

# ARTICLES

## Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law

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INTRODUCTION . . . . .	270
I. USING VALIDITY TO IMPLEMENT THE GOALS OF PATENT LAW . . . . .	274
A. THE GOALS OF PATENT LAW . . . . .	274
B. THE INQUIRY INTO PATENT VALIDITY . . . . .	276
II. THE PTO AND ADMINISTRATIVE LAW DOCTRINE . . . . .	279
A. PATENT LAW AND THE APA: GENERAL CONSIDERATIONS . . . . .	280
B. APPLYING ADMINISTRATIVE LAW DOCTRINE TO PTO ACTIONS . . . . .	284
1. Factual Determinations . . . . .	285
2. Legal Determinations . . . . .	293
3. Policy Decisions and Exercises of Discretion . . . . .	301
III. COMPARATIVE INSTITUTIONAL ANALYSIS AND JUDICIAL REVIEW . . . . .	308
A. JUDICIAL REVIEW GENERALLY . . . . .	309
B. JUDICIAL REVIEW IN THE EXISTING PATENT SYSTEM . . . . .	313
IV. BRINGING ADMINISTRATIVE LAW DOCTRINE AND NORMATIVELY ATTRACTIVE STANDARDS TOGETHER . . . . .	317
A. STATUTORY OR JUDICIAL ALTERATION OF THE STANDARDS OF REVIEW . . . . .	317
B. COMBINING NEW PROCEDURES WITH EXISTING ADMINISTRATIVE LAW PRINCIPLES . . . . .	320

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1. Post-Grant Review and Deference . . . . .	320
<i>a. Cost-Effective Post-Grant Review</i> . . . . .	320
<i>b. Improving Post-Grant Review Through Deference</i> . . . . .	326
2. Selecting Into Rigorous Examination . . . . .	328
C. ARE CHANGES TO THE STANDARDS OF REVIEW WORTH THE TROUBLE? . . . . .	330
CONCLUSION . . . . .	335

### INTRODUCTION

In the last few years, widespread dissatisfaction with the patent system—and particularly with the perceived poor quality of issued patents—has spurred a broad range of groups to call for reform. Congress is currently looking into the possibility of significant reform.<sup>1</sup> One important reform proposal upon which otherwise divergent groups broadly agree is fortification of administrative procedures, particularly through the institution within the Patent and Trademark Office (PTO) of a trial-type system of post-grant opposition.<sup>2</sup>

The emphasis on fortifying administrative procedures through new legislation is in accord with the Supreme Court's interest, demonstrated through its 1999 *Dickinson v. Zurko* decision,<sup>3</sup> in applying administrative law to the patent system. Indeed, the inattention to administrative law principles has long been a striking feature of the patent system. In contrast to commentators and practitioners in other technically complex areas (for example, environmental law, telecommunications law, and food and drug law), the patent law community has tended to pay little attention to administrative law.<sup>4</sup> In part, this has been because, until

1. See generally Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

2. Three entities that have endorsed post-grant review are the Federal Trade Commission (FTC), the National Academy of Sciences (NAS), and the American Intellectual Property Law Association. See FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 5, at 23–24 (2003) [hereinafter FTC REPORT]; STEPHEN A. MERRILL ET AL., NAT'L ACAD. OF SCIS., A PATENT SYSTEM FOR THE 21ST CENTURY (2004) [hereinafter NAS PROPOSAL]; AM. INTELLECTUAL PROP. LAW ASS'N, AIPLA RESPONSE TO THE NATIONAL ACADEMIES REPORT ENTITLED "A PATENT SYSTEM FOR THE 21ST CENTURY" 2 (2004), [http://www.aipla.org/Content/ContentGroups/Issues\\_and\\_Advocacy/Comments2/Patent\\_and\\_Trademark\\_Office/2004/NAS092304.pdf](http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Comments2/Patent_and_Trademark_Office/2004/NAS092304.pdf). That three entities with such different constituencies and roles would agree on the need for post-grant review is striking.

3. See 527 U.S. 150, 152 (1999) (concluding that Administrative Procedure Act standards for reviewing administrative findings of fact apply to findings made by the PTO).

4. Exceptions include one of the current authors in some of her prior work. See Arti K. Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL'Y 199, 221–26 (2000) [hereinafter Rai, *Addressing the Patent Gold Rush*]; Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1052–56 (2003) [hereinafter Rai, *Engaging Facts and Policy*]; see also John F. Duffy, *On Improving the Legal Process of Claim Interpretation: Administrative Alternatives*, 2 WASH. U. J.L. & POL'Y 109, 125–35 (2000); Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415,

1999, the primary expositor of patent law and policy, the Court of Appeals for the Federal Circuit (which hears all appeals in patent cases),<sup>5</sup> denied that the Administrative Procedure Act even applied to its review of the PTO.<sup>6</sup> Additionally, unlike such prominent agencies as the Environmental Protection Agency and the Federal Communications Commission, the PTO does not have any significant authority to issue substantive rules, and it does not typically render legal interpretations of the patent statute to which courts must give *Chevron* deference.<sup>7</sup>

Although administrative law thinking is now beginning to permeate the patent community, incorporation of such thinking is far from complete.<sup>8</sup> Some judges on the Federal Circuit have been resistant to the Supreme Court's command in *Zurko*. Perhaps the most striking example of the failure to consider administrative law is the prevailing position that post-grant opposition proceedings should be governed by rules of judicial review borrowed from civil procedure.<sup>9</sup> Indeed, of the major reform proposals, only the FTC's analysis takes administrative law seriously.<sup>10</sup> This is unfortunate, because an approach to post-grant opposition grounded in rules of civil procedure will suffer from the same collective action and public good problems that arise in trial court patent challenges and is therefore unlikely to achieve significant efficiency benefits.<sup>11</sup>

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1430–39 (1995). None of these prior articles, however, offers a theory of how administrative law should apply to the patent system in light of current proposals for reform. For a discussion that begins to offer such a theory, see Arti K. Rai, *Allocating Power Over Fact-Finding in the Patent System*, 19 BERKELEY TECH. L.J. 907 (2004).

5. The Court of Appeals for the Federal Circuit was established in 1982 to hear all appeals in patent cases. U.S. Court of Appeals for the Federal Circuit, About the Court, <http://www.fedcir.gov/about.html> (last visited Sept. 12, 2006).

6. The significance of 1999 is that the Supreme Court decided *Zurko* that year. In this decision, the Court explicitly rejected the “pre-APA standard of review.” *Zurko*, 527 U.S. at 155.

7. See *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984); see also *United States v. Mead Corp.*, 533 U.S. 218, 226–30 (2001) (indicating that deference to legal interpretations under *Chevron* is most often merited when an agency acts pursuant to a congressional grant of substantive rulemaking authority or pursuant to a congressional grant of authority to conduct formal adjudications); *infra* notes 150–53 and accompanying text.

8. In some respects, the administrative law gap in patent law has parallels in antitrust law. In that field, although Congress has given the FTC power to use both formal adjudication and substantive rulemaking to render legal interpretations under the FTC Act, courts have sometimes been resistant to invoke *Chevron* deference. See Daniel A. Farber & Brett H. McDonnell, “*Is There a Text in this Class?*” *The Conflict Between Textualism and Antitrust*, 14 J. CONTEMP. LEGAL ISSUES 619, 656 (2005) (noting that “[c]ourts have only occasionally engaged in *Chevron* deference in the antitrust context”). Some of the formal and functional problems raised by the failure to take administrative law seriously in the case of the FTC Act are addressed by Farber and McDonnell, *supra*, at 644–57 (“Antitrust raises tough, technical problems which require a sophisticated understanding of economics and business practices in order [for decisionmakers] to be able to make sound policy . . . . Agencies are much more likely to possess the required expertise than courts.”).

9. See *infra* notes 284–87 and accompanying text (discussing use of estoppel-type provisions in most reform proposals).

10. As we discuss further below, the FTC REPORT, *supra* note 2, argues that the results of post-grant review by the PTO should be given *Chevron* deference by the Federal Circuit. See *infra* note 297 and accompanying text.

11. See *infra* notes 267–87 and accompanying text.

In this Article, we go beyond the preliminary discussions contained in cases like *Zurko* and in the FTC report to provide a comprehensive account of the intersection of patent law and administrative law.<sup>12</sup> Such an account could proceed from first principles—for example, designing an ideal agency and ideal agency procedures from scratch, and then creating the desired judicial review by generalist appellate courts.<sup>13</sup> There is considerable value in accounts that design ideal institutions. But for better or worse, a new start from the ground up—whether in patent law or administrative procedure—is exceedingly unlikely. By contrast, an approach that assumed no changes whatsoever to the status quo might miss opportunities for improvement. In this Article, we adopt an intermediate position, looking at what theory and doctrine would suggest for the relationship between the judiciary and the PTO, and the ways in which realistic changes to the existing process might be attractive in light of that theory and doctrine. The result is a second-best solution—but one that is considerably more desirable than the status quo.

For the most part, judicial review based on ordinary administrative law doctrine, coupled with modest changes to existing PTO procedures, provides a result that is both politically possible and normatively desirable. Fortified administrative procedures could include not only post-grant opposition proceedings available throughout the life of the patent but also the possibility of self-selection into a more rigorous patent examination. Judicial review of these proceedings based largely on standard administrative law principles would create incentives for patents that are likely to be commercially significant to be channeled into the proceedings and would thus provide reasonably accurate, cost-effective determinations of patent validity. Additionally, proper application of administrative law principles would provide an institutional foundation for

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12. Such an account necessarily focuses on patent validity rather than issues (such as defenses to infringement, nuances of patent claim construction, and remedies) that are more specific to the enforcement of patents by trial courts in particular cases.

13. Cf. Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle* 5–6 (Case W. Reserve Univ. Sch. of Law, Working Paper No. 06-17, George Washington Univ. Law Sch., Research Paper No. 225, Sept. 5, 2006), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=928498](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=928498) (proposing a system under which multiple appellate courts would be responsible for reviewing patent cases). Under such an ideal system, a specialized trial court might also be desirable. See Arti K. Rai, *Specialized Trial Courts: Concentrating Expertise on Fact*, 17 BERKELEY TECH. L.J. 877 (2002). There has been some receptivity in Congress toward enhancing expertise at the trial level. See H.R. 5418, 109th Cong. (2006) (bill introduced by Representative Issa “[t]o establish a pilot program in certain United States district courts to encourage enhancement of expertise in patent cases among district judges”). Notably, the patent systems of most European countries, including the U.K. and Germany, as well as Asian countries like Japan, have specialization at the trial level. See James F. Holderman, *Judicial Patent Specialization: A View from the Trial Bench*, 2002 U. ILL. J.L. TECH. & POL’Y 425, 427–28. Another possible approach to an ideal system might involve bolstering the PTO’s economic expertise and giving it broad substantive rulemaking authority. Under such an approach, the PTO would receive *Chevron* deference for legal interpretations made during rulemaking. See *supra* note 7. However, given the tendency of rulemaking to be particularly subject to interest group pressures, see *infra* note 234 and accompanying text, the attractiveness of substantive rulemaking authority is unclear.

the determinations of economic policy that the patent system should be making, including economic policy determinations regarding how patent principles should apply with respect to different types of technological information.<sup>14</sup> In circumstances where rigorous administrative proceedings are in place, the result would be significantly greater deference than the Federal Circuit currently gives.

