

# William and Mary Law Review

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VOLUME 52

No. 6, 2011

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## RULES FOR PATENTS

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### ABSTRACT

*There is widespread agreement that the patent system in the United States is in need of reform. Most of the proposals for patent reform that have proliferated in recent years share two common assumptions: first, that patent policy is best made through case-by-case adjudication of the validity of individual patents; and, second, that the existing allocation of authority over patent policy, in which the courts are primarily responsible for interpreting and applying the broad language of the Patent Act, ought not to be disturbed. This Article challenges both assumptions. I approach the problem of patent reform primarily as a problem of sound administration rather than innovation policy and argue that Congress should grant the Patent and Trademark Office (PTO) substantive rule-making authority.*

*The administrative structure of the patent system has been largely unchanged since 1836. But the administrative tasks that a well-performing patent system must carry out have changed markedly*

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since that time. Most importantly, technology in the early- to mid-nineteenth century was relatively uniform. Today, by contrast, the process of innovation varies widely among different technologies and different industries. If the patent system is to meet its goal of providing incentives for innovation, it must self-consciously tailor the elements of patentability—both rules and standards—to those diverse circumstances.

Optimal patent policymaking requires forward-looking deliberation and cost-benefit analysis based on technological and economic expertise; clarity and predictability so that entities making investment choices based on the property-like aspects of patents can be confident in the legal regime governing those rights; and transparency and accountability to ensure that the public interest—which is often distinct from the interests of patent holders—is taken into account. Unlike courts, agencies acting through rulemaking can gather and expertly analyze all of the relevant information to make express policy judgments based on costs and benefits, can decide issues prospectively and avoid piecemeal decision making, and can systematically engage the public in the policy-making process. Although agencies are subject to certain well-understood institutional pathologies, such as capture by powerful interests, on balance they are more likely to make effective patent policy than courts.

Granting the PTO substantive rule-making authority would require significant changes to the structure and function of that agency, and to the role of the courts. The PTO would require the addition of a policy-making capacity separate but capable of drawing insights from the examination process. The courts in turn would play a constructive secondary role by surfacing issues that require attention in the interstices of agency rules and engaging in judicial review of those rules under traditional standards of administrative law.

TABLE OF CONTENTS

INTRODUCTION . . . . . 1750

I. THE CHANGING TASKS OF PATENT ADMINISTRATION . . . . . 1761

*A. Patent Administration in Historical Perspective* . . . . . 1762

*B. Administrative Tasks Confronting the Modern Patent System* . . . . . 1767

II. WHY PATENT POLICY SHOULD BE MADE THROUGH AGENCY RULEMAKING . . . . . 1776

*A. A Normative Theory of Patent Administration* . . . . . 1776

        1. *Reasoned Decision Making and Expertise* . . . . . 1777

        2. *Clarity and Predictability* . . . . . 1780

        3. *Transparency and Accountability* . . . . . 1782

*B. Allocating Policy-Making Authority* . . . . . 1783

        1. *Reasoned Decision Making and Expertise* . . . . . 1785

        2. *Clarity and Predictability* . . . . . 1791

        3. *Transparency and Accountability* . . . . . 1794

*C. Evaluation* . . . . . 1798

III. HOW RULEMAKING WILL CHANGE PATENT ADMINISTRATION . . . . . 1800

*A. The PTO* . . . . . 1800

*B. The Courts* . . . . . 1802

        1. *Judicial Review of Agency Rulemaking* . . . . . 1803

        2. *Litigation Over Patent Validity or Application Denials* . . . . . 1804

CONCLUSION . . . . . 1806

## INTRODUCTION

There is widespread agreement that the patent system in the United States is broken. A flood of critical commentary argues that the system is in “crisis,”<sup>1</sup> or that it is a “failure.”<sup>2</sup> At the foundation of these complaints is a belief that the system established in order “[t]o promote the Progress of Science and useful Arts”<sup>3</sup> no longer provides the optimal incentives for innovation.<sup>4</sup> A patent provides an incentive to invest in costly invention—or, more controversially, to develop or commercialize an invention<sup>5</sup>—by providing the inventor with a mechanism by which she may potentially recoup her investment in producing otherwise freely appropriable knowledge.<sup>6</sup> The standards for granting a patent are critical to ensuring that this incentive works. If patents are too few or too narrow, they do not provide sufficient protection for costly research and development

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1. See DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 1 (2009). Robert Merges leveled this charge against the patent system as early as 1999. See Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 *BERKELEY TECH. L.J.* 577, 591 (1999).

2. See JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* 1-2 (2008).

3. U.S. CONST. art. I, § 8, cl. 8.

4. In this Article, I assume that the goal of patent law is to provide incentives for innovation, according to the standard utilitarian account. See, e.g., WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 294-333 (2003). In that account, patents offer an incentive to engage in costly research and development because the fruits of that investment, which would otherwise be appropriable by the general public, are protected by a property right. See *id.* The patent system is open to critique from other perspectives that I do not address here. See generally William Fisher, *Theories of Intellectual Property*, in *NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY* (Stephen Munzer ed., 2001).

5. There is a significant debate among patent scholars over whether patent policy should be justified solely by virtue of patents' ex ante incentives to invent or, once the initial inventive step has been taken, by patents' ex post effects on the process of development and commercialization. See Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 *U. CHI. L. REV.* 129, 129-30 (2004). In a related work, I take a skeptical approach to certain ex post justifications for patents. See Michael J. Burstein, *Exchanging Information Without Intellectual Property* (May 27, 2010) (working paper). My argument here, however, is agnostic regarding this debate; the institutional reforms I propose will result in better policymaking directed toward either goal.

6. See, e.g., LANDES & POSNER, *supra* note 4, at 13, 294.

(R&D). If they are too numerous or too broad, they may over protect, inhibiting access to critical inputs by downstream inventors.<sup>7</sup>

The standards of patentability are defined by statute. Patents may issue for “any new and useful process, machine, manufacture, or composition of matter”<sup>8</sup> that is not “obvious at the time the invention was made to a person having ordinary skill in the art”<sup>9</sup> and that is described “in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same.”<sup>10</sup> Like any broadly written statute, the Patent Act requires interpretation to have any concrete meaning. Indeed, the patent statute requires policymaking to fill in the gaps that Congress left through its choice of broad terms.<sup>11</sup> That task has been delegated largely to the courts.<sup>12</sup> This Article argues that assigning the primary responsibility for articulating patent policy to the courts is suboptimal. Instead, Congress should grant the Patent and Trademark Office (PTO) the authority to make substantive rules implementing the Patent Act.

Most critics of the patent system make two assertions, either explicitly or implicitly, about the institutional structure of the patent system: first, that patent policy is best made through case-by-case adjudication of the validity of individual patents; and, second, that the existing allocation of authority over the standards for determining patent validity—in which the courts are primarily responsible for interpreting the broad language of the Patent Act—ought not to be disturbed. This Article challenges both contentions.

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7. For an overview of the access-incentive tradeoff, see, for example, Tim Wu, *Intellectual Property, Innovation, and Decentralized Decisions*, 92 VA. L. REV. 123, 131-34 (2006).

8. 35 U.S.C. § 101 (2006).

9. *Id.* § 103(a).

10. *Id.* § 112 para. 1.

11. The claim that the Patent Act, like the Sherman Act, creates space for express policy choices is not controversial. See, e.g., Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53 (2010) (“[T]he patent code, much like the Sherman Act, is a common law enabling statute, leaving ample room for courts to fill in the interstices or to create doctrine emanating solely from Article III’s province.”) (footnote omitted); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1041 (2003) (“[T]he history of the patent statute as well as its language strongly suggest that Congress has delegated policy-making responsibility in patent law to the judiciary.”).

12. See Rai, *supra* note 11, at 1041.

Most critics generally approach patent reform through the lens of innovation policy. They ask what the standards of patentability ought to be. I ask instead how the standards of patentability ought to be determined. My central claim is that our current institutional structure fails to produce optimal policy outcomes and should be reformed. Consider one recent example that illustrates the dysfunctional nature of patent policymaking: In 1982, the PTO issued the first patent on a human gene.<sup>13</sup> Almost thirty years later, a district court held that human genes were not patentable subject matter.<sup>14</sup> Human genes, in the court's view, were not a patentable "process, machine, manufacture, or composition of matter" to which the Patent Act applied.<sup>15</sup> In the time between the issuance of the first gene patent and the district court's decision, many issues surrounding the validity of patents on genes or DNA were litigated, including whether certain types of DNA molecules were sufficiently useful for patent protection,<sup>16</sup> whether a patentee seeking to patent DNA must disclose the entire genetic sequence he seeks to patent,<sup>17</sup> and whether isolated DNA sequences were "obvious" and therefore unpatentable.<sup>18</sup> Yet the fundamental question whether patents on human genes even constitute eligible subject matter was left unaddressed.<sup>19</sup> In the meantime, thousands of patents issued for DNA

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13. The first patents on human genetic material were issued in 1982. See Adrenocorticotropin-lipotropin Precursor Gene, U.S. Patent No. 4,322,499 (filed Dec. 22, 1978) (issued Mar. 30, 1982). It is believed that the PTO issued the first patents claiming "isolated DNA," the kind of stand-alone genes at issue in *Association for Molecular Pathology*, in the late 1980s. See Brief for the United States as Amicus Curiae in Support of Neither Party at 4-5, *Ass'n for Molecular Pathology v. PTO*, No. 2010-1406 (Fed. Cir. Oct. 29, 2010).

14. See *Ass'n for Molecular Pathology v. PTO*, 702 F. Supp. 2d 181, 227-32 (S.D.N.Y. 2010). The court did not address the validity of the patents cited *supra* note 13, but rather a set of patents for the human genes encoding proteins linked with breast cancer. See *id.* at 184-85.

15. 35 U.S.C. § 101; see *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 220-32.

16. See *In re Fisher*, 421 F.3d 1365, 1369-76 (Fed. Cir. 2005).

17. See *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567-68 (Fed. Cir. 1997).

18. See *In re Kubin*, 561 F.3d 1351, 1361 (Fed. Cir. 2009); *In re Deuel*, 51 F.3d 1552, 1559-60 (Fed. Cir. 1995).

19. See *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1293 (Fed. Cir. 2010) (Dyk, J., concurring in part and dissenting in part) ("Although we have upheld the validity of several gene patents, none of our cases directly addresses the question of whether such patents encompass patentable subject matter under 35 U.S.C. § 101.... [T]hus far the question has evaded judicial review.").

sequences.<sup>20</sup> An entire industry based on recombinant DNA technology grew up with the understanding that patents on DNA sequences were valid. The district court's decision cast the settled expectations of many in the biotechnology industry into doubt and threatened widespread chaos.<sup>21</sup>

This story illustrates at least two ways in which the system fails. The first concerns the substance of the court's analysis. The Patent Act does not answer directly the question whether human genes constitute patentable subject matter.<sup>22</sup> In the absence of legislative guidance, the goal of fostering innovation would be best served by an evaluation of the extent to which patents on genes would promote or inhibit incentives for research and development in biotechnology.<sup>23</sup> But such reasoning is absent from the court's opinion. The court instead drew primarily upon precedent to hold that genes are "products of nature" and therefore not the proper subjects of patent protection.<sup>24</sup> Of course, the "products of nature" exception itself is a judicially created limitation on patentable subject matter that developed not from economic analysis, but from the slow accretion of precedent.<sup>25</sup> The court's failure to focus on the economic factors that would shape a policy-based appraisal of gene patents' desirability is consistent with the judiciary's general approach to the problem of patentable subject matter.<sup>26</sup> That approach has drawn criticism from scholars who believe that the application of formalist legal reasoning is producing poor patent outcomes.<sup>27</sup>

The second failure arises from the uncertainty created by judicial decision making. In the case of gene patents, the vagaries of litigation prevented a core question of patentability from being

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20. See Brief for the Appellants at 3 n.1, *Ass'n for Molecular Pathology v. PTO*, No. 2010-1406 (Fed. Cir. Oct. 22, 2010).

21. See, e.g., Andrew Pollack, *After Patent on Genes Is Rejected, Taking Stock*, N.Y. TIMES, Mar. 31, 2010, at B1.

22. See 35 U.S.C. § 101 (2006).

23. See *infra* Part I.B; cf. *Ass'n for Molecular Pathology v. PTO*, 702 F. Supp. 2d 181, 207-11 (S.D.N.Y. 2010) (describing conflicting evidence of impact of gene patents on scientific research).

24. See *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 223-33.

25. See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 106-30 (4th ed. 2007).

26. See *infra* notes 216-23 and accompanying text.

27. See, e.g., BURK & LEMLEY, *supra* note 1, at 106-07.

litigated before the industry assumed significant reliance costs. Even after the question of patentable subject matter in the case was decided, there was little guidance concerning the status of gene patents in future related cases. Bessen and Meurer, among others, have criticized the patent system's failure to provide adequate notice to entrepreneurs and investors about the scope of patent rights.<sup>28</sup> Judicial uncertainty contributes mightily to this problem.<sup>29</sup>

The central problems that the patent system faces are not all that different from the institutional design problems that any government program faces. Yet there has been very little serious engagement between the patent system and administrative law. Indeed, until recently the two areas of law have been treated as largely separate, with little to do with or learn from one another.<sup>30</sup> That is perhaps because the patent system largely stands outside the familiar structure of Progressive Era and New Deal agencies.<sup>31</sup> The paradigm of decision making in the modern administrative state places primary responsibility for developing policy in the hands of agencies, while the courts ensure that agencies act reasonably and within their statutory authority.<sup>32</sup>

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28. See BESSEN & MEURER, *supra* note 2, at 46-72.

29. See *infra* Part II.B.2.

30. Others have made this observation. See, e.g., Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 270 (2007) ("In contrast to commentators and practitioners in other technically complex areas ..., the patent law community has tended to pay little attention to administrative law."); Adam Mossoff, *The Use and Abuse of IP at the Birth of the Administrative State*, 157 U. PA. L. REV. 2001, 2002 (2009) ("Throughout the twentieth century, administrative law and intellectual property law seemed as if they were hermetically sealed off from each other in both theory and practice.")

31. See John F. Duffy, *The FCC and the Patent System: Progressive Ideals, Jacksonian Realism, and the Technology of Regulation*, 71 U. COLO. L. REV. 1071, 1132-40 (2000).

