRESSIONS* 28, 33 (2007), <http://www.michiganlawreview.org/firstimpressions/vol106/eisenberg.pdf> (expressing skepticism that the Federal Circuit will do more than pay lip service to Supreme Court admonitions to adopt a more expansive and flexible approach).

<sup>306</sup> *COMM. ON INTELLECTUAL PROP. RIGHTS IN THE KNOWLEDGE-BASED ECON., THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21<sup>ST</sup> CENTURY* 6, 81 (Stephen A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004).

<sup>307</sup> *See* Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, *supra* note \_\_, at 1648, fn. 102 (citing several statements by Federal Circuit judges which reject the notion that the court should engage in questions of policy or refer to external sources such as legal scholarship or amicus briefs).

structural judicial change is necessary to realize pragmatic patent adjudication. Arti Rai has suggested that we bolster the lower courts' fact-finding role by designating one or more district courts to handle all patent cases.<sup>308</sup> Craig Nard and John Duffy advocate for a more radical structural change. They propose that at least one other circuit court be granted authority to hear district court patent appeals and that both the Federal Circuit and the D.C. Circuit should have jurisdiction over appeals from the PTO.<sup>309</sup>

Federal Circuit Judge Plager has criticized Nard and Duffy for proposing a solution to the court's perceived deficiencies without offering any empirical evidence to support it. Plager describes the proposal to replace the current regime with a multi-circuit model as a "theoretical and untested construct, the consequences of which can only be guessed."<sup>310</sup> To the extent that Plager's assessment is accurate, Nard and Duffy do not advocate a truly pragmatic approach. Additionally, there is some preliminary evidence suggesting that the Federal Circuit may be taking steps toward pragmatic patent adjudication. Its 2010 decision in *SEB v. Montgomery Ward*<sup>311</sup> is notable for the court's use of non-patent and non-Federal Circuit cases to aid its interpretation of "knowledge" in the context of inducement to infringement. The Federal Circuit's willingness to venture beyond the bounds of its own patent precedents may signal its burgeoning responsiveness to the Supreme Court's admonitions.<sup>312</sup> Significant restructuring of the patent judicial system may therefore be premature. The tenets of pragmatism dictate a cautious approach to structural reform that weighs the merits of radical change against the status quo and counsels a departure from settled expectations only in the face of compelling empirical evidence.

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<sup>308</sup> See Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, *supra* note \_\_, at 1134 (asserting that the trial courts would presumably be better able to apply policy-driven standards if they had greater fact-finding expertise).

<sup>309</sup> Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, *supra* note \_\_, at 1625.

<sup>310</sup> S. Jay Plager & Lynne E. Pettigrew, *Rethinking Patent Law's Uniformity Principle: A Response to Nard and Duffy*, *supra* note \_\_, at 1739.

<sup>311</sup> 594 F.3d 1360 (Fed. Cir. 2010).

<sup>312</sup> Dennis Crouch, *Broadening Federal Circuit Jurisprudence: Moving Beyond Federal Circuit Patent Cases*, 2010 PATENTLY-O PATENT L.J. 19, 20-21 (2010), available at <http://ssrn.com/abstract=1551937> (making this argument).