One might endorse an administrative approach in theory but wonder whether changes in standards of review actually produce observable differences in judicial behavior. In the area of administrative law, the available empirical evidence suggests that such changes can make a difference. Moreover, our own empirical analysis of ten years of cases decided by the Federal Circuit before and after the Supreme Court decision in *Dickinson v. Zurko* indicates that the case law has had an impact on judicial behavior.<sup>15</sup>

Incorporation of administrative law principles into patent law has a larger significance as well. In some situations, it may be tempting for judges and practitioners to announce that a particular area of law is *sui generis*, such that ordinary rules do not apply to it. Treating a particular area of law as an

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14. Note this is a more fine-grained position than the assertion that patents play different roles in different industries. See, e.g., Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577–78 (2003) (“[T]here is no reason to assume that a unitary patent system will optimally encourage innovation in the wide range of diverse industries that it is expected to cover.”); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 23–24 (Nat’l Bureau of Econ. Research, Working Paper No. 7552, 2000). Although one can make generalizations about industries, such generalizations are necessarily “rule-like”—that is, they are likely to be over-inclusive and under-inclusive. For example, Burk and Lemley, who tend to argue in favor of industry-specific policy, note that, even within industries, information can play different roles. See Burk & Lemley, *supra*, at 1624–26 (observing that, within the biotechnology industry, patents on DNA sequence information that can be used as a therapy operate very differently from patents on other types of DNA sequence information). At the same time, such generalizations do not necessarily have the easy applicability of rules. See *id.* at 1635 (noting that “boundaries between industries are vague and notoriously mutable”). For these reasons, at least in the context of validity determinations, we would generally prefer policy approaches that apply at the level of invention rather than industry. Cf. *id.* at 1641 (distinguishing “macro”-level policy levers, which operate at an industry level, from “micro”-level policy levers, which operate at the level of invention). Notably, many of the validity standards in the patent statute, such as the requirement that the applicant has made an advance that would be “nonobvious” to the “person having ordinary skill in the art,” seek to advance economic goals by operating—at least when implemented appropriately—primarily at the level of invention. See *id.* at 1648–49 (explaining that the “nonobviousness criterion” was originally understood as a “requirement that the claimed invention . . . not be obvious to one of ordinary skill in the art at the time the invention was made”). Indeed, one of the problems with much of the Federal Circuit’s jurisprudence, particularly in the biopharmaceutical arena, is that it has tended to paint with a broad brush—assuming, for example, that all invention in the biopharmaceutical area is inherently uncertain and therefore nonobvious. The better-reasoned cases, by contrast, look at the particular invention at issue. See, e.g., *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) (upholding a broad claim on the grounds that cell manipulation techniques are understood).

From an economic policy standpoint, one particularly useful distinction at the level of invention would be the distinction between infrastructural invention and more downstream activities. See Brett Frischmann, *An Economic Theory of Infrastructure and Commons Management*, 89 MINN. L. REV. 917, 929 (2005). For a discussion of how this distinction could be taken into account from a policy standpoint, see *infra* notes 194–206 and accompanying text.

15. See *infra* notes 319–22 and accompanying text.

exception to a broader regime allows judges and practitioners to take into account specific features of that area in fashioning rules. For example, patents may be different from some other regulatory regimes to the extent that the patent system predates the New Deal era during which the administrative state fully came into existence.<sup>16</sup> Or one might argue that patents are different because Congress chose to create a specialized appellate court to address patents. But *sui generis* approaches are notorious for opening the door to undue influence by groups whose interests focus on that area of law. Moreover, isolating patents from mainstream administrative law ignores the many commonalities between the PTO and other agencies. Patents are special, as are telecommunications, wetlands development, agriculture, and virtually every other regulated activity. But their regulation at the federal level entails similarities across agencies. Courts and practitioners that ignore those similarities may achieve private gain (in the form of benefits that flow from their specialized knowledge and access), but the costs and foregone benefits for the public can be considerable.

Part I introduces the goals of patent law and the manner in which determinations of patentability by the PTO seek to implement those goals. Part II considers how existing administrative law doctrine (that is, administrative law principles applied to other agencies) would apply to judicial review of PTO patent decisions. As this Part discusses, the Federal Circuit has resisted the application of ordinary administrative law doctrine to its review of the PTO. Part III turns to normative considerations, addressing what form of judicial (and particularly Federal Circuit) review of PTO patent decisions would be attractive. The choice between the PTO and the Federal Circuit is a comparative one, and we consider the strengths and weaknesses of each. Part IV addresses the degree to which application of existing administrative law doctrine would advance those normative considerations. It argues that, in the main, such application would in fact be normatively desirable, not only for existing PTO procedures but also for proposed new ones. Moreover, the empirical evidence suggests that changes in review standards could have some impact on Federal Circuit behavior.

## I. USING VALIDITY TO IMPLEMENT THE GOALS OF PATENT LAW

In this Section, we present a brief summary of the major normative goals of patent law. We then discuss the manner in which the inquiry into patent validity fosters these goals.

### A. THE GOALS OF PATENT LAW

On the conventional account, the major normative goal of patent law is

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16. 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, 1124–39 (2000) (discussing the early history of patent law).

fostering innovation—both initial invention and the commercialization of such invention. Although the importance of invention relative to commercialization continues to be hotly debated,<sup>17</sup> most patent scholars would agree that patents can, and should, be used in some measure to promote both invention and commercialization.<sup>18</sup> In recent years, scholars have also contended that patents play roles not directly connected with appropriation of profits from innovation. For example, they assist small firms in attracting venture capital by providing a signal that a firm has knowledge capital or is well-managed.<sup>19</sup> And they are used to form patent portfolios that are in turn used for a variety of different

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17. Generally speaking, those scholars who view patents as a species of property right emphasize the ways in which early and certain patent grants can promote efficient commercialization. See F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697 (2001); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 275–77 (1977) (presenting the commercial benefits of the patent system compared to the less attractive system of trade secrecy). Kitch's position, which analogizes early stage patent claims to mining claims in the American West, is sometimes called "prospect theory." Cf. John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 443–44 (2004) (asserting a defense of prospect theory that focuses not on patents as property rights but on the ways in which prospect theory may channel rent-dissipating patent races in the direction of patents that are granted early and hence expire early). Scholars who view patent rights as distinct, at least in part, from ordinary property emphasize that the information contained in inventions is a nonexclusive and nonrivalrous public good. See Mark Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1035 & n.8 (2005) (collecting articles by scholars who regard patent rights as different from ordinary property). These scholars contend that patents should generally be granted only to the extent necessary to generate the good; allowing additional patenting beyond this level is likely to increase deadweight loss, hinder further use and improvement, and promote rent-dissipating patent races. See *id.* at 1058–65.

At a high level of abstraction, debates regarding whether patents are or are not like property may be intractable, partly because of the well-known malleability of terms like property (and for that matter, the public domain and the commons). See James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33, 67–68 (2003) (discussing a "Legal Realism for the Public Domain" based on the reality that property has a similar messy history); Michael A. Carrier, *Cabining Intellectual Property Through a Property Paradigm*, 54 DUKE L.J. 1, 1 (2004) (discussing the many ways in which property law "is not as absolute as it is often claimed"); Carol M. Rose, *Canons of Property Talk, or, Blackstone's Anxiety*, 108 YALE L.J. 601, 603 (1998) (noting that "Blackstone himself was thoroughly aware of . . . pervasive and serious qualifications on exclusive dominion"). Another reason is because patents play different roles with respect to different types of information. See *infra* notes 18–26 and accompanying text.

18. Ashish Arora and Robert Merges have argued that patents promote technology markets. See Ashish Arora & Robert Merges, *Specialized Supply Firms, Property Rights, and Firm Boundaries*, 13 INDUS. & CORP. CHANGE 451 (2004). We view this argument as related to the appropriation of innovation rents story. Indeed, on this argument, patents are particularly valuable precisely because they allow innovation rents to be appropriated in markets rather than solely in vertically integrated firms. Whether the boundaries of patentable subject matter (and other patent law doctrines) have improperly been extended to include not only inventive technology but also inventive ideas with poorly defined boundaries is a question we do not take up here. For an interesting discussion, see Oren Bar-Gill & Gideon Parchomovsky, *A Marketplace for Ideas?*, 84 TEX. L. REV. 395, 396–97 (2005) (noting that "patent law is gradually extending its reach to cover . . . even naked ideas").

19. Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 653 (2002); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 141–43 (2000) (describing a "strong positive relationship between venture capital financing and patenting").

purposes—defensive and offensive.<sup>20</sup> Assuming these accounts’ descriptive accuracy,<sup>21</sup> we do not believe that they offer independent normative goals for patent law. Indeed, those who have discussed patent portfolios generally do not see the rise of such portfolios as a normatively attractive development.<sup>22</sup> But some commentators who argue in favor of an independent signaling function for patents appear to be more sanguine.<sup>23</sup> To the extent that these commentators are arguing for altered validity standards, we disagree. As an initial matter, patents are likely to be accurate signals of knowledge capital and good management only if they cover technologies that are either inventive or need patent protection for development.<sup>24</sup> Moreover, even if certain information outside these contexts occasionally demonstrates knowledge capital, any benefit that might accrue from altering patentability standards to allow patents on such information is outweighed by the costs that such patents would impose. In this Article, therefore, we focus on the goals of invention and commercialization.

#### B. THE INQUIRY INTO PATENT VALIDITY

As various commentators have noted, achieving the goals of patent law directly would, at least as a routine matter, probably be impractical.<sup>25</sup> Absent significant expenditure of resources—and perhaps even with such resource expenditure—it would be difficult for the PTO (or the courts, for that matter) to get traction on the question of whether a particular patent was necessary to promote innovation (whether invention or development/commercialization) with respect to a particular quantum of information.<sup>26</sup>

Indeed, the patent statute does not provide for such a direct inquiry. Instead of asking whether a given patent is necessary to promote innovation, the patent

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20. See Bronwyn H. Hall & Rosemarie Ham Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979–1995*, 32 RAND J. ECON. 101, 108–09 (2001); Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 36 (2005).

21. See Parchomovsky & Wagner, *supra* note 20, at nn.66–82 (noting that given the low quality of patents, individual patents are not likely to be good signals, and patent counts are likely to represent strategic thinking about the patent system rather than knowledge capital); Rai, *Engaging Facts and Policy*, *supra* note 4, at 1082–83 (arguing that the low quality of patents produced by the PTO creates very noisy signals for venture capitalists). *But see* Ronald J. Mann, *Do Patents Facilitate Financing in the Software Industry?*, 83 TEX. L. REV. 961, 992 (2005) (arguing that software patents may provide information about the firm).