32. Congress has generally delegated to agencies like the Federal Communications Commission "the authority to promulgate binding legal rules." Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 980-81 (2005); see, e.g., 47 U.S.C. § 201(b) (2006) ("The Commission may prescribe such rules and regulations as may be necessary in the public interest to carry out the provisions of this chapter."). When an agency uses that authority to "address[] ambiguity in [its governing] statute or fill[] a space in the enacted law," United States v. Mead Corp., 533 U.S. 218, 229 (2001), the rule of "*Chevron* requires a federal court to accept the agency's construction of the statute," so long as that construction is reasonable. *Brand X*, 545 U.S. at 980 (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843-44, 843 n.11 (1984)). The court must accept the agency's construction because "ambiguities in statutes within an agency's jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in reasonable fashion," and

The administrative structure of the patent system, however, predates that paradigm. The Patent Office was established in 1836.<sup>33</sup> At that time, Congress placed in the hands of the courts the authority to make policy choices that would implement the broad language of the Patent Act.<sup>34</sup> The PTO lacks substantive rule-making authority.<sup>35</sup> Its role is limited to reviewing applications for patents and then granting or denying them.<sup>36</sup> Of course, in granting or denying a patent, the PTO necessarily makes a legal judgment concerning the validity of that patent. But those judgments carry little legal weight.<sup>37</sup> Indeed, until the Supreme Court intervened in 1999, it was not clear that the Administrative Procedure Act (APA) even applied to the Patent Office.<sup>38</sup>

Before considering changes to the institutional structure of the patent system, it is important to understand how the system currently works. The examination process begins with the filing of an application for a patent. In 2009, the PTO received nearly

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“filling these gaps ... involves difficult policy choices that agencies are better equipped to make than courts.” *Id.*

33. Patent Act of 1836, ch. 357, § 1, 5 Stat. 117.

34. See Rai, *supra* note 11, at 1041.

35. The broadest of the PTO's statutory rule-making powers is the power to “establish regulations ... which ... shall govern the conduct of proceedings in the Office.” 35 U.S.C. § 2(b)(2)(A) (2006). The Federal Circuit has repeatedly held that § 2(b)(2)(A) “does NOT grant the Commissioner the authority to issue substantive rules.” *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996); see *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991) (“A substantive declaration with regard to the Commissioner's interpretation of the patent statutes, whether it be section 101, 102, 103, 112 or other section [sic], does not fall within the usual interpretation of [the language of § 2(b)(2)(A)].”). Instead, “[t]o comply with section 2(b)(2)(A), a Patent Office rule must be ‘procedural’—i.e., it must ‘govern the conduct of proceedings in the Office.’” *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335-36 (Fed. Cir. 2008).

36. See 35 U.S.C. § 131 (“The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the application is entitled to a patent under the law, the Director shall issue a patent therefor.”).

37. Under the Supreme Court's decision in *United States v. Mead Corp.*, the administrative interpretations most likely to receive judicial deference are those made pursuant to “a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement” that carries the force of law. 533 U.S. at 230.

38. Prior to the Court's ruling in *Dickinson v. Zurko*, the Federal Circuit—the court of appeals that hears most appeals in patent cases—consistently reviewed the PTO's factual determinations for clear error rather than applying the standards of review found in section 706 of the APA. 527 U.S. 150, 153-54 (1999). The Supreme Court held, however, that “the Federal Circuit's review of PTO fact-finding must take place within the framework set forth in the APA.” *Id.* at 154.

460,000 such applications and issued 166,706 patents.<sup>39</sup> The PTO employs more than 6,000 examiners, who are organized by technical expertise.<sup>40</sup> An examiner with relevant expertise reviews the application and makes an initial determination of patentability. Usually, this determination is only the starting point in a series of revisions carried out jointly with the applicant. After the initial review, the applicant may amend her claims to meet the examiner's approval, and another similar round of changes or arguments may follow.<sup>41</sup> As several commentators have noted, this interaction amounts to a negotiation between the PTO and the patent applicant;<sup>42</sup> savvy applicants often can "wear down" the examiner.<sup>43</sup> Given the large volume of applications and limited resources of the Office, it is estimated that a patent examiner will ultimately spend only eighteen hours on average examining each application.<sup>44</sup> Notably, this process is entirely *ex parte*. The only participants are the examiner and the applicant. There is no opportunity in the initial examination for other interested parties to come forward with information relevant to the decision whether the patent should issue.<sup>45</sup>

Following the PTO's decision, the question whether a patent should issue for a particular invention may reach the courts through several paths. First, an applicant whose patent is denied by the Board of Patent Appeals and Interferences (BPAI)—the PTO's internal review board—may appeal directly to the Federal Circuit.<sup>46</sup>

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39. See U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2009 112 tbl.1 (2010) [hereinafter PTO ANNUAL REPORT]. The figures cited exclude design patents, which are governed by distinct statutory criteria. See 35 U.S.C. §§ 171-173.

40. See PTO ANNUAL REPORT, *supra* note 39, at 11.

41. Through a device known as a "continuation," it is possible for the applicant who receives a final rejection to call for a "do over" at the PTO with very little negative consequence. BURK & LEMLEY, *supra* note 1, at 24. These continuations may be unlimited, making true final rejections rare. See *id.* at 24-25.

42. See, e.g., Mark A. Lemley & Bhaven Sampat, *Examining Patent Examination*, 2010 STAN. TECH. L. REV. 2, ¶ 6; R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of Festo*, 151 U. PA. L. REV. 159, 215-16, 216 n.194 (2002).

43. Benjamin & Rai, *supra* note 30, at 316.

44. See BURK & LEMLEY, *supra* note 1, at 23 & n.10.

45. See *id.* at 23; Benjamin & Rai, *supra* note 30, at 278.

46. See 35 U.S.C. § 141 (2006). A disappointed patent applicant may also file suit in the District Court for the District of Columbia, with a subsequent appeal to the Federal Circuit. See *id.* § 145; 28 U.S.C. § 1295(a)(4)(C). The en banc Federal Circuit has recently held that

Second, in an infringement suit brought in district court by a patent holder, a defendant may assert the invalidity of the patent as a defense. The district court's determination regarding validity can then be appealed to the Federal Circuit.<sup>47</sup> Originally created to bring national uniformity to patent law,<sup>48</sup> the Federal Circuit has become the most important expositor of the substantive law of patents in the United States. Indeed, the Federal Circuit has generally declined to give any legal weight to the PTO's substantive interpretations of patent law rendered in the process of granting or denying patent applications.<sup>49</sup> Although the Federal Circuit's judgments are reviewable in the Supreme Court on writ of certiorari, and the Court has been more active in recent years in taking patent cases, the Court's limited caseload means that much of the development of patent law is left to the Federal Circuit.

From the perspective of administration, then, the two most salient features of the patent system are its reliance on case-by-case adjudication to resolve policy questions in the interstices of the Patent Act and the delegation of that responsibility primarily to the courts rather than to an agency. None of the scholarly criticism of the patent system seriously questions these features. Some commentators observe that the system's performance could be improved through closer adherence to standard principles of administrative law, but their analyses ask how such principles might apply to the *current* institutional arrangement of actors in the

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review of the PTO's decision in such cases is limited to the record developed before the agency, as it would otherwise be in a typical challenge to agency action under the APA. See *Hyatt v. Kappos*, 625 F.3d 1320, 1322-23 (Fed. Cir. 2010) (en banc).

47. The Federal Circuit has exclusive jurisdiction over appeals in cases "arising under any Act of Congress relating to patents," 28 U.S.C. § 1338; see *id.* § 1295(a)(1), and in appeals of the PTO's patentability determinations, see *id.* § 1295(a)(4). In certain circumstances, parties may also seek a declaratory judgment of invalidity. See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007).

48. See Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 74 (1989); Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1620 & n.3 (2007).

49. As described above, the PTO lacks substantive rule-making authority. See *supra* note 35 and accompanying text. Its process for adjudicating patent validity, moreover, bears none of the hallmarks or formal processes of reasoned decision making that might qualify its judgments for deference under *Chevron* and *Mead*. See, e.g., *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1341 (Fed. Cir. 2004). The Federal Circuit has even declined to accord PTO judgments some—if not controlling—weight under the *Skidmore* doctrine. See Benjamin & Rai, *supra* note 30, at 299-300.

patent system. Stuart Benjamin and Arti Rai, for example, argue that “the Federal Circuit’s review of the PTO should be guided by administrative law doctrine.”<sup>50</sup> They then explore how the comparative institutional features of the Federal Circuit and the PTO, as they are currently structured, should shape the standard of review of PTO decisions.<sup>51</sup> They conclude that the PTO ought to receive *Chevron* deference, or at least significant *Skidmore* deference, for its interpretive choices made in the course of patent denials.<sup>52</sup> They do not, however, ask the question whether patent policy ought to be made through the process of examining patent applications.

Benjamin and Rai do consider how two potential changes to PTO procedures—a post-grant opposition proceeding and a more rigorous patent examination—would impact the appropriate standard of review for the PTO’s legal judgments. They decline, however, to pursue a broader project of “designing an ideal agency and ideal agency procedures from scratch” on the ground that such changes are not politically feasible.<sup>53</sup> Similarly, Craig Nard argues that “the PTO’s patentability determinations are questions of policy” and that the Federal Circuit’s current standards of review of those determinations are therefore “unsound,”<sup>54</sup> but he does not evaluate the underlying nature or structure of those determinations.

Others seeking the best approach to patent reform often argue in favor of common law development of patent policy over legislative solutions, but give short shrift to a third option: agency rulemaking. Dan Burk and Mark Lemley convincingly demonstrate that patent policy should be made with a sensitivity to the industry-specific nature of innovation. They argue that “policy levers,” those flexible provisions of the Patent Act and the judicial patent doctrine that allow patent law to be adopted to particular circumstances, should be applied based on an economic understanding of how innovation

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50. Benjamin & Rai, *supra* note 30, at 319.

51. *See id.* at 313-15.

52. *See id.* at 318; *see also* Arti Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL’Y 199, 226-27 (2000).

53. Benjamin & Rai, *supra* note 30, at 272. As described below, I am not persuaded that granting the PTO substantive rule-making authority is a political nonstarter. *See infra* notes 270-73 and accompanying text.

54. Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415, 1422-23 (1995).

works in particular contexts.<sup>55</sup> They also offer a compelling argument that legislative tailoring of the Patent Act to particular industries is bound to fail.<sup>56</sup> But they do not give serious consideration to the potential for agency rulemaking, noting simply that agencies are susceptible of capture by the communities they regulate and that the PTO in particular is exposed to only “one piece of the patent puzzle”—whether a patent should issue in the first instance—and not to infringement actions, licensing disputes, or remedies.<sup>57</sup>

Similarly, Rai makes a convincing case that the standards of patentability are fundamentally policy questions that need to be decided on the basis of sound economics.<sup>58</sup> She acknowledges the institutional limitations courts face in making such judgments.<sup>59</sup> Yet she dismisses the possibility of granting the PTO substantive rulemaking authority because “[i]n order for the PTO to be a reasonably good policymaker, ... Congress would have to change the PTO into an altogether different agency,” adding economic expertise and guarding against capture.<sup>60</sup> Others also discount the notion of a robust PTO.<sup>61</sup>

This Article undertakes a fresh evaluation of the administrative structure of the patent system. It asks whether case-by-case adjud-

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55. See BURK & LEMLEY, *supra* note 1, at 95, 109; see also *infra* Part I.B.

56. See BURK & LEMLEY, *supra* note 1, at 95-102.

57. *Id.* at 106-07.

58. See Rai, *supra* note 11, at 1101, 1116-22.

59. See *id.* at 1122-23.

60. *Id.* at 1134-35; see *id.* at 1132-33. Since Rai’s article was published, the PTO has begun the project of building its economic and policy expertise. See Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office’s Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2054-55 (2009).

61. See, e.g., Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn from the Supreme Court—and Vice Versa*, 59 AM. U. L. REV. 787, 802 (2010) (“I have left the U.S. Patent and Trademark Office out of this discussion because it was founded before the Administrative Procedure Act; lacks rule-making authority; and only sees the issues that arise when a patent is issued, not the ones that come up when patented information is used.”); John F. Duffy, *The Federal Circuit in the Shadow of the Solicitor General*, 78 GEO. WASH. L. REV. 518, 547 (2010) (“Vesting the PTO with a rule-making power would, however, have one overarching and unavoidable problem: rule-making powers give executive agencies the power to *change* the rules when political forces change.”); Nard, *supra* note 11, at 87-88 (“The preference for the present model may reflect the common law’s historically dominant role.”); Nard & Duffy, *supra* note 48, at 1640-41 (“The PTO guideline-writing process may be a good complement to appellate judging, but is not a perfect substitute.”).

ication of the validity of individual patents is the optimal manner in which to make patent policy, and whether the courts are the optimal actors to make patent policy. It answers both questions in the negative. It therefore makes the case for agency rulemaking instead of case-by-case judicial development of patent policy. Although this proposal has received scant attention in the academy, it is far from a political nonstarter. Indeed, the PTO has lobbied for substantive rule-making authority,<sup>62</sup> and Congress has at least considered such a grant.<sup>63</sup> This Article explains why that proposal is sensible and should be adopted in the next round of statutory patent reform.

Part I explains the dual nature of the administrative tasks that the patent system must perform. To be sure, the Patent Act has always required elaboration and policymaking, but because technology was mostly undifferentiated when the basic institutional structure of the patent system was established, there was not as strong a need to make *categorical* policy choices about the standards of patentability that would depend on the particulars of a technology and its application. Today, however, the tasks of adjudicating the validity of individual patents and of making patent policy may be distinguished from one another in concept and in practice. That is, there is a class of policy decisions that can be made separately from the process of granting and adjudicating individual patents.

Part II explores the optimal institutional structure for carrying out the distinct task of making patent policy. It begins by laying out a set of normative principles that should guide the institutional choice of patent policymaker. The decision-making qualities that are desirable for issuing and adjudicating patents are different from the characteristics that mark good policymaking. Sound patent policy

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62. See Letter from Gary Locke, Sec'y of Commerce, to Hon. Patrick J. Leahy, Chairman, S. Comm. on the Judiciary, and Hon. Jefferson B. Sessions III, Ranking Member, S. Comm. on the Judiciary 2-3 (Oct. 5, 2009), available at <http://judiciary.senate.gov/resources/documents/111Documents.cfm>.

63. See Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 11 (2007) (as introduced) ("In addition to the authority conferred by other provisions of this title, the Director may promulgate such rules, regulations, and orders that the Director determines appropriate to carry out the provisions of this title or any other law applicable to the United States Patent and Trademark Office or that the Director determines necessary to govern the operation and organization of the Office."). Similar language is not included in the patent reform bills introduced in the House and Senate in the 111th Congress. See Patent Reform Act of 2009, S. 515, 111th Cong. (2009); Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009).

rests on neither a highly fact-specific determination of an individual case nor speedy and accurate assessments of a large number of patents, but on reasoned deliberation and expertise, clarity and predictability, and transparency and accountability. Judged against these measures, the current patent system fails to make policy in a socially optimal manner. The PTO issues patents in great quantity and with minimal deliberation. But the adversarial process of litigation also fails to produce sound forward-looking policy. Courts do not allow wide participation, do not take appropriate account of economic analysis and the full range of factors that ought to go into evaluating the necessity of patent protection on an industry-by-industry basis, and do not provide sufficient predictability or clarity to support investment. Agency rulemaking fares better along each of these dimensions. Although agencies have a distinct set of pathologies of their own—the possibility of capture being the most prominent—institutional analysis must always be done in a comparative fashion, and the comparative advantages of agencies over courts outweigh the comparative disadvantages.

Finally, Part III describes changes to the existing institutions of the patent system that should or must accompany a shift to agency-based rulemaking. The PTO, for example, should remain the agency in charge of both patent examination and rulemaking, but it will have to be restructured significantly. A shift to rulemaking would have implications for other actors in the current system as well. It is not clear, for example, why judicial review of PTO rules should be confined to the Federal Circuit. Similarly, the advent of binding agency rules will significantly reshape the contours of patent validity litigation.

### I. THE CHANGING TASKS OF PATENT ADMINISTRATION

The administrative structure of the modern American patent system was first set forth in the Patent Act of 1836. It has remained largely unchanged. Yet the administrative tasks that the system must perform have changed markedly. Part I describes that change.