22. See Parchomovsky & Wagner, *supra* note 20, at 76 (noting that “the net effect of patent portfolios is likely to be negative” and suggesting a number of reform measures to reduce patent portfolios’ prevalence); *cf.* Mann, *supra* note 21 (noting that the creation of patent portfolios for purposes of cross-licensing is not likely to provide net benefits but that such portfolios may provide some information about the firm).

23. See generally Long, *supra* note 19, at 625–28.

24. See *supra* note 21.

25. See, e.g., FTC REPORT, *supra* note 2, ch. 1, at 11 (observing that the “more manageable standards of the patent statute” help to address the less administrable policy questions).

26. In any given case, it is easy to imagine economic experts having good faith disagreements on whether an invention would have arisen without the expectation of a patent. Alternatively, they might disagree on whether a patent is necessary to promote development and commercialization.



statute directs the PTO to determine whether the patent application meets validity standards that have scientific and technical underpinnings.<sup>27</sup> Specifically, when the PTO examines a patent application in order to determine whether to grant it, the PTO first construes the patent claims to determine exactly how much inventive territory the applicant is claiming.<sup>28</sup> Having determined the scope of the territory, the PTO then looks to whether the claims are valid. Most importantly, under the patent statute, the PTO must determine “if the differences between the subject matter sought to be patented and the prior [invention in the field] are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.”<sup>29</sup> The intuition behind this inquiry is that if the invention would have been technically obvious to a person having ordinary skill, it would have arisen without the patent incentive. Moreover, allowing patents on technically obvious inventions could cause races to patent such inventions, diverting resources away from more productive lines of inquiry.<sup>30</sup> In contrast, a nonobvious invention might not have arisen but for the patent incentive. Notably, the inquiry into technical nonobviousness takes into account the possibility that a particular invention may be “obvious to try” but nonetheless have only a limited possibility of success. Under boilerplate patent law, inventions are obvious only if the ordinary artisan attempting to make the invention would have a reasonable expectation of success.<sup>31</sup> Thus, inventions that are risky to make are considered nonobvious.<sup>32</sup>

As compared with the ultimate economic question of whether a patent is necessary to promote innovation, this intermediate scientific and technical question may have an answer that is more determinate.<sup>33</sup> To be sure, findings about how skilled the “ordinary” artisan is, and about what constitutes the relevant prior invention (known as “prior art”) of which this ordinary artisan should have been aware, will inevitably have components that are uncertain and subjective. But the uncertainty and subjectivity involved should be less acute than that involved in a direct economic inquiry. Indeed, to the extent that the PTO examiner is herself one of ordinary skill, she simply needs to be made

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27. See 35 U.S.C. § 103(b) (2000) (“nonobvious[ness]”); 35 U.S.C. § 112 (2000) (“enable[ment]”).

28. See, e.g., *In re Bass*, 314 F.3d 575, 577 (Fed. Cir. 2002) (discussing PTO claim construction).

29. 35 U.S.C. § 103(a) (2000). The prior invention in the field is called “prior art.” *Id.*

30. For a discussion of how this has arguably happened in biotechnology and software, see Rai, *Addressing the Patent Gold Rush*, *supra* note 4.

31. See *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1124–25 (Fed. Cir. 2000) (discussing the need for a “reasonable expectation of success”).

32. See generally Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 35–36 (1993) (discussing the importance of considering uncertainty in determining nonobviousness).

33. This argument is probably most accurate in those areas of natural science and engineering that are relatively well-understood. In those areas, the art and the level of skill in the art tend to be relatively well-defined. The claim’s accuracy in newly emerging areas such as nanotechnology or in other areas to which the patent system has extended, such as business methods, is less clear.

aware of all the prior art.<sup>34</sup>

Scientifically- and technically-based requirements such as nonobviousness can thus serve as reasonably good proxies for the ultimate economic inquiry. Nonetheless, for purposes of meeting the system's economic goals, the examination process set up by the Patent Act<sup>35</sup> has two deficiencies. First, although scientifically- and technically-based validity standards may generally be tractable proxies for the ultimate economic inquiry, these proxies do not always capture all of the economic policy reasons for granting a patent. For example, in some cases, although an invention might be technically obvious, both to try and to make, it might nonetheless be unusually expensive to make.<sup>36</sup> Alternatively, to the extent that the economic expense or risk associated with *developing* a technically obvious invention is substantial, allowing a patent on that invention could be useful.<sup>37</sup> Second, as numerous commentators have long observed, the *ex parte* proceedings upon which the PTO generally relies are unlikely to afford examiners the opportunity to deny even questionable patents.<sup>38</sup> Although applicants have an obligation to disclose prior art of which they are aware, they have no duty to conduct a prior art search.<sup>39</sup> Additionally, given the sheer volume of applications, patent examiners have a very limited amount of time to search for prior art themselves, or, indeed, to determine the relevance of prior art that may be submitted to them.<sup>40</sup>

How to address these deficiencies is not clear. With respect to the second deficiency noted above, the fact that many individual patent applications will have only minor market significance in the long term<sup>41</sup> probably militates

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34. As we discuss further below, the PTO examiner is probably more likely than any other *government* actor to have ordinary skill in the art. See *infra* text accompanying note 246.

35. See generally Patent Act of 1952, Pub. L. No. 593, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.).

36. See generally John Barton, *Non-Obviousness*, 43 IDEA 475, 506 (2003) (discussing this issue and proposing a standard "which looks more realistically at the actual role of patents as incentives").

37. See Kitch, *supra* note 17, at 265–67, 269 (advocating development as a significant reason for granting patent rights).

38. See, e.g., Shubha Ghosh & Jay Kesan, *What Do Patents Purchase? In Search of Optimal Ignorance in the Patent Office*, 40 HOUS. L. REV. 1219, 1225–26 (2004); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1499–1500 (2001); Cecil D. Quillen, Jr. & Ogden H. Webster, *Continuing Patent Applications and the Performance of the U.S. Patent and Trademark Office*, 11 FED. CIR. B.J. 1, 13 (2002); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 314–15.

39. See Lemley, *supra* note 38, at 1499–1500.

40. See FTC REPORT, *supra* note 2, ch. 5, at 5 (giving estimates of the total amount of time available to examine a patent application that range from eight to twenty-five hours).

41. The data on market significance, and particularly on licensing, are not as well-developed as one might hope, but they do suggest that many individual patents have low market value. One recent study based on a sample of 776 German and 222 U.S. patents found that (in approximate terms) the most valuable 10% of patents accounted for 80% of the value of the sample. See F.M. Scherer, *The Innovation Lottery*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 3, 7–8 (Rochelle Cooper Dreyfuss et al. eds., 2001). To the extent that litigation is seen to be a marker of value, similar "skewness" might be inferred from litigation statistics. Only about 2% of patents are the subject of litigation. See Lemley, *supra* note 38, at 1501.

against expending resources to improve examination procedures for all applications.<sup>42</sup> Hence, calls for reform have properly focused on post-grant review, which, at least when implemented in the European patent system, tends to target the relatively small percentage of patents that are likely to be commercially significant.<sup>43</sup> This Article identifies administrative-law-based mechanisms of judicial review that would allow the U.S. system to take full advantage of the cost savings and increased accuracy potentially offered by post-grant review. As for the first problem noted above, there is good reason to be wary of giving any government institution plenary authority to make relatively free-form inquiries into economic policy. Thus, consistent with standard administrative law doctrine, we would propose dividing authority for policymaking between the PTO and the courts.

We turn, then, to the administrative law context for our argument. In the next Part, we discuss how, as a matter of formal doctrine, administrative law principles currently apply to review of existing PTO proceedings.

## II. THE PTO AND ADMINISTRATIVE LAW DOCTRINE

In most technically complex areas, administrative law looms large. Federal statutes, known as organic statutes, create administrative agencies and empower them to take a range of actions, usually including informal rulemaking and different types of adjudication. Those organic statutes sometimes specify the standards that courts should use in reviewing agency actions. Usually, the organic statute does not, however, specify the standards applicable in all situations. Indeed, some organic statutes do not specify any standards. Insofar as the organic statutes do not provide such standards, the regime enunciated in the Administrative Procedure Act (APA) provides the governing standards.<sup>44</sup> The idea behind the APA was that it would provide the default rules for all agencies (and both “agency” and “agency action” were defined very broadly in the APA<sup>45</sup>), with the result that it would create a new legal regime for agencies with organic statutes that included little procedure.<sup>46</sup> Thus, for any given agency

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42. The minimal level of review that should be accorded to every application is difficult to assess. For a discussion of the problems that could be caused by “low market value” patents of low quality, see Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System—Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J. 989, 992–94 (2004); Rai, *Engaging Facts and Policy*, *supra* note 4, at 1082–83.

43. See Hall & Harhoff, *supra* note 42, at 1006 (summarizing studies showing that “particularly valuable patents are selected with higher likelihood than less valuable ones”).

44. See 5 U.S.C. §§ 551–559, 701–706 (2000 & Supp. II 2002).

45. See 5 U.S.C. § 701(b)(1) (defining “agency” as “each authority of the Government of the United States, whether or not it is within or subject to review by another agency,” with only a few narrow exceptions); see also 5 U.S.C. § 551(1) (same); 5 U.S.C. § 551(13) (defining “agency action” as “the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act”).

46. See H.R. Rep. No. 79-1980, at 15 (1946), *reprinted in* LEGISLATIVE HISTORY OF THE ADMINISTRATIVE PROCEDURE ACT, 1944–46, at 250 (stating that Congress intended the APA “to be operative ‘across the board’ in accordance with its terms, or not at all” and that “[n]o agency has been favored by special

the central question is the degree to which its organic statute specifies the relevant standards and thus displaces the APA.<sup>47</sup> How does this apply to the PTO? Strikingly, although the organic statute provides very little guidance, the Federal Circuit has often failed to apply the APA. In the next sections we address the application of administrative law doctrine to PTO actions, specifically patent grants and denials.

#### A. PATENT LAW AND THE APA: GENERAL CONSIDERATIONS

At the time of the APA's enactment in 1946, the patent statute did not contain any language concerning how PTO actions were to be reviewed by courts. In the absence of statutory language, regional courts of appeals had enunciated judicial standards of review as patent common law. Courts had generally applied a rebuttable presumption of validity with respect to PTO decisions to grant a patent, but different courts articulated different standards for how the presumption was to be rebutted.<sup>48</sup> As for patent denials, the Court of Customs and Patent Appeals (CCPA)—the predecessor to the Federal Circuit that heard all appeals from patent denials—failed to enunciate a uniform standard of review.<sup>49</sup> To the extent there was a salient pattern in CCPA review of patent denials, it was that the CCPA often mentioned agency expertise as a reason for deference.<sup>50</sup> Given the absence of language in the patent statute, and the absence of a uniform direction in the case law, the APA filled in the gaps and provided the standard of review—or should have been construed to do so.