Technology in 1836 was largely uniform. The patent system therefore was concerned primarily with defining and enforcing the boundaries of the exclusive rights that patents conferred. The ad-

ministrative system that Congress enshrined in the 1836 Act reflected the nature of that task. Today, by contrast, the patent system must also adapt patent law to the unique and changing needs of diverse industries and technologies. That task of self-conscious policymaking is far more complex than the tasks confronting the nineteenth-century patent system. It is therefore worth questioning whether the existing system—itsself a product of historical circumstance and path dependence—remains optimal in light of the new tasks it must perform.

#### *A. Patent Administration in Historical Perspective*

This Section provides a brief overview of how the current institutional structure of the patent system came into being. A full evaluation of the historical structure of the patent system is beyond the scope of this Article. Instead, I offer this summary in the service of two more limited points: first, that there is some degree of historical contingency or path dependence to the current arrangement of institutional actors; and, second, that the modern administrative tasks the system confronts are at least different enough that we should look with fresh eyes at whether the 1836 arrangement remains optimal.

The modern system of patent examination and administration has its origin in the Patent Act of 1836.<sup>64</sup> That statute established within the Department of State a “Patent Office,” which the Act empowered to examine patent applications and to issue patents.<sup>65</sup> The 1836 Act thus “created the first real examination system in the United States.”<sup>66</sup> But the Patent Office’s role was limited to determining whether a particular patent application met the statutory criteria for patentability, and, if it did, the Office was duty-bound to issue a patent.<sup>67</sup> The Act also provided for judicial review of the

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64. Patent Act of 1836, ch. 357, 5 Stat. 117.

65. *See id.* §§ 1-2, 6-7. The 1836 Act allowed patents for “any new and useful art, machine, manufacture, or composition of matter” or any “new and useful improvement on” such. *Id.* § 6. The statute required putative patentees to submit an application containing a written description of their inventions and other data. *See id.*

66. Oren Bracha, *The Commodification of Patents 1600-1836: How Patents Became Rights and Why We Should Care*, 38 LOY. L.A. L. REV. 177, 235 (2004).

67. *See* Patent Act of 1836 § 7.

Patent Office's decisions. An infringement defendant could challenge the patent's validity,<sup>68</sup> and a disappointed patent applicant could appeal the rejection of his application to a "board of examiners."<sup>69</sup> In hearing these cases, the judiciary remained the primary expositor of patent law.<sup>70</sup> This basic structure—an executive body that examined applications to determine whether the substantive criteria of patentability were met, coupled with judicial review to interpret and explicate the standards of patentability—has survived in more or less identical form to this day.<sup>71</sup>

Of course, the 1836 structure was a product of its time. It reflected both the particulars—and particular problems—of patent practice in the early nineteenth century and the prevailing norms of antebellum administrative governance. Several features of nineteenth-century patent and administrative practice are important to understanding the Act's allocation of authority between the executive and the judiciary.<sup>72</sup>

Although the establishment of an independent agency that conducted robust pre-issuance examination was novel, the courts' primacy in matters of substantive patent law was long-standing. The first patent statute, passed in 1790, provided for the Secretaries of State and War and the Attorney General to review patent applications.<sup>73</sup> The "patent board," so constituted, was generally understood to have great discretion in granting or denying patents so long as certain broad statutory criteria were met.<sup>74</sup> Patents in this era

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68. *See id.* § 15.

69. *See id.* § 7. Three years later, the structure of judicial review was completed with the addition of review of patent denials in the federal courts. *See Act in Addition to "An Act To Promote the Progress of the Useful Arts,"* ch. 88, § 11, 5 Stat. 353, 354-55 (1839).

70. *See, e.g.,* Andrew P. Morriss & Craig Allen Nard, *Institutional Choice and Interest Groups in the Development of American Patent Law: 1790-1870*, 19 SUP. CT. ECON. REV. (forthcoming 2011) (manuscript at 14), available at <http://ssrn.com/abstract=1262970>.

71. *See* Bracha, *supra* note 66, at 238 ("While other parts of patent law were still to undergo important changes, by the mid-nineteenth century the ... institutional model of patents ... acquired its modern form."); Duffy, *supra* note 31, at 1079 ("[T]he patent system continues to thrive with much the same structure that it was given in 1836."); *see also* EDWARD C. WALTERSCHEID, *TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION, 1787-1836*, at 432 (1998).

72. The scant legislative history of the 1836 Act does not evince any self-conscious debate over the distribution of tasks between the newly constituted Patent Office and the courts. *See* WALTERSCHEID, *supra* note 71, at 421-27.

73. Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 109-10 (repealed 1793).

74. Bracha, *supra* note 66, at 220 ("The patent board was not merely an administrative

still bore the hallmarks of governmentally granted “privileges” rather than “rights.”<sup>75</sup> This system proved quickly to be unworkable.

In 1793, Congress passed a new patent statute that eliminated patent examination; instead, a patent that satisfied minimal formal requirements would issue upon filing of the application with the Patent Office in a process that became known as “registration.”<sup>76</sup> An inventor simply “registered” his invention and received a patent. For more than forty years during the registration era, then, the courts were entirely responsible for the development of patent law.<sup>77</sup> It is therefore perhaps unsurprising that the courts would retain most of this role under the new regime.

Indeed, the new Patent Office appears to have been intended to serve primarily as “a check upon the granting of patents,” rather than as an institution for tackling and solving the substantive issues that arise in patent enforcement.<sup>78</sup> That position was also consistent with then-prevailing views of administrative governance. As John Duffy and others have observed, Jacksonian governance was skeptical about the competence and reliability of administrative institutions, and that skepticism extended to the new Patent Office.<sup>79</sup>

The task of elaborating the criteria for patentability in the first half of the nineteenth century was also significantly different from

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agency assigned the mere task of certifying the fulfillment of standard patentability criteria and the duty of issuing a patent when they were met. Instead, it was an arm of the sovereign with full discretionary power to weigh public policies and make case-specific decisions as to whether to grant.”).

75. *Id.* at 222-23.

76. Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 318-21; see Bracha, *supra* note 66, at 227.

77. See WALTERSCHEID, *supra* note 71, at 355 (“[A] registration system placed the burden of determining patent issues on the courts.”); Bracha, *supra* note 66, at 228 (“[A]ll substantive decisions regarding patents were now to be made by the courts whenever a conflict was laid at their doors.”); Morriss & Nard, *supra* note 70, at 7 (“The 1793 Act shifted the *ex ante* gatekeeper role performed by an examination to an *ex post* proceeding in the courts.”). As described above, the new Patent Office was not granted the authority to promulgate substantive rules. See *supra* note 35 and accompanying text.

78. WALTERSCHEID, *supra* note 71, at 425 (quoting 1836 Senate Committee Report, 18 J. PAT. & TRADEMARK OFF. SOC’Y 853 (1936)); see also Jerry L. Mashaw, *Administration and “The Democracy”: Administrative Law from Jackson to Lincoln, 1829-1861*, 117 YALE L.J. 1568, 1580 (2008) (“Under this system, the Patent Office took some of the load off of the courts, but the development of the law of patentability remained largely in judicial hands, as it is today.”).

79. See Duffy, *supra* note 31, at 1132-39. See generally Mashaw, *supra* note 78.

what it is today. As Robert Merges has explained, nineteenth-century technology was fairly uniform—“[a]t the very least ... if you put technology in a bag and shook it, it would make some noise.”<sup>80</sup> That is, most technological innovations took place within a well-defined sphere of invention: “Everyone knew that manufactures and machines were at the core of the patent system. Agricultural and industrial machinery was almost synonymous with ‘patents.’”<sup>81</sup> Although there was some variety in the industrial settings in which mechanical inventions were used,<sup>82</sup> the underlying technology still comprised basic machinery. Patentable subject matter was therefore a rarely discussed concept in the patent jurisprudence of the first half of the nineteenth century.<sup>83</sup>

Instead, patent litigation and the judicial development of patent law prior to 1836 focused primarily on the establishment and enforcement of patent boundaries. As one commentator noted, “[p]atent law rather quickly came to be recognized as property law directed to that particular form of intellectual property known as patents.”<sup>84</sup> The analogy to land often was explicit. Grants of property from the public lands were known as “land patents,” and “[c]ross-citation of patent cases in public lands cases and vice versa ... was common.”<sup>85</sup> The “boundaries” of patents were policed primarily by juries sitting in infringement cases.<sup>86</sup> Patent litigation was highly fact specific.<sup>87</sup> Morriss and Nard describe the process as follows:

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80. Merges, *supra* note 1, at 585.

81. *Id.* (footnote omitted); *see also* *Bilski v. Kappos*, 130 S. Ct. 3218, 3242-46 (2010) (Stevens, J., concurring) (describing the eighteenth and nineteenth century understanding of the “useful arts”); Brief for the Respondent at 16-25, *Bilski*, 130 S. Ct. 3218 (No. 08-964) (same).

82. *See* B. ZORINA KHAN, *THE DEMOCRATIZATION OF INNOVATION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790-1920*, at 72 tbl.3.2 (2005) (defining relevant industrial sectors to include agriculture, building, manufacturing, transport, and “other”).

83. Merges, *supra* note 1, at 585.

84. WALTERSCHEID, *supra* note 71, at 305.

85. Julie E. Cohen, *Copyright, Commodification, and Culture: Locating the Public Domain*, in *THE FUTURE OF THE PUBLIC DOMAIN* 121, 130 & n.32 (Lucie Guibault & P. Bernt Hugenholtz eds., 2006) (citing cases).

86. *See* Morriss & Nard, *supra* note 70, at 8-10.

87. Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction?*, 157 U. PA. L. REV. 1743, 1770 (2009) (“[T]he parties litigated validity and infringements as largely factual questions.”).

During litigation, the jury would peruse the written description to determine what the invention was, or at least, the principle underlying the invention. The jury, however, had the difficult job of comparing the accused product with the patentee's invention because the jury was required to discern abstract principles of the invention from the patent document's textual description and schematic representations.<sup>88</sup>

To be sure, the courts developed interpretations of the key patentability requirements, including novelty and utility. But the development of those concepts was often decidedly case specific. In one line of cases interpreting the utility requirement, for example, the courts viewed that criterion as a mechanism "to review patents based on their discretionary assessments of the net public effects of specific inventions."<sup>89</sup> This inquiry did not implicate general policy concerns, but rather was focused on "substantive evidence and arguments regarding the social benefits and effects of the relevant inventions."<sup>90</sup>

Taking these factors together, the 1836 administrative structure appears to reflect the tasks of the 1836 patent system. Technology was relatively undifferentiated and patent disputes were mostly fact specific.<sup>91</sup> Administrative governance was in the early stages of development and robust federal agencies had yet to come into being.<sup>92</sup> As a result, the administrative structure enshrined in the 1836 Act provided for the development of patent law in a case-specific manner focused on the courts. Regardless of whether that structure was optimal at the time, there can be little doubt that underlying changes in patent practice over time give us cause to reconsider whether it is optimal today.

### *B. Administrative Tasks Confronting the Modern Patent System*

Nearly 175 years have passed since the patent system's modern form took shape. Those intervening years have seen vast changes in technology and industry. The first iteration of the Patent Office

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88. Morriss & Nard, *supra* note 70, at 9.

89. Bracha, *supra* note 66, at 230.

90. *Id.* at 231.

91. *See supra* notes 80-83, 86-88 and accompanying text.

92. *See supra* notes 72-79 and accompanying text.

employed seven people—two examiners, two assistant examiners, two draftsmen, and a machinist—for the first decade of its existence.<sup>93</sup> Between 1840 and 1849, those examiners issued roughly 5500 patents primarily for developments in mechanical technology.<sup>94</sup> In 2009, the PTO issued over 150,000 patents.<sup>95</sup> In so doing, it employed over 6000 examiners<sup>96</sup> spread across eight different “technology centers”:<sup>97</sup> biotechnology and organic chemistry; chemical and materials engineering; computer architecture and software; networking, multiplexing, cable, and security; communications; semiconductors, electrical and optical systems and components; transportation, construction, electronic commerce, agriculture, national security, and license and review; and mechanical engineering, manufacturing, and products and designs.<sup>98</sup> The advent of significantly differentiated technology coupled with the high volume of patent applications received and reviewed means that there are at least two separate administrative tasks that the system must now accomplish: determining the validity of individual patents and making policy judgments about the application of patent law to diverse technologies.

The first administrative task has changed in degree since the inception of the patent system. At each stage of the process of determining a patent’s validity, the volume of such determinations has increased markedly. The PTO now receives close to 500,000 patent applications each year.<sup>99</sup> An examiner will spend eighteen hours on average examining a patent application to determine whether it meets the criteria for a patent to issue.<sup>100</sup> The courts, in turn, have seen a marked increase in the volume of patent litigation. From 1830 to 1839, the federal courts heard 37 patent cases.<sup>101</sup> Today, the number of patent lawsuits filed per year is over 2500,

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93. See Morriss & Nard, *supra* note 70, at 5 n.13.

94. See KHAN, *supra* note 82, at 71 tbl.3.1.

95. See *supra* note 39 and accompanying text.

96. See U.S. Patent & Trademark Office, Utility, Plant, and Reissue Examiner Staffing, <http://www.uspto.gov/patents/stats/examstaffing.jsp> (last visited Mar. 14, 2011).

97. Excluding the technology center for design patents. See *supra* note 39.

98. See U.S. Patent & Trademark Office, Patents Organization, <http://www.uspto.gov/patents/organization.jsp> (last visited Mar. 14, 2011). Within each of those technology centers, examiners are broken down into further areas of specialization called “art units.”

99. PTO ANNUAL REPORT, *supra* note 39, at 112 tbl.1.

100. See *supra* note 44 and accompanying text.

101. KHAN, *supra* note 82, at 71 tbl.3.1.

and that number is increasing.<sup>102</sup> The last twenty years in particular have seen an explosion of patent litigation.<sup>103</sup> The key challenges posed by increasing volume include figuring out how to process and adjudicate such a large volume of patents.

Distinct from the task of determining whether an individual patent is valid is the task of elaborating the criteria of patentability. That task requires some amount of abstraction from the particulars of individual inventions. Such abstraction may occur at a variety of levels of more or less generality.<sup>104</sup> In all events, it requires the relevant decision maker to draw distinctions based on the technological and economic characteristics of highly diverse industries and inventions. In a series of influential works, Burk and Lemley have chronicled the increasing technological and economic variety of innovation and what it means for the patent system.<sup>105</sup> They demonstrate that different industries exhibit marked differences in the ways in which they innovate. The cost of R&D, and therefore the need to recoup significant upfront investment, is quite different from one industry to another.<sup>106</sup> Pharmaceutical innovation, for instance, requires enormous time and capital, owing in no small part to the significant regulatory requirements for the approval of new human drugs.<sup>107</sup> The archetype of software innovation, on the other hand, is two guys working in a garage.<sup>108</sup> Similarly, the availability of other mechanisms for appropriating the gains from investments in R&D—and the need, therefore, for the *ex ante* incentives provided by patents—varies on an industry basis.<sup>109</sup> Most

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102. BESSEN & MEURER, *supra* note 2, at 122 fig.6.1.

103. *Id.*

104. *See infra* notes 130-50 and accompanying text.

105. *See* BURK & LEMLEY, *supra* note 1, at 49; Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156-57 (2002); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577 (2003) [hereinafter Burk & Lemley, *Policy Levers*].

106. BURK & LEMLEY, *supra* note 1, at 38-41.

107. *Id.* at 39.

108. *Id.* at 40.