Six years after the passage of the APA, Congress passed the Patent Act of 1952.<sup>51</sup> The 1952 statute was silent as to patent denials. It did articulate a presumption of validity for patent grants, but the language stating this presumption was quite sparse. Section 282 of the Patent Act now states that “[a] patent shall be presumed valid” and that “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.”<sup>52</sup>

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treatment”); S. Rep. No. 79-752, at 1 (1945), *reprinted in* LEGISLATIVE HISTORY OF THE ADMINISTRATIVE PROCEDURE ACT, 1944–46, at 187 (1946) (stating that the APA would provide a “simple and standard plan of administrative procedure” that would respond to the “widespread demand for legislation to settle and regulate the field of Federal administrative law and procedure”).

47. *See* *Am. Paper Inst., Inc. v. Am. Elec. Power Serv. Corp.*, 461 U.S. 402, 412 n.7 (1983).

48. *See, e.g., Radio Corp. of Am. v. Radio Eng'g Lab.*, 293 U.S. 1, 7 (1934) (noting the presumption of validity but also noting that “[t]he force of that presumption has found varying expression in this and other courts”).

49. *See Dickinson v. Zurko*, 527 U.S. 150, 155–56, 158, 160 (1999).

50. *See id.* at 160 (noting that in half of eighty-nine pre-APA cases in its sample, the CCPA mentioned PTO expertise, and in three-fourths it mentioned that PTO factfinding in denials had been passed upon by two or sometimes more tribunals).

51. Patent Act of 1952, Pub. L. No. 593, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.).

52. 35 U.S.C. § 282 (Supp. II 2002). The 1952 language was even simpler. It provided: “A patent shall be presumed valid. The burden of establishing invalidity of a patent shall rest on the party asserting it.” Patent Act of 1952, Pub. L. No. 593, 66 Stat. 792, 812. Since 1952, Congress has added language to section 282, leading to the somewhat more convoluted language quoted in the text.

This is the only provision of the Patent Act that even plausibly supersedes the APA for purposes of patent review. Did these provisions in section 282 displace or modify the APA? The short answer is “no.”

The Supreme Court's longstanding view has been that agency actions are presumed valid, and a plaintiff seeking to overcome that presumption has the burden of establishing invalidity. The Court articulated this view before the passage of the APA (indeed, in the nineteenth century) and has adhered to it ever since.<sup>53</sup> These provisions of section 282 say no more; they merely confirm that this presumption and burden also apply to patent grants. So why enact legislation containing these statements? The congressional materials accompanying the legislation do not shed any light, but the principal drafter of the Patent Act explained:

The first paragraph of Section 282 declares that a patent shall be presumed valid and that the burden of establishing invalidity of a patent shall rest on a party asserting it. That a patent is presumed valid was the law prior to the new statute, but it was not expressed in the old statute.<sup>54</sup>

Another drafter (who later became a judge on the Federal Circuit) stated that “[s]ection 282 puts into the statute the presumption of validity for the benefit of those cynical judges who now say the presumption is the other way around.”<sup>55</sup> In other words, section 282 had the modest effect of clarifying that the general presumption of validity applicable to agency actions was also applicable to

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53. See, e.g., *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 415 (1971) (“Certainly, the Secretary’s decision is entitled to a presumption of regularity.”); *Hynes v. Grimes Packing Co.*, 337 U.S. 86, 101 (1949) (“An administrative order is presumptively valid.”); *Thompson v. Consol. Gas Utils. Co.*, 300 U.S. 55, 69–70 (1937) (“It is settled that to all administrative regulations purporting to be made under authority legally delegated there attaches a presumption of the existence of facts justifying the specific exercise. But, obviously, the proration orders would not be valid if shown to bear no reasonable relation either to the prevention of waste or the protection of correlative rights, or if shown to be otherwise arbitrary. The plaintiffs have assumed the heavy burden of overcoming the presumption and of establishing that the order is an arbitrary taking of their property.” (citing *Pac. States Box & Basket Co. v. White*, 296 U.S. 176, 185 (1935))); *Pac. States Box & Basket Co.*, 296 U.S. at 186 (“[W]here the regulation is within the scope of authority legally delegated, the presumption of the existence of facts justifying its specific exercise attaches alike to statutes, to municipal ordinances, and to orders of administrative bodies.”); *Martin v. Mott*, 25 U.S. (12 Wheat.) 19, 32–33 (1827) (“When the President exercises an authority confided to him by law, the presumption is, that it is exercised in pursuance of law. Every public officer is presumed to act in obedience to his duty, until the contrary is shown; and, *a fortiori*, this presumption ought to be favourably applied to the chief magistrate of the Union.”).

54. P. J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC’Y 161, 215 (1993) (reprinted from 35 U.S.C.A. (1954 ed.)).

55. *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). The drafter was Giles Rich, who became Judge Rich. In *American Hoist*, Judge Rich introduced the quotation in text by saying, “[t]he named author of this opinion, who also worked on the 1952 act with Mr. Federico, explained it to the New York Patent Law Association on November 6, 1952 (in a speech of limited publication) in these words . . .” *Id.*

patent grants.<sup>56</sup>

Reasonable minds can differ over whether this clarification was necessary. After all, courts might have reached the same conclusion by applying ordinary background principles of administrative law. What seems clear, however, is that section 282 did not supplant the APA. Section 559 of the APA provides in part that a “[s]ubsequent statute may not be held to supersede or modify [the APA] . . . except to the extent that it does so expressly.”<sup>57</sup> This prevents the displacing of the APA by implication.<sup>58</sup> Nothing in section 282 suggests that it is superseding the requirements of the APA.<sup>59</sup>

Even if section 559 did not exist, there would be little basis for treating section 282 as supplanting the APA. Organic statutes superseding the APA generally indicate that they are doing so and contain specific standards of review (for example, “substantial evidence”).<sup>60</sup> These provisions tell courts how

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56. Indeed, the prominent administrative law opinion *United States v. Mead Corp.*, 533 U.S. 218 (2001), which reviewed a tariff classification decision by the United States Custom Service, relegates to a footnote the organic statute’s provision that such classifications are “presumed to be correct.” *Id.* at 2174 n.16 (citing 28 U.S.C. § 2639(a)(1) (2000)). Although some commentators have criticized the *Mead* Court for ignoring this provision, these commentators acknowledge that the provision could be seen as simply placing the burden of proof on the importer who challenges the classification. David J. Barron & Elena Kagan, *Chevron’s Nondelegation Doctrine*, 2001 SUP. CT. REV. 201, 220–21.

57. 5 U.S.C. § 559 (2000).

58. *See, e.g.*, *Marcello v. Bonds*, 349 U.S. 302, 310 (1955) (“Exemptions from the terms of the Administrative Procedure Act are not lightly to be presumed in view of the statement in [section 559] that modifications must be express.” (citing *Shaughnessy v. Pedreiro*, 349 U.S. 48, 75 (1955))); *Ninilchik Traditional Council v. United States*, 227 F.3d 1186, 1193 (9th Cir. 2000) (quoting this language from section 559 and then stating: “This language leaves us to conclude that challenges to agency actions are subject to the APA’s judicial review standard unless Congress specifies a contrary intent . . .”).

59. The main line of cases in which the Supreme Court has found that an organic statute supplanted the APA is instructive. The statute involved, the Immigration and Nationality Act of 1952, ch. 477, 66 Stat. 163, 209 (current amended version at 8 U.S.C.A. § 1252 (West 2005)), provides that “[t]he procedure (herein prescribed) shall be the sole and exclusive procedure for determining the deportability of an alien under this section.” As the Supreme Court held, that is the sort of express statement that does displace the APA. *See Marcello*, 349 U.S. at 309 (relying on the quoted language in so holding); *see also Ardestani v. INS*, 502 U.S. 129, 134 (1991) (same).

60. *See, e.g.*, Toxic Substances Control Act, 15 U.S.C. § 2618(c)(1)(B)(i) (2000) (“[T]he court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record . . . .”); *see also* 5 U.S.C. § 552(a)(4)(B) (2000) (prescribing de novo review for agency determinations under the Freedom of Information Act); 5 U.S.C. § 7703(c)(1) (2000) (directing courts to set aside conclusions of the Merit Systems Protection Board if they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . or . . . unsupported by substantial evidence”); 10 U.S.C. § 1558(f)(3) (2000) (“A court of the United States may review a recommendation of a special board or an action of the Secretary of the military department concerned on the report of a special board. In any such case, a court may set aside the action only if the court finds that the recommendation or action was—(A) arbitrary or capricious; (B) not based on substantial evidence; (C) a result of material error of fact or material administrative error; or (D) otherwise contrary to law.”); 12 U.S.C. § 1848 (2000) (“Any party aggrieved by an order of the Board under this chapter may obtain a review of such order in [a] United States Court of Appeals . . . . The findings of the Board as to the facts, if supported by substantial evidence, shall be conclusive.”); 15 U.S.C. § 78y(b)(4) (2000) (“The findings of the Commission as to the facts identified by the Commission as the basis, in whole or in part, of the rule, if supported by substantial evidence, are conclusive. The court

much evidence (and, often, what kind) challengers must marshal to argue successfully for the invalidation of an agency action. Such specification both demonstrates that the organic statute is, indeed, intended to supersede the APA and also tells courts what sort of review to apply. A lack of specificity deprives courts of statutory language to guide them in reviewing agency action and thus underscores that the APA still applies. Without the APA, courts would have no meaningful statutory guideposts—the precise phenomenon that the APA was designed to eliminate. Neither section 282 nor any other section of the Patent Act contains any standards of review for patent grants (or patent denials, for that matter). There is no language putting forward the quantum of evidence necessary to support (or, conversely, to overturn) an agency action. All we have is the bare statement of a presumption of validity, and that does not communicate the relevant standards to the courts.

If section 282 does not supersede the APA, might it nonetheless modify the APA? Again, section 559 imposes a barrier because even a modification of the APA must be expressly stated—and, again, the bare language of section 282 does not so indicate. Assuming that section 559 did not exist, how would section 282 modify the APA? As we will discuss in greater detail in the following section, under the APA courts review factual determinations in informal proceedings under an “arbitrary, capricious, [or] an abuse of discretion” standard, and review findings of fact in formal proceedings under a “substantial evidence” standard.<sup>61</sup> If the presumption of validity in section 282 modifies these standards, in which direction does it do so? Does it suggest more deference to the agency’s decisions on the theory that the presumption was Congress’s way of saying, “Give more than usual deference to the agency”? That hypothesis seems unlikely. As we noted above, the longstanding presumption has been that agency actions are presumed valid, with the burden on the challenger to the agency’s action.