109. *Id.* at 42-46; Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1257 (2009); Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 784-86 (1987); Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, 2-5 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000).

mechanical inventions, for example, are “self-disclosing,” that is, they can be reverse engineered by competitors with minimal effort.<sup>110</sup> Others are less easily replicated and therefore patent protection is less important.<sup>111</sup>

Finally, the degree to which innovation requires access to critical inputs that themselves may be the subject of intellectual property protection varies. It is well understood that innovation often is a cumulative process.<sup>112</sup> But the importance of cumulative innovation, and the effect of intellectual property on the efficiency of cumulative innovation, varies by technology. In pharmaceuticals, for example, products tend to be stand-alone. A single patent covers a single product, without much need for follow-on work. In software, by contrast, cumulative innovation is a critical component of the product development cycle. As Burk and Lemley note, the conventional wisdom in the software industry is that “you shouldn’t buy version 1.0 of any program. The expectation is that the programs will be incrementally improved over time.”<sup>113</sup> In some areas of biotechnology, cumulative innovation works differently. Because much of product development depends on applying the tools of basic science, a large number of inputs are needed for new innovation. When those research tools are themselves the subjects of patent protection, an “anticommons” may arise, in which follow-on research is inhibited by the need to clear rights to many different inventions.<sup>114</sup>

As a result of these systematic variations in the underlying technology and economics of innovation, different industries experience the patent system in different ways.<sup>115</sup> Burk and Lemley point to industry-based differences in firms’ propensities to seek patent protection in the first instance, and to differences in the patent prosecution process, in the scope of patents, and in the use and enforcement of patents. Bessen and Meurer demonstrate empirically that the value of patents differs markedly by industry.

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110. See Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 105.

111. See Burstein, *supra* note 5.

112. See, e.g., Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991).

113. BURK & LEMLEY, *supra* note 1, at 47.

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

115. See BURK & LEMLEY, *supra* note 1, at 49-59.

Indeed, they conclude that pharmaceutical and chemical patents provide a net benefit to their holders after litigation costs; patents in most other industries do not.<sup>116</sup>

The conclusion that Burk and Lemley draw from these observations is straightforward: the patent system “can, and should, apply the general rules of patent law with sensitivity to the characteristics of particular industries.”<sup>117</sup> If a particular rule results in social welfare gains when it is applied to one technology, but social welfare losses when applied to another, it should be applied to the former and not the latter. This common-sense observation implies that the patent system must sometimes make categorical judgments about the application of general rules to particular industries or technologies.

This is not to say, however, that all decisions implementing the Patent Act will optimally create a one-to-one correspondence between a single legal principle and a single industry. Sometimes sensitivity to technological and economic particulars will require making a policy that is specific to a single type of invention.<sup>118</sup> At other times, however, the categorical choice will be drawn more broadly. Although Burk and Lemley’s insight has led some critics to complain about the prospect of a balkanized patent system in which the rules vary by technology, technology-sensitive policymaking may not necessarily lead to such a system.<sup>119</sup> Patent law already accommodates technological specificity in part by virtue of the fact-specific nature of many patentability determinations.<sup>120</sup> Take, for

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116. See BESSEN & MEURER, *supra* note 2, at 138-42, 139 fig.6.5.

117. BURK & LEMLEY, *supra* note 1, at 109.

118. See *id.* at 110.

119. See, e.g., R. Polk Wagner, *(Mostly) Against Exceptionalism*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 367, 372 (F. Scott Kieff ed., 2003) [hereinafter Wagner, *Against Exceptionalism*] (describing how Burk and Lemley’s proposal “shifts consideration of the patent law from a general background principle of property rights to a vehicle for particularistic, technology-specific innovation policy choices”); see also Clarisa Long, *Our Uniform Patent System*, 55 FED. L. 44, 47-49 (2008) (“Special rules for each industry run the danger of defining a market that will be difficult to change.”); R. Polk Wagner, Comment, *Exactly Backwards: Exceptionalism and the Federal Circuit*, 54 CASE W. RES. L. REV. 749, 750 (2004) [hereinafter Wagner, *Exactly Backwards*] (distinguishing Burk and Lemley’s proposal from “micro-exceptionalism, .... [t]he normal course of things”).

120. See Wagner, *Against Exceptionalism*, *supra* note 119, at 370-72; Wagner, *Exactly Backwards*, *supra* note 119, at 750. It is worth noting that Burk and Lemley likely would not disagree entirely with this proposition. They distinguish between “macro” policy levers and “micro” policy levers. In their view, the “micro” levers continue to operate on a case-by-case

example, the determination whether an invention “would have been obvious at the time the invention was made to a person having ordinary skill in the art.”<sup>121</sup> This standard is expressly tied to an industry- or technology-specific determination about the level of skill of an average practitioner in the field. Through this and other similar standards that are flexibly applied to different technologies, patent law necessarily exhibits some tailoring.<sup>122</sup>

The question whether such tailoring should be case-specific or more general ultimately is a new iteration of the classic jurisprudential debate between rules and standards.<sup>123</sup> In the usual formulation, rules are costlier to establish but easier to apply and enforce, while standards are cheaper to establish but harder to apply.<sup>124</sup> Rules are bright-line and clear. Standards are flexible and adaptable. The question whether rules or standards make for better patent law is complicated.<sup>125</sup> It is sufficient here to note several features of the debate that suggest that a preference for standards over rules does not eliminate the need for industry- or technology-specific patent policymaking. First, the choice between rules and standards is itself a policy choice. One key lesson from the literature on rules and standards is that there is not a bipolar choice to be made in fashioning legal principles. Instead, the choice between rules and standards is a question of optimization.<sup>126</sup> Second, the choice between rules and standards is necessarily context specific. In Louis Kaplow’s framework, for example, the choice of a rule or a standard is driven by the cost of creating or articulating the legal

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basis, but have a disparate impact on an industry that arises through application. *See* BURK & LEMLEY, *supra* note 1, at 109-10.

121. 35 U.S.C. § 103(a) (2006).

122. *See* Mark D. Janis, Comment, *Equilibrium in a Technology-Specific Patent System*, 54 CASE W. RES. L. REV. 743, 743 (2004).

123. The literature on rules versus standards is deep and rich. For classic contributions to the debate, see, for example, Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65, 66 (1983); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 562 (1992); and Cass R. Sunstein, *Problems with Rules*, 83 CAL. L. REV. 953, 959 (1995).

124. *See* Kaplow, *supra* note 123, at 577.

125. For some discussion of this problem, see, for example, John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609 (2009); John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771 (2003); and Wagner, *supra* note 42, at 234-37.

126. *See* Diver, *supra* note 123, at 71-79.

principle and the ease of conforming one's conduct to that principle.<sup>127</sup> In the context of patent policy, those factors will be determined by, *inter alia*, the extent to which a given type of technology has clearly defined uses, the volume of patents likely to emerge from a given technological class, and the uncertainty associated with individualized determinations of patentability.<sup>128</sup> Evaluating these various factors requires deep knowledge of technological and economic particulars.

The space for technology-specific policymaking, therefore, is not reduced by a reliance on standards. Indeed, it is perhaps even expanded; the choice of a rule or a standard in the first instance is a policy choice no less than the formulation of that particular rule or standard.<sup>129</sup> Both determinations are subject to analysis that takes into account the particular technological and economic contexts in which the legal principle is to operate. A few examples highlight the range of potential decisions to be made.

In some instances, a bright-line rule will be the most appropriate legal principle. Consider, for example, the problem of patents for expressed sequence tags (ESTs). ESTs are short sequences of DNA that are derived from longer genes.<sup>130</sup> An EST's primary use is to serve as a "marker" to identify a full-length gene that can then be analyzed to determine their functions.<sup>131</sup> ESTs can be produced, however, without any knowledge about the genes to which they correspond, the proteins that those genes encode, or the biological functions that those proteins perform.<sup>132</sup> It is possible, therefore, to produce a large number of ESTs in a relatively short amount of time, and then to use the ESTs over years of subsequent research into the genes to which they correspond.<sup>133</sup> Controversy erupted over the patenting of ESTs in 1991 when the National Institutes of

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127. See Kaplow, *supra* note 123, at 562-63.

128. *Cf. id.* at 563-64.

129. See *infra* notes 146-50 and accompanying text.

130. See *In re Fisher*, 421 F.3d 1365, 1367 (Fed. Cir. 2005); Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 2-3 (1995).

131. See *In re Fisher*, 421 F.3d at 1367.

132. See *id.* at 1373.

133. See *id.* ("Essentially, the claimed ESTs act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes.").

Health (NIH) submitted patent applications claiming over 6800 ESTs produced during preliminary work on the Human Genome Project.<sup>134</sup> Critics contended that if patents were to issue for these short segments of DNA prior to isolation and analysis of the full genes and proteins to which they correspond, the EST patent holders would effectively control all uses of those subsequent inventions.<sup>135</sup> There would also be the potential for an “anticommons” problem because many ESTs held by different patent holders could correspond to a single gene.<sup>136</sup> Although the NIH abandoned its patent claims in 1994,<sup>137</sup> the PTO continued to grapple with the problem. In 2001, following public notice and comment, the PTO promulgated guidelines for its examiners that concluded that applicants claiming ESTs could not satisfy the utility requirement of the Patent Act without showing that they had actually used the ESTs to isolate or perform research on the downstream genes.<sup>138</sup> The Federal Circuit adopted a similar approach.<sup>139</sup> This requirement of specific utility is usually not invoked with respect to other technologies.<sup>140</sup> But because of the particular characteristics of ESTs and their interaction with downstream research, a bright-line rule in this context made the most sense.

In the case of ESTs, the technological and economic circumstances in which the inventions would be used were clear enough to make the development of a bright-line rule appropriate. In other areas of patent law, a mix of rules and standards—and a mix that changes over time—may prove optimal. Consider the problem of business method patents. It has long been the case that abstract ideas are not patentable subject matter.<sup>141</sup> As John Duffy has explained, “the doctrine against abstractions is a general standard without crisp delineations.”<sup>142</sup> The inquiry into whether an invention represents

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134. See Eisenberg & Merges, *supra* note 130, at 2; Heller & Eisenberg, *supra* note 114, at 699

135. See Eisenberg & Merges, *supra* note 130, at 18-19, 38.

136. See Heller & Eisenberg, *supra* note 114, at 699.

137. See Eisenberg & Merges, *supra* note 130, at 3.

138. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093-94 (Jan. 5, 2001).

139. See *In re Fisher*, 421 F.3d 1365, 1372, 1374 (Fed. Cir. 2005).

140. See BURK & LEMLEY, *supra* note 1, at 112.

141. See *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

142. Duffy, *supra* note 125, at 646.

an abstract idea is fact specific and blends with other considerations of patentability. In *Bilski v. Kappos*, the Supreme Court held that the question whether business methods are patentable is to be decided on a case-by-case basis in accordance with the prohibition on abstract ideas.<sup>143</sup> But that need not have been its conclusion. The Federal Circuit had held that the patentability of business methods turned on whether the process was “tied to a particular machine or apparatus” or “transforms a particular article into a different state or thing.”<sup>144</sup> That is a more rule-like formulation, though it is still highly general; in other words, it could apply to any number of technological or economic settings. More particularly, Justice Stevens, dissenting from the Court’s reasoning in *Bilski*, would have held simply that business methods were categorically excluded from patentability.<sup>145</sup>

The choice among these three approaches to the problem of business method patents is a policy choice. The legal principle one adopts depends on one’s views of the relative merits of more rule-like or more standard-like formulations. And one’s view of the merits of that choice depends on an analysis of the relative costs and benefits of different legal principles; that analysis inevitably turns on the specific technological and economic context of the rule or standard. Rules and standards, moreover, need not be mutually exclusive, nor does the choice of a rule or a standard need to remain constant over time. As the *Bilski* Court acknowledged, there remained room for the “development of other limiting criteria” that may have fared better than the Federal Circuit’s “machine-or-transformation” test.<sup>146</sup> Categorical rules can be carved out from broader standards as experience and changing circumstances dictate.<sup>147</sup>

Finally, even where a pure standard is optimal, there are still policy decisions to be made in formulating that standard. The Supreme Court has articulated, for example, several “secondary considerations” that are relevant to the question of obviousness.<sup>148</sup>

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143. 130 S. Ct. at 3231.

144. *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc).

145. *See Bilski*, 130 S. Ct. at 3232 (Stevens, J., concurring).

146. *Id.* at 3231.

147. *See Duffy*, *supra* note 125, at 614-15.

148. *See KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham v. John*

These considerations include the commercial success of the invention, whether it meets a long-felt but unsolved need, whether others have failed in trying to achieve the same goal, and other such expressly policy-based considerations.<sup>149</sup> These secondary considerations together form a standard—they are applied neutrally across technologies, yet ultimately produce different outcomes based on particular facts and circumstances.<sup>150</sup> But as Burk and Lemley explain, the Supreme Court’s choice of secondary factors to include in the analysis is “policy-based ... result[ing] from the court’s belief that the reaction of the market,” for example, “will show that certain inventions are more deserving of protection than others.”<sup>151</sup>

Regardless whether a rule or a standard is adopted to govern an element of patentability, policy analysis plays a critical role in articulating the legal principle. That policy analysis, moreover, need not be coupled with the determination of the validity of a particular patent. The PTO’s Utility Examination guidelines were formulated in response to a particular *class* of patents: ESTs.<sup>152</sup> Of course, the analysis was informed by the particulars of that class, but the PTO could and did carry it out separately from the examination process.<sup>153</sup> Similarly, a policymaker could decide to exclude categories of patentable subject matter or articulate secondary considerations of nonobviousness outside the confines of a particular case. Indeed, this policymaking is what agencies with substantive rule-making authority do with great frequency. The next Part considers whether these policy judgments are best made through case-by-case adjudication in agencies and courts or through rulemaking.

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Deere Co., 383 U.S. 1, 17-18 (1966)).

149. See *id.*; see also BURK & LEMLEY, *supra* note 1, at 117-18 (discussing policy-based nature of secondary considerations of nonobviousness).

150. See BURK & LEMLEY, *supra* note 1, at 117.

151. *Id.*

152. See *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005); Press Release, USPTO Publishes Final Guidelines for Determining Utility of Gene-Related Inventions (Jan. 4, 2001), available at <http://www.uspto.gov/news/pr/2001/01-01.jsp>; *supra* note 135 and accompanying text.

153. Cf. *In re Fisher*, 421 F.3d at 1372.

## II. WHY PATENT POLICY SHOULD BE MADE THROUGH AGENCY RULEMAKING

Sound patent administration requires significantly more policymaking than it did at the time the major institutions of the system were established. This Part asks whether the old institutional structure remains optimal. I first develop a set of normatively attractive decision-making attributes for patent policy. I next explain why the current institutional arrangement fails to uphold these principles, and suggest that they are better implemented through agency-based rulemaking. Of course, agency rulemaking is not an institutional arrangement free from flaws. Nevertheless, I argue that on balance such a system would represent an improvement over the current arrangement.

### A. *A Normative Theory of Patent Administration*

A well-functioning patent system will perform two distinct tasks: it will assess the validity of individual patents and engage in forward-looking policymaking with respect to the standards of patentability.<sup>154</sup> But performing each of these tasks well requires different skills in the relevant decision maker. Take patent examination first.<sup>155</sup> The PTO must process a significant volume of patent applications, and must do so with both speed and accuracy.<sup>156</sup> That requires organizing a large number of examiners, incentivizing them, and giving them clear direction.<sup>157</sup> It also requires the development of tools and processes for making relatively quick legal judgments that are necessarily subject to further revision where

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154. See *supra* Part I.B.