Meanwhile, in contrast to the sparse language of the Patent Act regarding review of patent grants, its standards for reviewing a patent denial are nonexistent. Section 282 does not apply to patent denials, and no other provision covers the review of patent denials. Thus, in the context of denials, nothing in the organic statute even arguably displaces the APA.

The foregoing is boilerplate administrative law. But the courts applying the Patent Act had other ideas. Despite the passage of the APA, courts did not apply the APA and instead developed common law to flesh out the sparse language of

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shall affirm and enforce the rule unless the Commission’s action in promulgating the rule is found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or without observance of procedure required by law.”); 33 U.S.C. § 1319(g)(8) (2000) (“[The reviewing] court shall not set aside or remand such order unless there is not substantial evidence in the record, taken as a whole, to support the finding of a violation or unless the Administrator’s or Secretary’s assessment of the penalty constitutes an abuse of discretion.”).

61. 5 U.S.C. § 706(2)(A), (E) (2000); *see infra* note 68 and accompanying text.

the Patent Act. Before 1982 (when Congress established the Federal Circuit to hear all patent appeals), regional courts ignored the APA and referred instead to section 282. Interestingly, when they applied section 282, they adopted a variety of different standards—representing a wide range of deference. Some regional courts of appeals took the presumption to mean that an issued patent could be invalidated only if the challenger showed “clear and convincing evidence” of invalidity.<sup>62</sup> Others determined that issued patents could be invalidated under a preponderance of the evidence standard.<sup>63</sup> That is, as the discussion above suggests, section 282 did not give courts much guidance and accordingly the courts that applied section 282 had varying interpretations of the amount of deference that it entailed.

The 1982 legislation creating the Court of Appeals for the Federal Circuit did not flesh out, or alter, the section 282 standard. The Federal Circuit has continued the common law trend started by the regional courts—ignoring the APA and citing section 282. Unlike the regional courts, the Federal Circuit has, however, uniformly upheld a strong presumption of validity. Specifically, the court has held that the presumption of validity can be overturned only through “clear and convincing” evidence, even in cases where the alleged infringer uncovers information that was not considered by the PTO.<sup>64</sup> In the context of patent denials, the Federal Circuit has also (at least until recently) ignored the APA.

#### B. APPLYING ADMINISTRATIVE LAW DOCTRINE TO PTO ACTIONS

Assuming, then, that the APA applies to the PTO, how precisely does it operate? Agency actions are conventionally broken down into three categories: fact, law, and policy (with policy sometimes divided into policy decisions and discretionary acts).<sup>65</sup> Although the distinctions between these categories do of course blur at the margins,<sup>66</sup> they represent useful mechanisms for characterizing different types of agency action. Each category has its own standards of

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62. See 2 DONALD S. CHISUM, PATENTS § 5.06, at 5-697 & n.34 (Supp. 2003) (listing cases that applied this standard).

63. See, e.g., Mark Janis, *Reforming Patent Validity Litigation: The “Dubious Preponderance,”* 19 BERKELEY TECH. L.J. 923, 928–29 & n.28 (2004) (listing cases from the Sixth Circuit applying this standard).

64. See *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984).

65. As we discuss at greater length *infra* notes 170–74 and accompanying text, policy choices are discretionary, and the decisions that fall into the “discretionary” category in administrative law are applications of policy choices. Thus policy choices and discretionary acts can be considered as two parts of one category. The difference is that policy decisions are broad legislative-like choices, and discretionary decisions are specific implementations of policy choices.

66. As we discuss below, see *infra* note 175 and accompanying text, the line between legal interpretation and policy can sometimes be blurry. Lines can also blur in cases where (as is often the case in decisions regarding patent validity) law is being applied to factual determinations. Indeed, some administrative cases from the pre-*Chevron* era tended to assimilate application of law to fact to the category of fact. However, the more recent trend in administrative law has been to treat applications of law to fact as legal determinations. See *infra* note 135.



review, so we consider each separately here.

### 1. Factual Determinations

Factual determinations play a major role in PTO decisionmaking because they are central to many of the inquiries in which the PTO engages. For example, as we noted in Part I, the Patent Act requires that a patented invention be nonobvious. As the Supreme Court emphasized in the 1966 case *Graham v. John Deere Co.*, the statute specifies a number of factual inquiries that are necessary to resolve the question of nonobviousness: what the ordinary skill in the art was at the time of invention; what the relevant prior invention was; and the “differences between the prior art and the claims at issue.”<sup>67</sup>

Turning, then, to judicial review of PTO factfinding, section 706 of the APA provides the relevant standard. Under section 706, courts review agency findings of fact in informal proceedings to determine if they are “arbitrary, capricious, [or] an abuse of discretion” and review agency findings of fact in formal proceedings to determine if they are “unsupported by substantial evidence.”<sup>68</sup> In light of the absence of different standards in the Patent Act, these are the relevant provisions applicable to the PTO.

This conclusion would seem unexceptional to administrative law scholars. Until the Supreme Court’s intervention in 1999, however, the Federal Circuit explicitly rejected the application of section 706 to PTO factfinding. In the context of patent denials, which are appealed directly to the Federal Circuit, the Federal Circuit instead applied the “clearly erroneous” standard, which is less deferential to the agency than either of the standards articulated in section 706.<sup>69</sup> The Federal Circuit articulated its rationale for this conclusion in *In re Zurko*.<sup>70</sup> The court relied on a portion of section 559 of the APA, which provides in part that the statute does “not limit or repeal additional requirements imposed by statute or otherwise recognized by law.”<sup>71</sup> The Federal Circuit in

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67. 383 U.S. 1, 17 (1966).

68. 5 U.S.C. § 706(2)(A), (E) (2000). The Supreme Court has not resolved the question of whether these sections differ in the quantum of evidence necessary to support an agency factfinding. When he was on the D.C. Circuit, then-Judge Scalia wrote an opinion holding that “arbitrary [or] capricious” under section 706(2)(E) entailed the same degree of judicial scrutiny as did “substantial evidence” under section 706(2)(A). *Ass’n of Data Processing Serv. Org., Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 683–84 (D.C. Cir. 1984). Note that even if the two provisions entail the same level of deference, they clearly differ as to the kind of record that is involved. As then-Judge Scalia emphasized, formal proceedings are confined to the evidence presented at the hearing, but informal proceedings are not so limited. *Id.* at 683. As it happens, this distinction has become quite important for the Federal Circuit. *See infra* notes 80–97 and accompanying text.

69. *See In re Zurko*, 142 F.3d 1447, 1450 (Fed. Cir. 1998) (noting that “clearly erroneous” is less deferential than the APA standards of review), *rev’d sub nom.* *Dickinson v. Zurko*, 527 U.S. 150 (1999); *see also Dickinson v. Zurko*, 527 U.S. 150, 153 (1999) (same).

70. 142 F.3d at 1452.

71. *See* 5 U.S.C. § 559 (2000). Note that this is the section of the APA that also provides that a subsequent statute will not supersede the APA unless it does so expressly. *See supra* note 57 and accompanying text.

*Zurko* stated that, prior to the enactment of the APA, courts reviewed PTO findings of fact in patent denials under the clearly erroneous standard, and it concluded that this judicial practice constituted an “additional requirement[] . . . recognized by law.”<sup>72</sup> Accordingly, the Federal Circuit concluded that the clearly erroneous standard applied to the PTO notwithstanding section 706.<sup>73</sup>

This reasoning was striking, because a total of only eight federal cases had invoked the “repeal additional requirements” language in the more than fifty years between the passage of the APA and *Zurko*. Moreover, in each of those cases the “additional requirements” took the form of a statutory provision (in the relevant organic statute) that conflicted with a provision of the APA, rather than a line of judicial opinions that conflicted with the APA.<sup>74</sup> Indeed, in all of those cases the court found that the statutory provision in the organic statute controlled. The court’s invocation of section 559 simply buttressed the general rule that the organic statute controls where it provides specific standards of review.<sup>75</sup>

That the Federal Circuit’s position lacked a judicial antecedent made it unprecedented, but not necessarily wrong. It might be that the best reading of “additional requirements imposed by statute or otherwise recognized by law” encompasses standards of review arising from an established line of cases. As the Supreme Court’s decision in *Zurko* emphasized, however, the problem for the Federal Circuit was that the pre-APA cases did not establish clearly erroneous review as the relevant standard.<sup>76</sup> The cases used varying word formula-

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72. *Zurko*, 142 F.3d at 1452.

73. *See id.* at 1457 (applying the common law tradition of “clear error”).

74. *See infra* note 75.

75. The eight cases were: *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 238 (1973) (citing section 559 for the proposition that a provision in the organic statute could require the agency to hold an oral hearing even though the APA did not so require); *Pan-Atl. S.S. Corp. v. Atl. Coast Line R.R. Co.*, 353 U.S. 436, 446 n.5 (1957) (citing a predecessor to section 559 in support of its statement that “[a]n earlier special statute controls over a later general statute”); *United States v. Menendez*, 48 F.3d 1401, 1409 (5th Cir. 1995) (citing section 559 for the proposition that the specific language in the Endangered Species Act controlled); *Gostovich v. Valore*, 257 F.2d 144, 145–46 (3d Cir. 1958) (citing section 559 in support of its holding that a statutory limitation of ten dollars for compensation to an attorney handling a veteran’s claim controlled over a general provision of the APA regarding representation by counsel); *SEC v. Morgan, Lewis & Bockius*, 209 F.2d 44, 48–49 (3d Cir. 1953) (citing a predecessor to section 559 in support of its holding that a specific statute regarding attorneys’ representation before the SEC controlled over a general provision of the APA regarding representation by counsel); *Willapoint Oysters, Inc. v. Ewing*, 174 F.2d 676, 696 (9th Cir. 1949) (citing a predecessor to section 559 for the proposition that a general provision of the APA does not control in light of a specific provision in the organic statute); *Rolla Cable Sys., Inc. v. City of Rolla*, 761 F. Supp. 1398, 1404 (E.D. Mo. 1991) (noting one party’s argument that application of the APA would override a more specific statute and thus run afoul of section 559); *SEC v. Morgan, Lewis & Bockius*, 113 F. Supp. 85, 90 (E.D. Pa. 1953) (citing section 559 in support of its holding that a specific statute regarding attorneys’ representation before the SEC controlled over a general provision of the APA regarding representation by counsel).

76. *See Dickinson v. Zurko*, 527 U.S. 150, 155 (1999) (“[W]e have examined the 89 cases which, according to respondents and supporting *amici*, embody the pre-APA standard of review . . . and we conclude that those cases do not reflect a well-established stricter court/court standard of judicial review

tions, rather than using “clearly erroneous” as a term of art. Indeed, with respect to the CCPA cases reviewing patent denials, “not one of the 89 opinions actually uses the precise words ‘clear error’ or ‘clearly erroneous,’ which are terms of art signaling court/court review.”<sup>77</sup> Similarly, as we noted earlier, pre-APA cases reviewing patent grants did not establish consistent standards of review.

The absence of a consistent standard of review for patent-related factfinding is not surprising. A big part of the impetus behind the passage of the APA was that courts had not created clear standards to govern their review of agency actions.<sup>78</sup> As it turns out, review of the PTO was no exception. So, more than half a century after the enactment of the APA, the Supreme Court instructed the Federal Circuit that the APA does indeed provide the governing standards for the judicial review of PTO factfinding that underlies patent denials.

The Federal Circuit managed to find the path of less deference, however. The Supreme Court in *Zurko* was not squarely presented with, and hence did not address, the specific question of whether PTO factfinding should be reviewed under the “arbitrary [or] capricious” standard applicable to informal proceedings or the “substantial evidence” standard applicable to formal proceedings.<sup>79</sup> When the issue arose at oral argument, Justice Breyer suggested that arbitrary or capricious review was the proper choice given the ex parte, informal nature of the PTO proceedings.<sup>80</sup> But Justice Breyer’s opinion for the majority addressed only the threshold issue of APA applicability briefed by the parties.<sup>81</sup>

In *In re Gartside*, the Federal Circuit confronted the question whether “arbitrary [or] capricious” or “substantial evidence” was the appropriate standard.<sup>82</sup> The court began its analysis by stating that “arbitrary [or] capricious” is the most deferential standard of review under the APA, “analyz[ing] only whether a rational connection exists between the agency’s factfindings and its ultimate action.”<sup>83</sup> The court characterized “substantial evidence,” by contrast, as “a less deferential review standard than ‘arbitrary, capricious’”—one that required more than a rational connection.<sup>84</sup>

This is a contested construction of “arbitrary [or] capricious” and “substantial evidence.” As the opinion in *In re Gartside* noted, there is some case law in support of it. But the court did not acknowledge, much less discuss, case law

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for PTO factfinding, which circumstance fatally undermines the Federal Circuit’s conclusion.” (internal citation omitted).

77. *Id.* at 158.

78. As the Supreme Court noted in *Zurko*, “[t]he APA was meant to bring uniformity to a field full of variation and diversity. It would frustrate that purpose to permit divergence on the basis of a requirement ‘recognized’ only as ambiguous.” *Id.* at 155.

79. *Id.* at 154.

80. See Transcript of Oral Argument at \*4–\*8, *Dickinson v. Zurko*, 527 U.S. 150 (1999) (No. 98-377), available at 1999 WL 190969 (asserting that the “arbitrary-capricious standard . . . applies to all determinations . . . not based on a closed record”).

81. *Zurko*, 527 U.S. at 154.

82. 203 F.3d 1305, 1312 (Fed. Cir. 2000).

83. *Id.* at 1312.

84. *Id.*

indicating that the two terms provide exactly the same level of deference. Indeed, the most widely cited—and followed—case on this question, by then-Judge Scalia for the D.C. Circuit, held that “arbitrary [or] capricious” and “substantial evidence” entail the same (very great) level of deference to agency factfinding.<sup>85</sup>

The *Gartside* court’s distinction between the deference entailed by “substantial evidence” and that entailed by “arbitrary [or] capricious” proved to be significant, in light of the court’s subsequent determination regarding which standard applies to the PTO. Section 706(2)(A) provides “arbitrary [or] capricious” review as the default, and section 706(2)(E) sets out a particular circumstance where “substantial evidence” instead will apply: “in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute.”<sup>86</sup> Determining which provision applies to the PTO might seem easy: section 706(2)(E) applies to formal proceedings,<sup>87</sup> which means oral hearings in which evidence is presented to a presiding officer (usually an administrative judge); the parties have the right to present evidence, present rebuttals, and to cross-examine; and the officer’s decision must be based on the record.<sup>88</sup> On this reading, the second half of section 706(2)(E) would apply to similar oral hearings that are created by an organic statute but are not specifically subject to sections 556 and 557. That is, the two halves of section 706(2)(E) appear to apply to formal hearings, whether covered by sections 556 and 557 or by the relevant organic statute. On this understanding, no PTO action would be subject to section 706(2)(E) because there are no formal, on-the-record hearings in the PTO.<sup>89</sup>

The Federal Circuit had other ideas. In *Gartside*, it acknowledged that the

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85. See *Ass’n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 683–84 (D.C. Cir. 1984) (stating the difference between these tests is “largely semantic” (citation omitted)); see also *Borough of Columbia v. Surface Transp. Bd.*, 342 F.3d 222, 241 n.3 (3d Cir. 2003) (adopting this conclusion from *Association of Data Processing Service Organizations*); *IBP, Inc. v. Herman*, 144 F.3d 861, 866 (D.C. Cir. 1998) (same); *Coteau Props. Co. v. Dep’t of Interior*, 53 F.3d 1466, 1483 (8th Cir. 1995) (same); *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1575 (10th Cir. 1994) (same); cf. *supra* note 69 (noting that the “clearly erroneous standard” entails less deference than either standard of review under section 706).

86. 5 U.S.C. § 706(2)(A), (E) (2000). Note that section 706(2)(A) is the catch-all default not only for factual findings but also for other determinations. See *Ass’n of Data Processing Serv. Orgs.*, 745 F.2d at 683 (noting that section 706(2)(A) is a “catchall, picking up administrative misconduct not covered by the other more specific paragraphs”); *infra* notes 182–88.

87. 5 U.S.C. § 706(2)(E).

88. See 5 U.S.C. §§ 556(b), (d), 557 (2000) (laying out these requirements). Some formal hearings do not have to be oral, but none of the exceptions applies to patent decisions. Specifically, “[i]n rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.” § 556(d) (emphasis added).

89. See *Thomas G. Field Jr., Zurko, Gartside and Lee: How Might They Affect Patent Prosecution?*, 44 IDEA 221, 225 (2004) (“35 U.S.C. § 32 cases aside, all PTO adjudications, statutory and non-statutory, are ‘informal.’”). This statute deals with suspending or excluding lawyers from practice before the PTO if they have committed some transgression, and so it is not relevant to the PTO determinations on which we focus in this Article. See 35 U.S.C. § 32 (2000 and Supp. II 2002).

PTO did not conduct proceedings under sections 556 and 557. It found, however, that PTO proceedings satisfied the second half of section 706(2)(E) because one statutory provision says that the Federal Circuit “shall review the decision from which an appeal is taken on the record before the Patent and Trademark Office,”<sup>90</sup> and another provision refers to an appeal being “heard” and to a “rehearing”<sup>91</sup> (though it does not use the word “hearing”).<sup>92</sup> One problem with this reasoning, as Justice Breyer noted at oral argument in *Zurko*, is that it is inconsistent with the longstanding practice of reviewing factfinding in informal rulemakings and informal adjudications under arbitrary or capricious review.<sup>93</sup> In addition, 35 U.S.C. § 7(b) provided that the Board of Patent Appeals and Interferences (BPAI) shall “review” examiners’ decisions, rather than requiring a “hearing.”<sup>94</sup> This may seem like a small point, but in a closely related context it has loomed large: Courts have found that the absence of an explicit requirement of a “hearing” means that an adjudication is informal under section 554 of the APA.<sup>95</sup> Statutes routinely require an agency “hearing,” and courts have found that the absence of that magic word is significant. It also bears noting that, if the substantial evidence standard were appropriate for review of PTO patent denials, that would probably mean that patent denials would be the sort of adjudication to which the Federal Circuit had to give *Chevron* deference—that is, significant deference on the ultimate legal question of validity.<sup>96</sup>

Although the substantial evidence standard is, when applied properly, relatively lenient, the standard is supposed to apply only to formal adjudicative

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90. 35 U.S.C. § 144 (2000 & Supp. II 2002) (“The United States Court of Appeals for the Federal Circuit shall review the decision from which an appeal is taken on the record before the Patent and Trademark Office.”).

91. *See* 35 U.S.C. § 7(b) (1994) (current version codified at 35 U.S.C. § 6(b) (2000 & Supp. II 2002)) (“The Board of Patent Appeals and Interferences shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents and shall determine priority and patentability of invention in interferences declared under section 135(a) of this title. Each appeal and interference shall be heard by at least three members of the Board of Patent Appeals and Interferences, who shall be designated by the Commissioner. Only the Board of Patent Appeals and Interferences has the authority to grant rehearings.”).

92. *See Gartside*, 203 F.3d at 1313 (relying on the 1994 codification of these provisions in holding that PTO proceedings satisfy section 706(2)(E)).

93. Transcript of Oral Argument at \*5–\*7, *Dickinson v. Zurko*, 527 U.S. 150 (1999) (No. 98-377), available at 1999 WL 190969.

94. *See Gartside*, 203 F.3d at 1313. Note that the current version of section 7(b)—codified at 35 U.S.C. § 6(b)—uses the language of “review[ing].”

95. *See* John F. Stanley, *The “Magic Words” of § 554: A New Test for Formal Adjudication Under the Administrative Procedure Act*, 56 HASTINGS L.J. 1067, 1073–75 (2005). Indeed, the debate has been whether a statute needs to require a “hearing” or a “hearing on the record” in order to entail formal, rather than informal, adjudication. *Compare* *Seacoast Anti-Pollution League v. Costle*, 572 F.2d 872, 876–78 (1st Cir. 1978) (holding that a statute requiring a “hearing” thereby entails formal adjudication), with *City of W. Chicago v. NRC*, 701 F.2d 632, 644–45 (7th Cir. 1983) (finding that a statute must require a hearing “on the record” in order to entail formal adjudication); *see also* *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414–15 (1971).

96. *See infra* notes 122–58 and accompanying text.

proceedings, where witnesses are called, evidence is taken, and a full evidentiary record is developed. Highly aggressive application of this standard to the PTO's informal proceedings—where the only formal evidence on which the PTO can rely to make the case against patentability is written prior art<sup>97</sup>—yields the paradoxical result of rigorous review.

Consider, for example, the determination of nonobviousness. To the traditional interpretation of the nonobviousness standard set out by the Supreme Court in *Graham v. John Deere Co.*,<sup>98</sup> the Federal Circuit has added a controversial requirement—now the subject of a case on which the Supreme Court has granted certiorari in its 2006 term<sup>99</sup>—that the examiner show a motivation to combine prior art references.<sup>100</sup> Like many inquiries surrounding nonobviousness, questions regarding motivation to combine are questions of fact.<sup>101</sup> In the 2002 case of *In re Lee*, a panel of the Federal Circuit applied the substantial evidence standard to mandate that the PTO include in the record explicit documentary evidence of a motivation to combine.<sup>102</sup> In that case, the PTO argued that “common knowledge and common sense” would motivate the ordinary artisan who wanted to produce a demonstration mode for adjusting a video display to combine prior art containing such a video demonstration mode with prior art showing a menu display that could be used to adjust pictures.<sup>103</sup> The *Lee* court rejected the PTO's argument, holding that such “[c]ommon knowledge and common sense,” even if assumed to derive from [the PTO's] expertise” did not represent the sort of evidence within “the four corners of the record” required by *Gartside*.<sup>104</sup> Under boilerplate administrative law, however, informal adjudications simply do not produce formal records subject to substantial evidence review.