155. A significant literature has developed around the problem of poor patent “quality.” This literature seeks to improve the operation of the PTO to reduce the number of granted patents that do not meet the statutory criteria for patentability. See, e.g., R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2138 (2009). The question of how to improve the patent examination process is distinct from the question of how to improve the patent *policy-making* process, and is beyond the scope of this Article.

156. Michael Abramowicz and John Duffy refer to these tasks as the “production problem” and the “mass-justice” problem. See Michael Abramowicz & John F. Duffy, *Ending the Patenting Monopoly*, 157 U. PA. L. REV. 1541, 1546-64 (2009).

157. See *id.* at 1546-58.

time and resources permit.<sup>158</sup> Lemley calls this understanding “rational ignorance”—“[b]ecause so few patents are ever asserted against a competitor, it is much cheaper for society to make detailed validity determinations in those few cases than to invest additional resources examining patents that will never be heard from again.”<sup>159</sup>

Once a granted patent, or a denied application, is the subject of litigation, the adjudication of patentability requires courts to make quite detailed and nuanced applications of law to the particular factual circumstances of the patent and the dispute.<sup>160</sup> Determining patent validity in the face of third-party challenges requires detailed fact-finding about the circumstances surrounding the invention, the characteristics of the invention itself, and the place of the invention in the broader technological art of which it is a part.

Patent policymaking requires different skills. Policymaking is prospective. It is categorical. It requires neither the high-throughput speed and accuracy of patent examination nor the comprehensive fact-finding of litigation. Instead, it requires the decision maker to abstract from particular circumstances to formulate more general rules or standards. Recall that the normative goal of the patent system is to provide incentives for innovation.<sup>161</sup> The standards of patentability are key policy levers by which those incentives can be adjusted toward the optimum.<sup>162</sup> In setting those standards, the following decision attributes are critical.

### *1. Reasoned Decision Making and Expertise*

“Innovation policy” aims to use the mechanisms of government to foster and promote the optimal level of technological innovation in a society.<sup>163</sup> Patent policy in particular requires the application of

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158. *Id.* at 1558-64.

159. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1497 & n.6 (2001).

160. *See id.* at 1502.

161. *See supra* note 4.

162. *See* BURK & LEMLEY, *supra* note 1, at 95 (defining “policy levers” as those flexible provisions of the patent statute and its associated judicially developed doctrines that allow the rules of patent to be tailored to particular circumstances).

163. *See* Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 11-12 (2008). Neo-Schumpeterian economics teaches that technological change is an “endogenous” variable, the magnitude of which is determined in part by government policy. *See id.* at 12; Paul M. Romer, *The Origins of Endogenous*

technological and economic analysis to a set of legal tools—“policy levers” in Burk and Lemley’s parlance—set forth in the patent statute. Determining when and how to use those mechanisms requires reasoned decision making, which itself requires that the policymaker have access to economic and technological information, that the policymaker be capable of analyzing and interpreting that information, and that it have sufficient authority to choose among competing alternative solutions to any given policy problem.

Because the characteristics of technological innovation vary systematically by industry and technology, the policymaker must be able to acquire sufficient industry- and technology-specific information to operate the policy levers effectively.<sup>164</sup> There are at least three sources of critical information that a policymaker needs in order to determine how patent law should be implemented on an industry- or technology-specific basis. The decision maker first needs information about the relevant technology. This may include data about a specific invention or class of inventions that could be the subject of an application or a patent. But it also more broadly includes information about the technological *field* of which any particular invention is a part. Second, the decision maker needs information about the economics of R&D broadly and more specifically in the context of a particular industry or industries.<sup>165</sup> Finally, the decision maker needs information about the industrial organization and market structure of a particular industry and about noneconomic factors that may be important to the analysis.<sup>166</sup> In short, determining whether a given set of rules promotes or deters innovation requires an understanding of the relevant technology, the relevant economic principles, and the relevant industry.

With that information in hand, the decision maker can then engage in policy analysis. That analysis is expressly pragmatic in nature—it asks what policy is most likely to reach a desired normative outcome. The dominant paradigm of analysis for innovation policy—much like economic policy more broadly—is cost-benefit analysis.<sup>167</sup> In cost-benefit analyses, the policymaker determines the

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*Growth*, 8 J. ECON. PERSP. 3 (1994).

164. See *supra* notes 105-11 and accompanying text.

165. BURK & LEMLEY, *supra* note 1, at 38-41.

166. *Id.* at 41-42, 44-46.

167. See DAVID L. WEIMER & AIDAN R. VINING, POLICY ANALYSIS: CONCEPTS AND PRACTICE

likely costs or benefits of a particular government intervention, and compares that calculus with the alternatives. In the modern administrative state, cost-benefit analysis is a defining principle:

In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider.<sup>168</sup>

Finally, policy analysis necessarily entails a choice among competing options to best achieve a desired goal. This is especially so with respect to patent policy. Although there is broad agreement that patent law exists to foster innovation, agreement among experts ends there. The theoretical justifications for patent law are a subject of debate.<sup>169</sup> And economic analysis does not provide a perfect measure of the performance of individual policies in implementing those goals.<sup>170</sup> To take just one example, Michael Heller and Rebecca Eisenberg articulated in 1998 the possibility that patents on research tools in biotechnology were contributing to the formation of an “anticommons,” in which fragmented ownership of inputs prevented their use in downstream innovation.<sup>171</sup> It is disputed in the literature whether the anticommons model is correct as a matter of theory, and therefore whether it should guide patent policy in biotechnology.<sup>172</sup> It is also disputed as an empirical matter whether

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340-41 (4th ed. 2005).

168. Exec. Order No. 12,866, 3 C.F.R. 638, 639 (1993).

169. As Burk and Lemley note, competing theories of patent policy also operate on an industry-specific basis. See BURK & LEMLEY, *supra* note 1, at 66-78.

170. See, e.g., Frank H. Easterbrook, *Cyberspace and the Law of the Horse*, 1996 U. CHI. LEGAL F. 207, 209-10; Daniel A. Farber & Brett H. McDonnell, *Why (and How) Fairness Matters at the IP/Antitrust Interface*, 87 MINN. L. REV. 1817, 1838 (2003) (“[E]ven as basic a question as the optimal length of copyright or patent terms is incredibly hard to answer using an efficiency-based economic analysis.”).

171. See Heller & Eisenberg, *supra* note 114, at 698.

172. See, e.g., Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1061-62 (2008).

the phenomenon that Heller and Eisenberg posited actually occurs.<sup>173</sup>

In an ideal world, the efficacy of patent policy could be determined with certainty and used to guide legal and regulatory choices. But we do not live in such a perfect world. Ultimately, then, there must be a premium placed on the exercise of reasoned judgment with respect to patent policy, bringing the available economic tools to bear on informed decision making.

## 2. *Clarity and Predictability*

Patents can be thought of as a kind of property right, at least in some respects.<sup>174</sup> A patent grants its holder the right to exclude others from making, using, or selling her invention.<sup>175</sup> A significant body of legal and economic literature has explained that property rights function optimally when they are clear and stable.<sup>176</sup> When property rights are well-defined and easy to enforce, they can provide incentives for investment and a basis for efficient market exchange.<sup>177</sup> Conversely, when property rights are ill-defined, or the rules governing those property rights are insufficiently clear or secure, the system may not yield efficient results.<sup>178</sup> These insights apply to the patent system just as they do to real property. In order

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173. See *id.* at 1063-75 (reviewing empirical studies).

174. See BESSEN & MEURER, *supra* note 2, at 2, 29-34; Duffy, *supra* note 125, at 610; Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742, 1745 (2007). Of course, patents are not completely analogous to traditional rights in tangible property, such as land. See BESSEN & MEURER, *supra* note 2, at 33. And patents may be conceptualized other than as property rights. For a treatment of patents as public regulation, see, for example, Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After Eldred*, 19 BERKELEY TECH. L.J. 1315, 1317 (2004). There is no reason, moreover, that patents cannot be conceived of both in property and public regulation terms. After all, property rights in land are subject to significant regulation through modern land-use regimes. It also is worth noting that the importance of clarity in property rights does not diminish the case for clarity in regulation. Regulations, too, must be clear in order to be effective.

175. See 35 U.S.C. § 271 (2006).

176. See Duffy, *supra* note 125, at 610 n.1.

177. BESSEN & MEURER, *supra* note 2, at 34-35; see also Richard Epstein, *Property and Necessity*, 13 HARV. J.L. & PUB. POL'Y 2, 4 (1990); Carol Rose, *Crystals and Mud in Property Law*, 40 STAN. L. REV. 577, 577-78, (1988).

178. BESSEN & MEURER, *supra* note 2, at 38-39; Epstein, *supra* note 177, at 7; Rose, *supra* note 177, at 590.

for patents to succeed, the rules that govern their issuance and validity must be clear and predictable.<sup>179</sup>

As a practical matter, the need for secure property rights suggests two important characteristics that sound policymaking should embody. The first is prospectivity. That is, at the time the rules are set, they should be understood to operate prospectively without change through happenstance. Policy in this area should aim to shape expectations *ex ante*. Once reasonable expectations of the state of the law regarding patents are in place, inventors and entrepreneurs will make investment decisions in reliance upon those settled expectations. Of course, changes in policy are inevitable in light of ever-changing technological and economic conditions. But those changes ideally should not occur spontaneously. Instead, they should reflect considered responses to recognized changes in the relevant circumstances. Although there will always remain a role for *ex post* dispute settlement, setting *ex ante* expectations is critical to well-performing property systems.<sup>180</sup>

The second characteristic of sound policymaking is clarity. Although clear legal rules tend to promote stability and certainty, intellectual property policy puts a similar premium on flexibility.<sup>181</sup> That is because changes in technology and economics demand that the law adapt to different circumstances. As described above, the debate between rules and standards has particular salience in patent law.<sup>182</sup> Ultimately, the need to balance clear rules that promote investment with flexible standards that are adaptable to changing circumstances requires optimization. Sound patent policymaking, therefore, will attempt to optimize the specificity of the legal principle to provide adequate levels of both clarity and flexibility. I use the term “clarity,” therefore, not to refer to the choice between a rule and a standard, but rather to refer to the need to clearly articulate a legal principle regardless of its specificity or generality.

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179. Bessen and Meurer use the insight that property rights must be clear in order to be effective as the core of their critique of the patent system. *See* BESSEN & MEURER, *supra* note 2, at 46-47. Bessen and Meurer focus their argument on the scope of issued patents, contending that defects in the process of offering notice of valid patents lead to suboptimal follow-on innovation. *Id.* at 147. But their observation about the importance of predictability and clarity applies just as well to matters of patent policy.

180. *See supra* note 176 and accompanying text.

181. *See, e.g.,* Nard, *supra* note 11, at 55.

182. *See supra* notes 123-26 and accompanying text.

### 3. *Transparency and Accountability*

Most questions of patent policy are contested.<sup>183</sup> Policy analysis will not yield a single right answer to every disputed question. Instead, policy analysis requires the decision maker to understand competing viewpoints and make an informed decision—often an exercise of discretion—about which of those viewpoints is most likely to yield the best outcome. If the relevant decision maker is to resolve these disagreements, it must have access to all of the relevant arguments. The decision-making process must be broadly participatory.

This is particularly true with respect to patents. The most influential group of stakeholders in patent policy has traditionally been patent holders and their lawyers.<sup>184</sup> Perhaps unsurprisingly, those groups generally advocate for strong and broad patent rules that will result in the maximum benefit for patent holders.<sup>185</sup> Of course, maximal patent protection may not be the optimal policy in all circumstances. In setting patent policy, the decision maker must take into account the views of many different stakeholders. Those views will not be uniform even within the private sector. For years, for example, the pharmaceutical and information technology industries have taken opposing positions on critical questions of patent law that have been the subject of legislative debate.<sup>186</sup> Universities have played an expanded role in shaping innovation policy since the Bayh-Dole Act granted them the ability to patent inventions made through the use of government research grants.<sup>187</sup> Universities have

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183. Burk & Lemley, *Policy Levers*, *supra* note 105, at 1580 (noting disagreement).

184. See Morriss & Nard, *supra* note 70, at 4; see also Colleen V. Chien, *Patent Amicus Briefs: What the Courts' Friends Can Teach Us About the Patent System*, 1 U.C. IRVINE L. REV. (forthcoming 2011) (manuscript at 17), available at <http://ssrn.com/abstract=1608111> (noting that patent owners are the most frequent amicus participants in appellate patent proceedings).

185. See, e.g., Am. Intellectual Property Law Ass'n, *About AIPLA*, <http://www.aipla.org/about/who/Pages/AIPLA-Strategic-Plan.aspx> (last visited Mar. 14, 2011) (noting that a strong intellectual property system provides daily value and benefits).

186. See BURK & LEMLEY, *supra* note 1, at 101 (“The pharmaceutical and biotechnology industries opposed virtually all elements of patent reform directed at abuse.... On the other side, the software, electronics, Internet, and telecommunications industries generally lined up behind reform, but expressed skepticism toward those few reforms the pharmaceutical industry supported.”); Nard, *supra* note 11, at 52 & n.2.

187. See Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of*

become critical sources of innovation and key players in early-stage technology development.<sup>188</sup>

Finally, the non-patent-holding public at large has a significant interest in seeing that patent policy is made for the public good rather than for the private benefit of industrial, governmental, or academic actors in the system. A number of interest groups have sprung up in recent years to advocate for the public interest in intellectual property policy.<sup>189</sup> These groups approach the problem of innovation policy from a position different than that of industry. To take one example, the Public Patent Foundation “represents the public’s interests against undeserved patents and unsound patent policy.”<sup>190</sup> The diversity of views among competing interests is a positive for sound patent policymaking, and should be incorporated into patent policymaking.

### *B. Allocating Policy-Making Authority*

With an understanding of the characteristics of efficacious patent policymaking in place, the next question is whether courts or agencies are better positioned to make policy choices in a manner that reflects those characteristics. The answer depends on the comparative institutional competences of courts and agencies. One of the key insights from the literature on comparative institutional analysis is that no institutional arrangement will be perfect in all circumstances.<sup>191</sup> The following discussion, therefore, does not seek

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*Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290-91 (2003).

188. *Id.* at 291.

189. See, e.g., Pub. Patent Found., *About PUBPAT*, <http://www.pubpat.org/About.htm> (last visited Mar. 14, 2011) (“PUBPAT works to strengthen the patent system by introducing a healthy amount of non-patentee input to help the system achieve high quality and balanced policies.”); Public Knowledge, *Mission Statement*, <http://www.publicknowledge.org/about/what/mission> (last visited Mar. 14, 2011) (describing goal as “[e]nsuring that U.S. intellectual property law and policy reflect the ‘cultural bargain’ intended by the framers of the constitution: providing an incentive to creators and innovators while benefiting the public through the free flow of information and ideas”).

190. Pub. Patent Found., <http://www.pubpat.org> (last visited Mar. 14, 2011) (capitalization altered).

191. See NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY 5 (1994) (“The choice is always a choice among highly imperfect alternatives. The strengths and weaknesses of one institution versus another vary from one set of circumstances to another.”).

to construct an ideal institution. Instead, it expressly compares the potential benefits and drawbacks of patent policymaking through judicial adjudication and agency rulemaking.

The analysis below would be incomplete without briefly considering a third option: legislation. Like other commentators, I am skeptical of the efficacy of legislative tailoring of patent policy to suit the needs of particular industries or technologies.<sup>192</sup> The last several Congresses' inability to fashion a Patent Reform Act that could satisfy the needs of diverse industries is evidence of the difficulty of legislative change.<sup>193</sup> Although, as discussed below, administrative rules are subject to the problem of "ossification"; statutes are significantly less flexible than administrative rules.<sup>194</sup> Statutes can take years of legislative negotiation to enact. By the time proposed legislation passes both houses of Congress, technology often has moved on. The last two congressional attempts to create industry-specific patent legislation demonstrate this problem. Neither the Semiconductor Chip Protection Act<sup>195</sup> nor the biotechnology-specific amendments to the obviousness statute<sup>196</sup> have been invoked with any regularity to enforce the rights they purport to create. Both statutes were enacted after several years of legislative debate over the appropriate scope of intellectual property rights in their respective fields. By the time they were in place, they were of virtually no use.<sup>197</sup>

One further clarification is necessary: in the discussion that follows I contrast agency rulemaking with judicial adjudication. But agencies also have the power to make policy through adjudication.<sup>198</sup> I put the agency adjudication option largely to the side, for several

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192. See, e.g., BURK & LEMLEY, *supra* note 1, at 96-106; Nard, *supra* note 11, at 106-08; Rai, *supra* note 11, at 1127-31.

193. See Patent Reform Act of 2009, S. 515, 111th Cong. (2009); Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009); Patent Reform Act of 2008, S. 3600, 110th Cong. (2008); Patent Reform Act of 2007, S. 1145, 110th Cong. (2008) (as amended by Senate, Jan. 24, 2008); Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007) (as amended by House, Sept. 4, 2007); Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

194. See sources cited *infra* note 239.

195. See 17 U.S.C. §§ 901-914 (2006).

196. See 35 U.S.C. § 103(b).

197. See BURK & LEMLEY, *supra* note 1, at 98-99.

198. See, e.g., NLRB v. Bell Aerospace Co., 416 U.S. 267, 294 (1974) ("[T]he choice between rulemaking and adjudication lies in the first instance within the Board's discretion.").

reasons. First, agency adjudication and judicial adjudication share many of the same features and bugs. Measured against the criteria developed in Part II.A, agency adjudication is likely to be superior to judicial adjudication in marshalling relevant expertise, but the effectiveness of adjudication in achieving the remaining normative goals is likely to be the same regardless of the nature of the adjudicator. Second, agency adjudication has withered as a mechanism for making administrative policy in the face of sustained criticism from the courts and the academy.<sup>199</sup> The National Labor Relations Board, for example, is one of the few remaining agencies that makes policy largely through adjudication, and its process is roundly criticized as a failure.<sup>200</sup>

### *1. Reasoned Decision Making and Expertise*

Recall from the discussion in Part II.A.1 that sound patent policymaking depends on the ability of the decision maker to marshal relevant information, to analyze that information, and to make discretionary choices among policy options whose effects can be specified only imprecisely. On balance, agency rulemaking is more likely to reflect those characteristics than judicial adjudication.

Agencies are better able to access the full range of expertise required to make sound patent policy judgments. Agencies may be granted broad powers to conduct hearings, subpoena documents, and engage in fact-finding.<sup>201</sup> Rule-making procedures such as those found in the APA are expressly designed to facilitate the transmission of relevant information to the agency from any and all parties.

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199. See, e.g., 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 6.8 (5th ed. 2010); Katie R. Eyer, *Administrative Adjudication and the Rule of Law*, 60 ADMIN. L. REV. 647, 649-50 & nn.4-6 (2008).

200. See, e.g., Catherine L. Fisk & Deborah C. Malamud, *The NLRB in Administrative Law Exile: Problems with Its Structure and Function and Suggestions for Reform*, 58 DUKE L.J. 2013, 2016 & n.12 (2009).

201. The Federal Power Act, for example, grants the Federal Energy Regulatory Commission the authority to “investigate any facts, conditions, practices, or matters which it may find necessary or proper ... to aid in the enforcement of the provisions of this chapter or in prescribing rules or regulations thereunder.” 16 U.S.C. § 825f(a). The Commission also “is empowered to administer oaths and affirmations, subpoena witnesses, compel their attendance, take evidence, and require the production of any books, papers, correspondence, memoranda, contracts, agreements, or other records which the Commission finds relevant or material to the inquiry.” *Id.* § 825f(b).

Indeed, in rulemaking subject to the provisions of section 553 of the APA—which comprises most administrative rule-making proceedings—agencies are *required* to “give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity for oral presentation.”<sup>202</sup> The agency must then take those views into account in promulgating its regulations.<sup>203</sup> In the context of patent policy, these procedures would allow a properly empowered agency to collect technological and economic data that could inform sound policymaking.

Courts, by contrast, are largely confined to the record developed by the parties through the adversary process. Although parties in patent litigation can and do present expert witnesses to develop information for judges and juries to decide questions of validity and infringement, the evidence developed in the course of adjudicating a single patent or group of patents usually is too limited in scope to assist in broader policymaking. That evidence is also prone to bias in favor of whichever party presents it, resulting in an inevitable “battle of experts.”<sup>204</sup>

There are limited other mechanisms for courts to improve their access to information and expertise. For one thing, appellate courts may consider amicus curiae briefs from almost any interested party.<sup>205</sup> As Colleen Chien describes, the Federal Circuit in particular has made liberal use of amicus briefs in important patent cases.<sup>206</sup> In particular, the Federal Circuit typically invites amicus participation expressly in cases that it chooses to hear en banc, and will on occasion grant argument time to counsel for amici, an unusual practice among federal courts.<sup>207</sup> But this approach presents several problems. Even though amicus briefs may present

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202. See 5 U.S.C. § 553(c).

203. See, e.g., *City of Portland v. EPA*, 507 F.3d 706, 713 (D.C. Cir. 2007) (“The requirement that agency action not be arbitrary or capricious includes a requirement that the agency ... respond to ‘relevant’ and ‘significant’ public comments.” (quoting *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993))).

204. See Scott Brewer, *Scientific Expert Testimony and Intellectual Due Process*, 107 *YALE L.J.* 1535, 1616-25 (1998) (criticizing use of competing expert testimony to elucidate scientific facts); Rai, *supra* note 11, at 1099.

205. See SUP. CT. R. 37; FED. R. APP. P. 29.

206. See Chien, *supra* note 184, at 4-5.

207. See *id.* at 4 & n.15.

information that extends beyond the confines of the record or that may—particularly before the Supreme Court—suggest to the court some of the broader implications of a particular case, the actual decision is still confined to the questions of fact and law presented in the litigation.<sup>208</sup> In addition, a court does not have the power to order its *own* fact-finding, so it remains dependent on the happenstance of the right amicus submitting a brief that contains the right sort of information for making an informed policy choice. Finally, there remains the question of institutional capacity to analyze the information provided through amici.

Closely related to the problem of information gathering is the challenge of bringing the right expertise to analyze and understand that information. Sound patent policymaking requires analysis of complicated economic and technological data.<sup>209</sup> It requires decision makers who are trained not only in the relevant technological arts, but also in understanding the economic implications of various innovative policy decisions. Administrative agencies exist primarily for the purpose of bringing this kind of expertise to bear to solve policy problems within the statutory authority delegated by Congress.<sup>210</sup> Indeed, agencies in the New Deal and Progressive Eras were thought to bring needed expertise to government action.<sup>211</sup>

Some commentators dismiss the possibility that the PTO can play a significant role in patent policymaking on the ground that the Office as currently structured lacks the required expertise.<sup>212</sup> That is true so far as it goes. The PTO does not yet possess the relevant expertise—it has only recently filled a newly created chief economist position.<sup>213</sup> The PTO is set up primarily to perform the tasks of patent examination, which, as described above, are distinct from policymaking.<sup>214</sup> But it does not follow from these observations that

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208. See Joseph D. Kearney & Thomas W. Merrill, *The Influence of Amicus Curiae Briefs on the Supreme Court*, 148 U. PA. L. REV. 743, 775-79 (2000) (describing “legal model” of amicus participation, in which amicus briefs are useful legal inputs into standard judicial decision-making process).

209. See *supra* notes 163-66 and accompanying text.

210. See JAMES M. LANDIS, *THE ADMINISTRATIVE PROCESS* 23-24 (Greenwood Press 1974).

211. See *id.* at 21-22; Duffy, *supra* note 31, at 1091-94 (describing progressive administrative philosophy).

212. See *supra* notes 60-61 and accompanying text.

213. See Rai, *supra* note 60, at 2054-55.

214. See *supra* notes 39-45 and accompanying text.

*no* agency properly constituted could make patent policy successfully. In Part III.A, I discuss changes to the PTO's organizational structure and mission that could enable it to take on a fuller role in policy development.

It also is hard to conclude from the absence of economic expertise in the current PTO that the policy-making function should instead be located in the Federal Circuit or the district courts. In courts—even those courts that are well informed by robust amicus participation—the decision maker remains the judge rather than an expert trained in the relevant fields. Expertise is always external. This is so even with respect to specialized courts like the Federal Circuit. Part of the motivation for the creation of the Federal Circuit was to engage its judges frequently with patent law so that they could develop expertise in the law and its application.<sup>215</sup> And while it is true that many of the Federal Circuit judges have scientific backgrounds, they do not collectively have complete coverage of all relevant technologies.<sup>216</sup> Neither does a background in science necessarily prepare a judge for the economic analysis required for good policymaking.

Finally, agencies are expressly authorized to weigh costs and benefits—both quantitative and qualitative—and come to judgments about competing notions of what is likely to be good for society. That is, agencies are granted the authority to make discretionary judgments based on broad standards laid out in congressional statutes. For that very reason, their decisions are usually subject to judicial review only for arbitrariness or caprice.<sup>217</sup> The judicial review provisions of the APA are designed to allow the agency to choose between competing options; so long as the agency's decision is reasonable and supported, a court generally will not compel the choice of an equally plausible alternative. Courts are not in the habit of second-guessing the well-reasoned policy choices that agencies may make.<sup>218</sup>

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215. See Dreyfuss, *supra* note 48, at 74.

216. As Professor—now Federal Circuit Judge—Kimberly Moore has noted, “[i]t is a common misconception that all the Federal Circuit judges were first engineers or scientists.” Kimberly A. Moore, Markman *Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 245 (2005).

217. See 5 U.S.C. § 706(2)(A) (2006).

218. See, e.g., Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 40-44 (1983).

There is good reason for that hesitation: courts not only have difficulty gathering and processing economic and technological information, but they also are institutionally disinclined to make express policy judgments. The process of judicial decision making relies on arguments from statutory language, precedent, and logic. Every first-year law student learns the difference between arguments from precedent and “policy arguments.”<sup>219</sup> Courts usually eschew the latter. Indeed, courts are constrained by a variety of decision-making rubrics that operate to ensure that judges do not in fact simply exercise policy judgment. Reference to precedent, the use of legal formalisms, textual analysis of statutes, and the like are all mechanisms designed to rein in judges’ ability to act as policymakers. When judges do step outside these constraints to exercise policy judgment, they are criticized for doing so, sometimes harshly.<sup>220</sup> Norms of judicial decision making thus counsel against naked exercises of policymaking. In patent cases in particular, the Federal Circuit “rarely provides insight into the policy rationale for its own decisions. Indeed, some of the judges have publicly suggested that it would be wrong to explain—or even to be motivated by—policy.”<sup>221</sup>

This is not merely a rhetorical conceit that courts employ. Courts’ antipathy toward express policymaking is a serious intellectual handicap. In cases like those arising under ambiguous provisions of the Patent Act, the courts *do* in fact make policy. Their decisions interpreting and applying the statutory criteria are necessarily fraught with policy concerns, and constitute precedent on which reasonable parties will rely in ordering their primary behavior. Yet these policy decisions are not made honestly.<sup>222</sup> They are not made in the open. Rather than expressly weighing costs and benefits and explaining their reasoning in terms of public policy, courts frequently resort to legal formalism. That analytic move, in turn, can

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219. See Frederick Schauer, *A Critical Guide to Vehicles in the Park*, 83 N.Y.U. L. REV. 1109, 1112-15 (2008) (describing types of legal arguments).

220. See, e.g., Jack M. Balkin & Sanford Levinson, *Understanding the Constitutional Revolution*, 87 VA. L. REV. 1045 (2001).

221. Dreyfuss, *supra* note 61, at 803 & n.70.

222. Cf. David L. Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 HARV. L. REV. 921, 940 (1965) (arguing that rulemaking prevents decision makers from “hiding the ball” by making hard-to-discern rules through case-by-case adjudication).

lead to poor policy outcomes. Poor policy arising from legal formalism is especially commonplace in Federal Circuit patent cases. Several commentators have bemoaned the Federal Circuit's embrace of rule formalism.<sup>223</sup> Under that decision-making rubric, the Federal Circuit has adopted bright-line rules with respect to such policy-inflected judgments as what constitutes patentable subject matter and what evidence is probative of nonobviousness. As John Thomas has observed,

[t]he drive to formalism may ... distance the patent law from innovation policy. When deciding whether inventions from a particular sphere of endeavor should be patented, for example, the Federal Circuit does not query into that field's pace of innovation, need for interoperability, or industrial structure. The court merely asks whether the innovation is minimally useful.<sup>224</sup>

Burk and Lemley nevertheless argue that judges can be more sensitive to the "policy levers" built into the statute.<sup>225</sup> They defend their proposal against the criticism that it amounts to "judicial activism" on the ground that courts paying attention to patent policy are merely filling in the gaps in the patent statute that Congress left open.<sup>226</sup> The statute certainly does require gap-filling. But Burk and Lemley's defense of courts-as-gapfillers ignores the deeper criticism that express policymaking is somewhat antithetical to courts' usual way of doing business. The concern is not with judicial activism per se, but with a call for express policymaking by an institution that is temperamentally unsuited to the task. The distortions described in this Section make judicial reasoning less attractive as a means for determining patent policy than the expressly policy-based reasoning that an agency would be free to employ.

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223. See, e.g., Rai, *supra* note 11, at 1103-10; Thomas, *supra* note 125, at 774.

224. Thomas, *supra* note 125, at 774.

225. *Id.* at 107-08.

226. *Id.* See BURK & LEMLEY, *supra* note 1, at 109.

## 2. *Clarity and Predictability*

As described in Part II.A.2, certainty and clarity are particularly important in patent policy. Case-by-case adjudication, however, largely fails to produce clear and predictable policy.<sup>227</sup> This is true with respect to litigants' initial selection of issues, a court's initial resolution of those issues, and the judiciary's subsequent development of the law.