Additionally, even assuming substantial evidence were the appropriate standard, *Lee* fails to apply this standard properly. In proceedings subject to substantial evidence review, the APA allows administrators to take official notice of certain facts.<sup>105</sup> Moreover, under standard administrative law doctrine,

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97. While patent applicants can submit affidavits authored by their own experts, there is no provision in the PTO examination procedure for the use of external experts. Thus the PTO cannot request affidavits from its own outside experts.

98. 383 U.S. 1, 17 (1966) (addressing the scope of “nonobviousness”).

99. *KSR Int'l Co. v. Teleflex, Inc.*, 119 F.App'x 282 (Fed. Cir. 2005) (unpublished opinion), *cert. granted*, 74 U.S.L.W. 31713 (June 26, 2006) (No. 04-1350).

100. *See KSR Int'l Co.*, 119 F.App'x at 288.

101. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001).

102. *See 277 F.3d 1338, 1345* (Fed. Cir. 2002) (stating the need for “specialized knowledge and expertise” that is “articulated and placed on the record”).

103. *Id.* at 1341.

104. *Id.* at 1344–45 (asserting that such “common knowledge” cannot be a “substitute for authority”); *id.* at 1342 (stating the rule that “Board decisions ‘must be justified within the four corners of the record’” (quoting *In re Gartside*, 203 F.3d 1305, 1314 (Fed. Cir. 2000))).

105. *See 5 U.S.C. § 556(e)* (2000) (“When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.”).

official notice is broader than judicial notice. Although both doctrines allow adjudicators to take account of commonly acknowledged facts, official notice also allows an administrative agency to take notice of technical or scientific facts that are known within the agency's area of expertise.<sup>106</sup> The Federal Circuit's predecessor, the CCPA, had endorsed a limited form of the official notice doctrine in its review of PTO decisionmaking.<sup>107</sup> In *Lee*, however, Judge Newman rejected even the limited form of official notice recognized by the CCPA.<sup>108</sup> *Lee* is, therefore, squarely inconsistent with standard administrative law.<sup>109</sup>

The *Lee* case is not an isolated phenomenon. The *Zurko* litigation itself represents a situation where the Federal Circuit rejected the PTO's specialized expertise. On remand, the Federal Circuit applied the *Gartside* standard and found that the PTO could not use statements of "basic knowledge" possessed by one having ordinary skill in the art to meet its evidentiary burden of showing a motivation to combine.<sup>110</sup> Similarly, in its 2004 *In re Beasley* decision, a panel of the Federal Circuit emphasized that the PTO must have documentary evidence to support arguments that an ordinary artisan would have been motivated

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106. See *McLeod v. INS*, 802 F.2d 89, 93 n.4 (3d Cir. 1986) ("Official notice, rather than judicial notice, is the proper method by which agency decisionmakers may apply knowledge not included in the record. The Administrative Procedure Act allows a decisionmaker to take 'official notice' of material not appearing in the evidence in the record. Official notice is a broader concept than judicial notice. Both doctrines allow adjudicators to take notice of commonly acknowledged facts, but official notice also allows an administrative agency to take notice of technical or scientific facts that are within the agency's area of expertise." (citation omitted)); *de la Llana-Castellon v. INS*, 16 F.3d 1093, 1096 (10th Cir. 1994) (quoting *McLeod* and applying similar reasoning); see also *City of Erie v. Pap's A.M.*, 529 U.S. 277, 298 (2000) (plurality opinion) (stating that the agency is not confined to the evidence in the record and may take official notice of facts within its special knowledge); Jim Rossi, *Judicial Review of Issues of Fact*, in A GUIDE TO POLITICAL AND JUDICIAL REVIEW OF FEDERAL AGENCIES 159, 171–75 (John Duffy & Michael Herz eds., 2005) (discussing the breadth of official notice).

107. See, e.g., *In re Bozek*, 416 F.2d 1385, 1390 (C.C.P.A. 1969) (noting that the examiner could, in reaching a conclusion of obviousness, rely on "common knowledge and common sense of the person of ordinary skill in the art"). *Bozek* notwithstanding, the official notice doctrine endorsed by the CCPA generally extended only to facts generally known to lay persons—of the type that could be recognized under judicial notice. See, e.g., *In re Ahlert*, 424 F.2d 1088, 1091 (C.C.P.A. 1970) (using the term "judicial notice" and stating that it extends only to facts that "are capable of such instant and unquestionable demonstration as to defy dispute"); see also John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 753 (2002) (arguing that certain CCPA cases may allow for aggressive use of official notice in rejecting patents on trivial business methods).

108. *In re Lee*, 277 F.3d at 1345 (rejecting the PTO's arguments regarding CCPA decisions and limiting the reach of *Bozek*).

109. At certain points in the *Lee* opinion, Judge Newman attempts to find support in Supreme Court case law on "reasoned decisionmaking." See *id.* at 1344 (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 469 U.S. 29, 43 (1983)). However, this case law on reasoned decisionmaking relates to policy determinations made by agencies, see *infra* Part II.B.3, and does not in any way call into question the doctrine of official notice. See *infra* notes 185–89 and accompanying text.

110. *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001) ("[T]he Board cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.").

to combine references.<sup>111</sup> As Judge Dyk's dissent in that case pointed out, the majority opinion failed to allow any room for the PTO's specialized knowledge regarding what an ordinary artisan would know—even in a case where this knowledge was clearly presented to the applicant and left uncontradicted by anything other than “lawyer argument.”<sup>112</sup>

To be sure, as Judge Dyk's dissent indicates, Federal Circuit judges are hardly unanimous in resisting the deferential review mandated by the Supreme Court decision in *Zurko*. Indeed, as we discuss further, in Part IV.C, we believe that the Supreme Court decision has made a difference in Federal Circuit decisionmaking. Post-*Zurko*, various Federal Circuit judges have authored opinions that are quite deferential to PTO factfinding. Some of these opinions even appear to apply, at least de facto, a standard of arbitrary and capricious review. For example, in the 2003 case *In re Berg*, a Federal Circuit panel affirmed a decision by the PTO to reject as obvious, over the combination of various prior art references, an applicant's claim to a novel fusion protein.<sup>113</sup> The *Berg* court did not specifically invoke the “motivation to combine” requirement, instead stating that it would defer to the PTO's expert judgment regarding what the prior art references would motivate the person skilled in the art of biotechnology to do.<sup>114</sup> And a 2006 opinion, *In re Kahn*, noted that the PTO can find motivation to combine in sources other than documentary evidence.<sup>115</sup> The *Kahn* court agreed with the PTO's assertion that the nature of the problem to be solved provided the requisite motivation to combine references for creating the advanced reading machine for the blind claimed in the case.<sup>116</sup>

*Kahn* is, however, simply a panel opinion, with no greater precedential value than any other panel opinion. Moreover, the opinion cites *Lee* approvingly.<sup>117</sup> And the PTO appears to have erred on the side of caution in interpreting the somewhat confusing signals sent by the Federal Circuit.<sup>118</sup> Its Manual of Patent

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111. 117 F.App'x 739, 744 (Fed. Cir. 2004) (unpublished opinion).

112. *Id.* at 745–46 (Dyk, J., dissenting).

113. 320 F.3d 1310, 1315 (Fed. Cir. 2003).

114. *See id.* (stating that “examiners and administrative patent judges on the Board are responsible for making findings . . . as to the meaning of prior art references”).

115. 441 F.3d 977 (Fed. Cir. 2006).

116. *Id.* at 989.

117. *See, e.g., id.* at 988 (citing *Lee* for the proposition that “articulated reasoning” is required to reject a patent on obviousness grounds).

118. A forthcoming article reviewing cases in which the Federal Circuit has explicitly discussed a motivation to combine requirement argues that the court tends to require written documentation if the case involves complex technology. *See* Christopher Cotropia, *Patent Law Viewed Through an Evidentiary Lens: The “Suggestion Test” as a Rule of Evidence* (Tulane Pub. Law Research Paper No. 06-03, 2006), available at <http://ssrn.com/abstract=893965>. Leaving aside the issue of normative attractiveness (it is not clear, for example, why artisans in complex areas should be required to provide written documentation of knowledge that represents common sense any more than artisans in less complex areas), this argument is open to question as a descriptive matter. The *Kahn* case arguably involves technology that is quite complex. Moreover, cases such as *Berg* are combination cases involving technology that is quite complex. *Berg* is presumably excluded from Cotropia's analysis because the decision does not explicitly discuss the motivation to combine test. This results in a skewed sample: if



Examining Procedure prominently cites the statements in *Lee* and the *Zurko* case on remand to caution examiners against statements of official notice that are “unsupported by documentary evidence.”<sup>119</sup>

On first examination, given that section 282 does not displace the APA, it might appear that a parallel arbitrary and capricious standard also applies to judicial review of factfinding in PTO patent grants. However, administrative law doctrine allows—and, indeed, may require—differentiation between grants and denials. There is good reason to believe that courts, including the Supreme Court, sometimes tailor review of agency decisions to the rigor of the agency process. Indeed, in the *Dickinson v. Zurko* case itself, the Court noted that “the presence of internal agency review [is one factor that] will often prove more influential in respect to outcome than will the applicable standard of review.”<sup>120</sup> At the PTO, factfinding in the context of denials goes through precisely the sort of internal agency review to which the *Zurko* opinion alludes. As discussed further below,<sup>121</sup> a denial by the patent examiner is reviewed by the BPAI, and this Board reverses a very significant percentage of examiner determinations. Moreover, unlike appeals of patent denials, which do not typically involve new prior art, challenges to patent grants generally involve new prior art (or other factual information) on which the PTO has not articulated a position. Under standard administrative law doctrine (and as a matter of logic), no deference can be owed to factfinding that the PTO has not done. Thus, to the extent that, as a normative matter, we want courts to treat factfinding in PTO denials and grants asymmetrically, administrative law doctrine provides for that result. We discuss these issues further in Part IV.

## 2. Legal Determinations

With respect to judicial review of legal determinations, the language of the APA itself has played a relatively small role in the major Supreme Court cases. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*<sup>122</sup> did not even cite the APA, and in *United States v. Mead Corp.*,<sup>123</sup> the Court invoked the APA but did not primarily rely on it.<sup>124</sup> This does not mean, however, that the broad application of administrative law standards that characterizes review of factfinding is absent in the case of review of legal determinations. On the contrary, the Supreme Court has put forward a set of standards of review for agency legal

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certain judges on the Federal Circuit want to avoid aggressive review, they will simply omit explicit discussion of the test.