One problem with case-by-case adjudication is that any single case may not present the full range of issues or policy problems that ought to be decided together. Litigation is shaped not by the needs of public policy, but by the strategies and arguments of the parties to an individual case. This short-view approach means that lingering uncertainty might haunt patent rights in new technologies for a significant period of time after the technologies are developed. Take the example of gene patents.<sup>228</sup> By the mid-1980s, patents for human genetic material were proliferating and the biotechnology industry was taking off.<sup>229</sup> It should have been clear by that time that several critical issues regarding these patents needed to be resolved together, not the least of which was whether human genes constituted patentable subject matter at all. Yet the myriad issues surrounding gene patents were litigated piecemeal and are still being litigated today. The result is a decision like the court's in the BRCA gene patents litigation, which, by calling into question the validity of hundreds or thousands of issued patents, threatens significant disruption to the system of property rights that has emerged in biotechnology.<sup>230</sup>

A closely related problem arises in the selection of issues presented for litigation. Only a very small subset of issued patents are ever litigated. The set of issues that come before judges is, therefore, unlikely to be representative of the full range of policy problems

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227. Several commentators have made this observation. *See, e.g.*, PIERCE, *supra* note 199, at § 6.8; Richard K. Berg, *Re-examining Policy Procedures: The Choice Between Rulemaking and Adjudication*, 38 ADMIN. L. REV. 149, 163 (1986); Jim Rossi, *Redeeming Judicial Review: The Hard Look Doctrine and Federal Regulatory Efforts To Restructure the Electric Utility Industry*, 1994 WIS. L. REV. 763, 772; Shapiro, *supra* note 222, at 937-40.

228. *See supra* notes 13-20 and accompanying text.

229. *See* S.M. Thomas et al., *Ownership of the Human Genome*, 380 NATURE 387, 388 (1996).

230. *Ass'n for Molecular Pathology v. PTO*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

that confront the patent system.<sup>231</sup> Although a full evaluation of this problem is beyond the scope of this Article, it also is likely that the issues raised in litigation are systematically skewed. Litigated patents, for example, tend to have more claims than other patents, and tend to come disproportionately from certain industries—mechanical, computer, and medical devices rather than chemicals or semiconductors.<sup>232</sup> Because of this skew in the sample, courts making policy only through litigated patents inevitably will miss issues that arise less commonly among the set of litigated patents.

Rulemaking has the potential to mitigate these problems by allowing an agency to consider in a single proceeding all of the issues relevant to a particular policy challenge.<sup>233</sup> Rule-making proceedings that can address multiple issues at one time can bring some needed rationality to the policy-making process. An agency with rule-making authority can take public input and consider a range of issues respecting a class of patents, such as gene patents, at an earlier stage in their development, thereby contributing to more secure property rights.

Even when important policy issues are raised and resolved in litigation, the policy rule may be insufficiently clear for parties to build settled expectations. Policy certainly can be developed through the common law. The gradual accretion of precedent yields legal rules that can be articulated and defended.<sup>234</sup> But judicial precedents are fact-bound. Reasoning from those precedents turns primarily on analogies. Cases may be more or less distinguishable from one another. Patent cases in particular tend to be highly fact-specific. They involve challenges to the validity of a particular patent and often turn on quite specific comparisons, say, between the patent in issue and the relevant prior art. When policy is

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231. See John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 438 (2004).

232. See *id.*

233. See Rossi, *supra* note 227, at 772 (“Lawmaking by adjudication requires litigation before the agency in a series of highly fact-specific cases, whereas a single rule may settle policy questions across multiple case-specific scenarios.”).

234. In this analysis, I use the word “rules” broadly. Although the challenge described here intersects in part with the debate between rules and standards, see *supra* notes 123-25 and accompanying text, my point here is that regardless of whether a legal principle is articulated as a rule or a standard, it can be so articulated in either a prospective fashion, meant to be generally applicable, or through the decision in a particular case that purports to bind only the parties to that case.

articulated *wholly* through judicial precedent, there remains uncertainty in the process of discerning judicial rules, because a rule's applicability may depend on tenuous analogies across a long line of cases. One advantage of agency rulemaking is the ability to reduce that uncertainty by articulating the relevant rule or standard at a higher level of generality.<sup>235</sup> Agency rulemaking operates prospectively and it self-consciously seeks to articulate legal principles of general applicability. Judicial decisions by their terms bind only the parties in the case; rules or standards governing the conduct of nonparties are left to those parties' judgment about the interpretation and effect of precedent that has built up over the years.

I do not mean to overstate the case in either direction. Courts can and do articulate clear rules in the course of deciding cases. This is especially true of the Federal Circuit in patent cases. That court frequently uses the mechanism of rehearing en banc to clarify important disputed issues that have arisen through the workaday adjudication of patent cases.<sup>236</sup> Similarly, agency rulemaking often is far from pellucid. Administrative rules frequently require further elaboration by the agency or by the courts.<sup>237</sup> On balance, however, agency rules are likely to be more certain sources of policy guidance than judicial decisions.

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235. The APA defines a "rule" as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4) (2006). *See also* Rossi, *supra* note 227, at 770 ("Rules create law in the form of statements which are binding on those persons or entities to whom they are addressed, regardless of whether those persons or entities participated in the rule-making proceeding which generated the rule. Rules bind the agency in future cases.").

236. Most recently, for example, the Federal Circuit voted to rehear en banc the case of *Therasense, Inc. v. Becton, Dickinson and Co.*, which addressed the law of inequitable conduct. In its order granting rehearing, the court sua sponte defined six separate issues that it sought to resolve, some of which went beyond the scope of the initial briefing and decision in the case. *See* Order, *Therasense, Inc. v. Becton, Dickinson and Co.*, 374 Fed. App'x 35 (2010).

237. *See, e.g.*, *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000) ("The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in the regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities.").

Once a rule—or a standard—is in place, the relevant decision maker must be sufficiently flexible to change it when circumstances change. This flexibility is often seen as a significant advantage for courts. Courts have the ability to modulate their common law rules organically with changing circumstances.<sup>238</sup> If the next case presents a new fact pattern or issue, the relevant legal principle can be modified then and there. Agencies move much more slowly. Major rulemakings often take months or years to complete. Once in place, agency rules may be hard to change. A significant literature on the “ossification” of rulemaking suggests that rules may become more fixed than is optimal because the process of changing them is so cumbersome.<sup>239</sup>

Yet agencies do have one advantage over courts: when an agency seeks to change a previously promulgated rule, it must do so publicly.<sup>240</sup> That is, the very process that leads to ossification also ensures that rule changes are made with the same deliberation and participation as the promulgation of the initial rule itself. When a court changes the rules, on the other hand, the public is rarely on notice and generally is not given the opportunity to participate.

It is difficult to say for certain whether the net benefits of judicial flexibility are greater than the net benefits of administrative process with its attendant prospective notice of a policy change. This factor, therefore, may not favor one or another institution.

### 3. *Transparency and Accountability*

As described in Part II.A.3, sound patent policymaking requires the participation of multiple stakeholders. At the same time, policy-

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238. See Nard, *supra* note 11, at 56.

239. See, e.g., Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385 (1992); Richard J. Pierce, Jr., *Seven Ways To Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59 (1995). Duffy raises the opposite objection—“rulemaking powers give executive agencies the power to *change* the rules when political forces change.” Duffy, *supra* note 61, at 547 (emphasis in original). Although Duffy views the potential for such change as “anathema to stable property rights,” *id.* at 548, it is difficult to see how this objection applies more to agencies than to courts. Indeed, in related work, Duffy himself criticizes the courts for changing the rules governing the patentability of business methods no fewer than “three times in thirty years.” Duffy, *supra* note 125, at 612. The Supreme Court has now changed those rules yet again. See *Bilski v. Kappos*, 130 S. Ct. 3218, 3223 (2010).

240. See *supra* notes 202-03 and accompanying text.

making institutions must remain independent and committed to articulating policies that are in the public interest.

Agencies are generally much more open to participation than courts. Indeed, agencies have institutional mechanisms designed expressly to promote public participation. The notice-and-comment rule-making procedure is one such mechanism.<sup>241</sup> More and more, agencies are turning to technology to improve communication and interaction with entities that are interested in the outcomes of regulation.<sup>242</sup> Notwithstanding the Federal Circuit's aggressive solicitation of amicus briefs to inform its decision making,<sup>243</sup> federal courts simply are not institutionally designed to receive the range of viewpoints that is necessary for optimal patent policy.

Yet agencies have a particular drawback: they often are subject to "capture" by the entities they regulate.<sup>244</sup> Repeated interactions with the same body of law and the same group of regulated entities may result in two kinds of institutional pathology. In the first, often called "tunnel vision," the agency becomes institutionally aligned with the community it regulates simply through the ordinary day-to-day operation of regulations.<sup>245</sup> Regulators encountering the same set of issues in the same manner time after time lose the institutional ability to think creatively or to rethink settled rules.<sup>246</sup> The second is direct "capture" of the agency. "Agency capture" represents an application of basic principles of public choice theory. In this scenario, the regulated interests are concentrated and able to bring significant resources to bear to ensure that the policies the regulator enacts suit their interests.<sup>247</sup> Countervailing forces, meanwhile, tend to be diffuse and less able to exert significant influence.<sup>248</sup> The result

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241. See *supra* notes 202-03 and accompanying text.

242. See generally Beth Simone Noveck, *The Electronic Revolution in Rulemaking*, 53 EMORY L.J. 433, 438 (2004).

243. See *supra* notes 206-07 and accompanying text.

244. See, e.g., J.J. Laffont & J. Tirole, *The Politics of Government Decision Making: A Theory of Regulatory Capture*, 106 Q.J. ECON. 1089 (1991); M.E. Levine & J.L. Forrence, *Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis*, 6 J.L. ECON. & ORG. 167 (1990); G. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. 3 (1971).

245. See, e.g., Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669, 1685 (1975).

246. See, e.g., STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE* 11-19 (1993).

247. See Einer Elhauge, *Does Interest Group Theory Justify More Intrusive Judicial Review?*, 101 YALE L.J. 31, 32 (1991).

248. *Id.*

is that agency policy systemically tilts toward the interests of the regulated entities.<sup>249</sup> This dynamic may be reinforced by the movement of personnel between the regulator and the regulated, as often happens in industries that have concentrated interests before the government.

Several commentators have objected to the expansion of the PTO's authority on the ground that it will be—or already is—captured by patent holders.<sup>250</sup> As it is currently structured, the PTO interacts *only* with patent holders and patent applicants and their lawyers. This one-sided interaction gives rise to legitimate fears at least about tunnel vision.<sup>251</sup> More directly, the PTO's actions themselves suggest an orientation plainly in favor of patentees. The PTO has in the past referred to applicants as “customers,” revealing an institutional mindset that puts the needs of patent applicants first.<sup>252</sup> Although the PTO has stopped using that particular language, it quite clearly sees its mission as helping people to obtain patents rather than ensuring that patents are granted in the public interest.<sup>253</sup> As I describe in Part III.A, this attitude reflects primarily the *current* role of the PTO, and the addition of substantive rule-making authority would necessitate significant changes in the PTO's structure and function.

Nevertheless, the point remains that agencies are susceptible of capture. Two potential factors, however, weigh against dismissing agency rulemaking in the patent context solely because of concerns over agency capture. First, there is reason to believe that the problem of agency capture will be less pronounced with respect to a rule-making patent agency than with respect to other regulatory bodies such as the Federal Energy Regulatory Commission or the FCC. That is because the powerful interests in patent policy often fall on opposite sides of major questions.<sup>254</sup> With input coming from various

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249. *Id.* at 35-44 (explaining modern interest group theory).

250. *See, e.g.*, BURK & LEMLEY, *supra* note 1, at 106-07.

251. *See id.* at 107 (“The PTO by design sees only one piece of the patent puzzle—the question whether a patent should issue in the first place. It never sees infringement disputes, or licenses, or has to allocate remedies.”).

252. U.S. PATENT & TRADEMARK OFFICE, CORPORATE PLAN 23 (2001), *available at* <http://www.uspto.gov/web/offices/com/corpplan/index.htm>.

253. *See, e.g.*, PTO ANNUAL REPORT, *supra* note 39, at 8 (describing the PTO's mission as “high quality and timely examination of patent and trademark applications”).

254. *See supra* note 186 and accompanying text; *see also* Clarisa Long, *The PTO and the*

equally powerful interests, the likelihood of any single interest capturing the policy process is lower.<sup>255</sup> It remains true that capture is a possibility when the patent agency makes rules that will govern a single industry or technology. But there is no reason to think that the agency will be more or less susceptible to capture than any other agency. There exists a well-developed set of tools that can mitigate the threat of capture, including judicial review<sup>256</sup> and public participation.<sup>257</sup>

Second, recall that the institutional analysis here is *comparative* in nature. Agency capture represents a significant objection to rulemaking only if the judicial alternative is better. Judicial policy-making may in fact be subject to the same capture problems. The Federal Circuit is the exclusive venue for hearing appeals in patent cases.<sup>258</sup> That specialization has led some to suggest that the dynamics of industry capture common in agency settings applies equally well to the Federal Circuit.<sup>259</sup> Indeed, the Federal Circuit is in many ways the primary steward of substantive patent law. Its development of the law in recent years has, at times, been idiosyncratic, leading to a number of reversals in the Supreme Court.<sup>260</sup> At the very least, this is suggestive of the “tunnel vision” problem described above.<sup>261</sup>

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*Market for Influence in Patent Law*, 157 U. PA. L. REV. 1965, 1992-93 (2009).

255. See Rochelle Cooper Dreyfuss, *What the Federal Circuit Can Learn from the Supreme Court—and Vice Versa*, 59 AM. U. L. REV. 787, 791 (2010) (“People in the research and development business are both producers and users of technology. They do not want overly protective law for the cases where they are accused of infringing, and they do not want overly permissive law for the cases where they are the right holders.”); John M. Golden, *The Supreme Court as “Prime Percolator”: A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. REV. 657, 684-85 (2009) (describing heterogeneity of the patent bar and arguing that divergent interests make capture of the relevant decision maker less likely).

256. See, e.g., Thomas W. Merrill, *Capture Theory and the Courts: 1967-1983*, 72 CHI.-KENT L. REV. 1039, 1052 (1997).

257. See, e.g., Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1709 (1975). For a good discussion of these and other mechanisms by which agencies may avoid being captured, see generally Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Institutional Design*, 89 TEX. L. REV. 15 (2010).

258. See 28 U.S.C. §§ 1295(a)(1), 1295(a)(4)(A), 1333 (2006).

259. See, e.g., Rai, *supra* note 11, at 1111.

260. *Id.* at 1039.

261. See Long, *supra* note 254, at 1971 (describing “judicial self-aggrandizement” in which “[j]udges in specialized courts may come to identify a little too closely with the areas of law in which they specialize”); Rai, *supra* note 11, at 1110 (describing the basis for tunnel vision at the Federal Circuit); *supra* notes 244-46 and accompanying text.

More provocatively, the Federal Circuit may be subject to capture just as much as an agency.<sup>262</sup> It is well understood that courts and litigation processes are susceptible to the influence of interest groups.<sup>263</sup> This influence may be particularly pronounced when it is concentrated on a single court that bears outsized responsibility for the development of a single area of the law.<sup>264</sup> The practitioners who come before the Federal Circuit to argue patent cases are drawn almost exclusively from a patent bar that—regardless of whether a lawyer is representing a plaintiff or defendant in a particular case—benefits from strong and broad patent protection.<sup>265</sup> Some empirical work supports this conclusion: the Federal Circuit does in many ways appear to be a pro-patent court.<sup>266</sup> Although it is difficult to say for certain that the Federal Circuit has been captured by the patent bar, that possibility suggests at least that agency capture may not be as strong an argument in favor of judicial policymaking as one might think.

### C. Evaluation

The choice between agencies and courts ultimately turns on the nature of the decision to be made. As the patent system has increased in complexity, the set of policy choices confronting decision makers has come to look increasingly regulatory in nature.<sup>267</sup> In most other administrative systems in which the government is charged with providing benefits to applicants, the

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262. Rai, *supra* note 11, at 1110.

263. See Elhauge, *supra* note 247, at 67-68 (“[T]he same interest groups that have an organizational advantage in collecting resources to influence legislators and agencies generally also have an organizational advantage in collecting resources to influence the courts.”).

264. See Benjamin & Rai, *supra* note 163, at 17-18.

265. See Rai, *supra* note 11, at 1110 & n.340.

266. Empirical evidence has demonstrated that the Federal Circuit is significantly more likely to find patents valid and infringed than did the regional appellate courts prior to 1982. See ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 104-06 (2004). But the evidence of capture is mixed. Rai, for example, cites some evidence that the Federal Circuit is biased toward patent holders, but finds it ultimately inconclusive. See Rai, *supra* note 11, at 1110-14.

267. Cf. Ghosh, *supra* note 174 (discussing the applicability of theories of patent law and proposed reforms within a regulatory theory context).

rules that govern the award of those benefits are set by an agency charged with interpreting and implementing Congress's directives. Only the awards themselves are subject to case-by-case adjudication.<sup>268</sup>

That model increasingly makes sense for the patent system as well. Along each of the three relevant dimensions—reasoned decision making and expertise, clarity and predictability, and transparency and accountability—agencies offer significant advantages over courts. Agencies are better equipped to evaluate technological and economic data, to use that data in the service of cost-benefit analysis, and to choose among plausible alternative policies. Agency rules are likely to be more conducive to certainty and predictability in patent law. To be sure, there are some trade-offs: courts are likely to be more flexible and less susceptible to capture by organized interests. But neither of those concerns is significant enough to outweigh the benefits of rulemaking.

It is important to note, however, that while rulemaking would give an agency *primary* authority to make policy, it would not give an agency *exclusive* authority to do so.<sup>269</sup> The next Part explains how courts still have a role to play even if it is secondary to the agency. The courts' comparative advantage in flexibility and independence—to the extent it exists—can and should be brought to bear in the context of judicial review of agency rules and later gap-filling of regulations as necessary to resolve patent litigation. My proposal therefore is not meant to suggest that the courts should stay out of policymaking entirely. Instead, recognizing the benefits and limitations of courts and agencies as institutions, I seek only to allocate to each the optimal type of decision making.

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268. The Social Security Administration, for example, has long “rel[ied] on rulemaking to resolve certain classes of issues ... that do not require case-by-case consideration.” *Heckler v. Campbell*, 461 U.S. 458, 467 (1983). Those classes of issues decided by rulemaking are then applied in individual disability determinations, in which other, previously unresolved issues also are addressed. *Id.* at 467-68.

269. *See Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982-83 (2005).

### III. HOW RULEMAKING WILL CHANGE PATENT ADMINISTRATION

The introduction of an agency with substantive rule-making authority would represent a marked shift in authority over patent policy from the courts to an agency. Some commentators have therefore concluded that implementing rulemaking within the agency is practically or politically infeasible.<sup>270</sup> Neither is true. As a practical matter, it is true that significant changes to the PTO's capabilities, organization, and funding will be necessary. But none of those changes are unfamiliar in modern administrative governance. As a political matter, legislation granting the PTO substantive rule-making authority can hardly be considered beyond the pale when the agency itself has lobbied for such authority and Congress has considered it.<sup>271</sup> It is true that industry groups likely will be opposed to any substantial expansion of regulatory authority.<sup>272</sup> But public opposition is not uniform,<sup>273</sup> and legislation in the face of organized opposition is hardly uncommon.

This Part briefly considers some of the changes to the current institutional structure that would be required to accommodate a shift in authority from the courts to an agency.

#### A. *The PTO*

Throughout this Article, I have been careful to talk about a rule-making agency generally, rather than the PTO specifically. As it is currently structured, the PTO lacks both the capabilities and incentives to engage in sound policymaking.<sup>274</sup> More particularly, it lacks the personnel and infrastructure to make economic judgments

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270. See Benjamin & Rai, *supra* note 30, at 272.

271. See *supra* notes 62-63 and accompanying text.

272. As Clarisa Long points out, the amicus briefs in *Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009), in which the PTO argued before the Federal Circuit for an expansive interpretation of its grant of procedural rule-making authority, "ran thirteen-to-two against the PTO." See Long, *supra* note 254, at 1992 n.133. No industry group supported expanded rule-making authority. See *id.*

273. See Long, *supra* note 254, at 1992.

274. See, e.g., Dreyfuss, *supra* note 61, at 802; Rai, *supra* note 11, at 1132-33; Rai, *supra* note 60, at 2055.

concerning innovation policy.<sup>275</sup> If the PTO is to promulgate substantive rules, it must add a policy-making apparatus. That includes personnel dedicated to the policy-making function who possess the right kinds of skills and training in both technology and economics.

The policy-making function, moreover, must be organized and incentivized to produce sound rules and standards in the public interest. The current organizational structure of the patent examination function within the PTO is not likely to translate well to that additional task. Right now, for example, patent examiners have structural incentives to grant patents rather than deny them. These incentives arise in part from the PTO's system for evaluating examiner performance, in which examiners are rewarded for taking final action on applications,<sup>276</sup> and in part from the structure of the examination process, in which applicants can repeatedly avoid denials.<sup>277</sup> Put together, the easiest way for an examiner to secure a favorable evaluation is to grant many patents.

The PTO as a whole also faces an institutional incentive that favors patent grants over patent denials. This incentive arises from the funding and fee structure of the agency. The PTO is currently funded entirely through fees imposed on patent holders and patent applicants.<sup>278</sup> These fees fall into three categories: filing fees, which are paid upon the filing of a patent application; issuance fees, which are paid upon the grant and issuance of a patent; and maintenance fees, which patent holders pay to renew their patents.<sup>279</sup> The bulk of the PTO's revenue comes from issuance fees.<sup>280</sup> On the theory that bureaucratic entities seek to maximize their budgets (and, therefore, their flexibility),<sup>281</sup> examiners are likely to be favorably disposed toward granting rather than denying patents.

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275. See, e.g., Rai, *supra* note 11, at 1132-33.

276. See Abramowicz & Duffy, *supra* note 156, at 1549-50; see also Michael J. Meurer, *Patent Examination Priorities*, 51 WM. & MARY L. REV. 675, 699-700 (2009) (calling for reform of examiner incentives).

277. See *supra* notes 41-43 and accompanying text.

278. See Long, *supra* note 254, at 1984-85.

279. 35 U.S.C. § 41 (2006).

280. See Melissa F. Wasserman, *The PTO's Asymmetric Incentives: The Pressure To Expand Substantive Patent Law*, 72 OHIO ST. L.J. (forthcoming 2011) (manuscript at 26), available at <http://ssrn.com/abstract=1782988>.

281. See, e.g., WILLIAM A. NISKANEN, JR., BUREAUCRACY AND REPRESENTATIVE GOVERNMENT 38-41 (1971).

These factors raise a serious question whether the patent examination function and the patent policy-making function ought to be carried out by the same agency. As Michael Abramowicz and John Duffy note, “[p]lacing responsibility for both the regulatory function and the production function on the same officials creates a risk that the production task will influence the PTO in the conduct of its regulatory responsibilities.”<sup>282</sup> Nevertheless, there is likely to be significant value in keeping the two functions housed in the same agency. For one thing, patent policy cannot be carried out in the abstract. The issues deserving of policy attention will surface first through applications for patents, and the examiners will be the front line in dealing with novel questions of patentability. For another, there is significant expertise housed among the ranks of patent examiners; that expertise can be of great use in formulating patent policy.<sup>283</sup>

Setting aside for the moment the possibility of changes to the incentive or funding structure for examination, the ideal organization of the newly constituted PTO may be to keep the examination and policy-making functions housed within the same agency but with (a) separate budgets and personnel policies on one hand, and (b) clear channels of communication for policy development on the other.

### *B. The Courts*

The introduction of agency rules with the force of law will significantly change the role of the courts in making patent policy. *Chevron U.S.A., Inc. v. Natural Resources Defense Council* and its progeny hold that where Congress has delegated interpretive responsibility to an agency, the courts generally will not interfere in the agency’s exercise of that responsibility:<sup>284</sup> “If a statute is ambiguous, and if the implementing agency’s construction is reasonable, *Chevron* requires a federal court to accept the agency’s construction of the statute, even if the agency’s reading differs from what the

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282. Abramowicz & Duffy, *supra* note 156, at 1561-62.

283. See Wasserman, *supra* note 280 (manuscript at 34-36) (describing examiners’ roles in formulating substantive patent law).

284. 467 U.S. 837, 843-44 (1984).

court believes is the best statutory interpretation.”<sup>285</sup> That is because filling gaps left in statutory language “involves difficult policy choices that agencies are better equipped to make than courts.”<sup>286</sup> Patent policy choices fundamentally rest on interpretations of the Patent Act that—if made by an agency with substantive rule-making authority—would qualify for *Chevron* deference.<sup>287</sup> Similarly, agency rules that implement the statute but do not raise significant interpretive dilemmas would be subject to deferential review under the APA’s “arbitrary and capricious” standard.<sup>288</sup>

Granting the PTO substantive rule-making authority would therefore mark a profound shift in authority over patent law. It would not, however, totally preclude a role for the courts. Although the PTO would have primary responsibility for making patent policy, the courts would continue to play an important role in shaping patent law in at least two ways: First, courts would review and interpret the fruits of the PTO’s rulemaking. Second, courts would step in to fill the gaps of that rulemaking in the course of deciding validity disputes.

### *1. Judicial Review of Agency Rulemaking*

Unless Congress chooses otherwise, an agency’s actions are subject to judicial review under the APA.<sup>289</sup> Many agencies’ rules are reviewable upon petition for review in the courts of appeals.<sup>290</sup> It likely makes sense for the PTO’s new rules to be similarly reviewable; the rule-making function contemplated here is primarily legal, and review of the PTO’s rules would not require the development of a factual record in the district court. One interesting question that arises is whether this review should take place in the Federal Circuit or elsewhere. The rationale for the creation of the Federal Circuit was largely to achieve a measure of national uniformity that

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285. *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005) (citing *Chevron*, 467 U.S. at 843-44, 843 n.11).

286. *Id.*

287. *See United States v. Mead Corp.*, 533 U.S. 218, 230-31 (2001) (holding that interpretations promulgated through notice-and-comment rulemaking presumptively qualify for deference).

288. *See* 5 U.S.C. § 706(2)(A) (2006).

289. *Id.* § 704; *Dickinson v. Zurko*, 527 U.S. 150, 152 (1999).

290. 28 U.S.C. § 2342.

had been lacking in the patent system when different regional circuits took different views of patent doctrine.<sup>291</sup> The need for uniformity in judicial decision making is less pronounced when courts are reviewing agency rules. Although substantive patent law certainly plays a role in such review, courts' discretion is cabined by the doctrines of administrative law.<sup>292</sup> Moreover, whereas the application of administrative law principles varies slightly from circuit to circuit, the differences are not so pronounced as to have prompted the kinds of uniformity concerns that drove the creation of the Federal Circuit.<sup>293</sup>

More broadly, it is worth noting that an agency with rule-making authority would achieve a similar—if not greater—degree of uniformity in patent law by promulgating rules that are binding nationwide than the Federal Circuit can in the existing arrangement. The addition of rulemaking therefore calls into question the rationale for maintaining a centralized and specialized court of patent appeals.<sup>294</sup>

## 2. *Litigation over Patent Validity or Application Denials*

The courts would continue to play an important role in interpreting patent law in the course of validity litigation, but that role would be more limited than it is today. In some cases, for example, litigants may raise arguments that are addressed directly by a PTO rule. In these cases, the court would apply the rule without further interpretation. Review of many agencies' rules is governed in part by the Hobbs Act, which provides that a petition for review filed in a federal court of appeals is the exclusive mechanism for judicial review.<sup>295</sup> This statute has been interpreted to preclude collateral challenges to validly promulgated rules in subsequent litigation.<sup>296</sup> This arrangement has the benefit of allowing for judicial review of a rule, and then holding that rule to be settled law immune from

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291. See *supra* note 48 and accompanying text.

292. But see Nard & Duffy, *supra* note 48, at 1666.

293. See *id.* at 1669.

294. Cf. *id.* at 1620, 1625 (arguing that optimal uniformity may involve appellate review by more than one court).

295. 28 U.S.C. § 2342.

296. See, e.g., *U.S. W. Commc'ns, Inc. v. Jennings*, 304 F.3d 950, 958 n.2 (9th Cir. 2002); *GTE South, Inc. v. Morrison*, 199 F.3d 733, 743 (4th Cir. 1999).

further challenge once it is upheld. Application of the Hobbs Act to patent rulemaking would provide needed stability and uniformity in patent law.

The addition of settled agency rules to validity proceedings has implications for a long-running debate in patent scholarship over the statutory presumption of validity. Under current law, issued patents are presumed valid.<sup>297</sup> Some scholars have questioned whether this presumption is warranted, or have proposed modifications to the presumption of validity based on the extent of the examination to which patents are subjected.<sup>298</sup> The addition of agency rules would likely strengthen the presumption of validity for those patents issued pursuant to such rules. This is because the underlying principles of patentability have already been vetted by the agency and, potentially, by a court on direct review. There is little reason to second guess the issuance, or denial, of a patent pursuant to these rules.

In other cases, a party might raise challenges to the validity of a patent that implicate an ambiguity of the agency's rule or that fall outside the scope of the rule altogether. In those cases, the courts will shape patent policy in the interstices of the agency's rules: it will be for the courts to decide in the first instance what the appropriate legal principle ought to be. Note, however, that under the Supreme Court's decision in *Brand X*, agencies with interpretive authority over the statutes they administer retain the authority to make binding legal determinations about the meaning of ambiguous terms, even in the face of contrary judicial precedent.<sup>299</sup>

This structure is likely to result in productive exchange between the courts and the PTO. Novel issues of patentability will inevitably surface first in litigation. Courts can utilize their comparative

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297. See 35 U.S.C. § 282.

298. See, e.g., Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45 (2007).

299. See *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982-83 (2005) ("A court's prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion.... Only a judicial precedent holding that the statute unambiguously forecloses the agency's interpretation, and therefore contains no gap for the agency to fill, displaces a conflicting agency construction."); *id.* at 983 ("[W]hether Congress has delegated to an agency the authority to interpret a statute does not depend on the order in which the judicial and administrative constructions occur.").

advantage in deciding these issues on a case-specific basis. When an issue has become sufficiently important or has percolated in the courts for sufficiently long, the agency can step in and rationalize the legal principle through rulemaking. That rule in turn will be subject to further review and interpretation again in the courts. In this fashion, courts and agencies will engage in something of a dialog with respect to novel issues of patentability.

### CONCLUSION

The institutional structure of the patent system has been with us for over 170 years. It has outlived its usefulness. In a world of sharply differentiated technology and an extremely high volume of patent activity, judicial development of the “policy levers” that modulate the standards of patentability will not produce optimal outcomes. Instead, this Article has made the case for granting the PTO substantive rule-making authority. As should be clear, agencies are far from perfect. But the likely gains that would result from bringing the patent system in line with the modern administrative state are significant. Given the importance of innovation to economic growth and cultural well-being, it is critical that the institutions responsible for making innovation policy decisions be rationalized. Granting the PTO substantive rule-making authority is a good first step.