119. See U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 2144.03(B) (8th ed. 2005).

120. 527 U.S. 150, 163 (1999).

121. See *infra* notes 251–52 and accompanying text.

122. 467 U.S. 837 (1984).

123. 533 U.S. 218 (2001).

124. See *id.* at 227, 229; see also John F. Duffy, *Administrative Common Law in Judicial Review*, 77 TEX. L. REV. 113, 189–91 (1998) (noting that the Supreme Court's *Chevron* opinion did not mention or consider the APA).

interpretations that apply to all such interpretations by all agencies, unless Congress specifically provides otherwise.<sup>125</sup> Thus, as with findings of fact, lower courts are not free to fashion their own standards or modify existing ones in the context of particular agencies. The same broad principles of administrative law apply to all agencies—including, of course, the PTO.

Before 2000, many courts and commentators believed that *Chevron* applied when an agency interpreted a statute that it administered in the course of a final, authoritative agency action.<sup>126</sup> The only significant exception to this rule involved legal interpretations made in regulations by agencies that did not have authority to issue regulations.<sup>127</sup> Under *Chevron*, if the statute is clear, then courts do not defer and instead must give effect to congressional intent; if the statute is silent or ambiguous on the specific issue, then courts defer to the agency's interpretation as long as it is reasonable.<sup>128</sup> The relevance for entities like the PTO was that, before 2000, it seemed that its interpretations of the Patent Act (which it is authorized to administer through adjudication) would generally be subject to *Chevron* deference when those interpretations were contained in its adjudications of patent validity.<sup>129</sup>

In the 2000 case of *Christensen v. Harris County*, the Supreme Court held that agency opinion letters were not entitled to *Chevron* deference.<sup>130</sup> More dramatically, in its 2001 *Mead* opinion, the Court narrowed the scope of *Chevron* deference.<sup>131</sup> The precise import of the *Mead* decision, particularly as interpreted through the Court's subsequent decision in *Barnhart v. Walton*,<sup>132</sup> has been the subject of vigorous scholarly commentary.<sup>133</sup> However, a few basic

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125. See *infra* text accompanying notes 126–139.

126. See, e.g., Thomas W. Merrill & Kristin E. Hickman, *Chevron's Domain*, 89 GEO. L.J. 833, 838–39 (2001) (describing the very broad role that most courts and commentators assumed *Chevron* played); Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2093 (1990) (“*Chevron* might be taken to suggest that whenever an agency is entrusted with implementing power—whether to be exercised through rulemaking or adjudication—agency interpretations in the course of exercising that power are entitled to respect so long as they are reasonable.”).

127. See *EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 257 (1991) (rejecting EEOC's claim that Title VII applies extraterritorially in part because the agency did not deserve significant deference due to the fact that Congress failed to grant rulemaking authority to the agency).

128. See *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842–44 (1984).

129. See Rai, *Addressing the Patent Gold Rush*, *supra* note 4, at 225 n.95 (citing *INS v. Aguirre-Aguirre*, 526 U.S. 415, 424 (1999), for the proposition that non-rulemaking agencies entrusted with adjudicatory power were entitled to deference for interpretations issued during adjudication, formal or informal). Although *Mead* appears to suggest that the *Aguirre-Aguirre* case involved formal adjudication, see *United States v. Mead Corp.*, 533 U.S. 218, 230 n.12 (2001), this suggestion is misleading.

130. 529 U.S. 576, 587 (2000).

131. See generally *Mead*, 533 U.S. 218.

132. 535 U.S. 212 (2002).

133. See generally, e.g., Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467 (2002); Thomas W. Merrill, *The Mead Doctrine: Rules and Standards, Meta-Rules and Meta-Standards*, 54 ADMIN. L. REV. 807 (2002); Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187 (2006); Adrian Vermuele, *Introduction: Mead in the Trenches, Recent Decisions of the United States Court of Appeals for the District of Columbia Circuit*, 71 GEO. WASH. L. REV. 347 (2003).

principles are clear. As an initial matter, the Court's position is that the default judicial treatment of agency legal interpretations of an unclear statute<sup>134</sup> is that articulated in the 1944 case *Skidmore v. Swift & Co.*<sup>135</sup> *Mead* found that *Skidmore* applies except "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority."<sup>136</sup> In those circumstances, *Chevron* applies. The emphasis that the *Mead* Court placed on congressional intent to delegate authority led it to conclude that the precise determination of when *Chevron* deference applies would be specific to particular statutes. Nonetheless, the Court stated "[i]t is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force."<sup>137</sup> The Court then suggested that either informal rulemaking or formal adjudication would ordinarily satisfy this standard.<sup>138</sup> Similarly, although the opinion in *Barnhart* emphasized the need for case-by-case inquiry,<sup>139</sup> the Court did not disturb the principle that formal procedure was

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134. If a statute is clear, then courts do not defer to the agency's legal determination. See *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842–43 (1984). This is known as "*Chevron* step one" because that case articulated two steps (the second entails very great deference to agency interpretations of an unclear statute). The notion that courts do not defer if the statute is clear did not start with *Chevron*. *Chevron's* innovation was its holding that, if the statute does not speak to the precise question at issue, then courts permit any reasonable agency interpretation. See *id.* at 843.

It may be that the level of clarity necessary to satisfy *Chevron* step one (meaning that Congress has already answered the relevant question) is different from the level of clarity necessary to satisfy the clarity question for *Skidmore/Mead*, but the Court did not address this question in *Mead*. For an argument that step one is the same in both contexts, see Ronald M. Levin, *Mead and the Prospective Exercise of Discretion*, 54 Admin. L. Rev. 771, 778–81 (2002).

135. See 323 U.S. 134, 140 (1944) (asserting a sliding scale balancing test for deference). The *Mead* Court's focus on *Skidmore* is significant for another reason. Some pre-*Chevron* cases other than *Skidmore* had distinguished pure questions of law from applications of law to fact (sometimes called mixed questions of law and fact), according no deference to the former and substantial deference to the latter. See *NLRB v. Hearst Publ'ns, Inc.*, 322 U.S. 111, 131 (1944) (a pre-APA case according no deference to a pure question of law and substantial deference to an application of law to fact); *Gray v. Powell*, 314 U.S. 402 (1941) (same). But see *Packard Motor Car Co. v. NLRB*, 330 U.S. 485 (1947) (according no deference to an application of law to fact, involving the same statute that was at issue in *Hearst*); GARY LAWSON, *FEDERAL ADMINISTRATIVE LAW* 433–35 (3d ed. 2004) (noting that "[e]ven today, *Packard* is widely viewed as inconsistent with at least *Hearst*" because it did not defer to the NLRB's application of law to fact). *Mead* did not cite to any of those cases or mention the possible revival of that distinction, and instead applied *Skidmore* deference to the legal determination in that case—a legal determination that was an application of law to fact. See *Mead*, 533 U.S. at 237–38. Thus *Mead* does not support drawing a distinction between pure legal questions and mixed questions. See Barron & Kagan, *supra* note 56, at 226 (stating that "*Mead* does not revive the distinction between pure questions of law and mixed questions of law and fact that in part determined the level of deference prior to *Chevron*").

136. 533 U.S. at 226–27.

137. *Id.* at 230.

138. *Id.* at 230–31.

139. See *Barnhart v. Walton*, 535 U.S. 212, 222 (2002) (emphasizing factors such as the "interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to

sufficient (if not always necessary) to infer congressional delegation and hence *Chevron* deference.

As a conceptual matter, the difference between the approach taken by *Skidmore* and *Chevron* deference is nontrivial. *Skidmore* stated that “[t]he weight [accorded to an administrative] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”<sup>140</sup> As the Court noted in *Mead*, *Skidmore* entails a sliding scale of weight for an agency’s determination from “great respect” to “near indifference,” depending on factors like the agency’s consistency in maintaining its interpretation and the thoroughness of its procedures.<sup>141</sup> By contrast, under *Chevron*, courts will defer to “a reasonable interpretation” of an unclear statute, regardless of the thoroughness of its reasoning or its consistency with earlier or later pronouncements.<sup>142</sup> Indeed, in *Chevron* itself the agency legal interpretation at issue conflicted with earlier interpretations the agency had made (and thus would have been entitled to little deference under *Skidmore*), but the Supreme Court deferred nonetheless.<sup>143</sup> Unsurprisingly, agency interpretations of statutes deemed to be unclear are almost always “reasonable,” and thus permissible, under the *Chevron* analy-

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administration of the statute, . . . and the careful consideration the Agency has given the question over a long period of time”).

140. 323 U.S. at 140; see *Mead*, 533 U.S. at 228 (stating that “Justice Jackson summed things up in *Skidmore v. Swift & Co.*” and then quoting this exact language); *id.* (“The fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency’s care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency’s position.”).

141. 533 U.S. at 228. Justice Scalia, in his *Mead* dissent, suggested that *Skidmore* deference is more apparent than real. See *id.* at 247 (“*Skidmore* deference gives the agency’s current position some vague and uncertain amount of respect . . .”); *id.* at 250 (“[T]he rule of *Skidmore* deference is an empty truism and a trifling statement of the obvious . . .”); *id.* at 241 (“The Court has largely replaced *Chevron*, in other words, with that test most beloved by a court unwilling to be held to rules (and most feared by litigants who want to know what to expect): th’ol’ ‘totality of the circumstances’ test.”); *id.* at 239 (referring to “so-called *Skidmore* deference”). But, Justice Scalia overstates the case. *Skidmore* is not across-the-board deference like *Chevron* is, to be sure, but it still directs courts to defer to judgments that they would not reach in the first instance where the agency has followed procedures that tend to show that the agency itself has acted with care.

142. *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 844 (1984).

143. *Id.* at 853–59 (noting changes in EPA interpretations of the statutory term “source”). *Matz v. Household International Tax Reduction Investment Plan*, 265 F.3d 572 (7th Cir. 2001), presents a particularly clear example of the difference in outcomes that can result from the application of *Skidmore* deference instead of *Chevron* deference. In that case, the Seventh Circuit (shortly before *Mead* was decided) found that *Chevron* deference applied to an IRS interpretation (presented in an amicus brief), and it found the interpretation reasonable under *Chevron*. The Supreme Court remanded the case for reconsideration in light of *Mead*. On remand, the Seventh Circuit held that, in light of *Mead*, the IRS interpretation was entitled only to *Skidmore* deference, and it found the interpretation unpersuasive under *Skidmore*. *Id.* at 575–76. We discuss the general question of whether changes in levels of deference affect outcomes in Part IV.

sis.<sup>144</sup> In fact, in the more than twenty years since the *Chevron* test has been in force, only two Supreme Court cases have held that an administrative interpretation of an unclear statute was unreasonable and hence invalid.<sup>145</sup>

For many agencies, the relevant organic statutes often do not speak precisely to the question at issue. Similarly, the patent statute's standards for patent validity allow for some legal interpretation. For example, as we discussed earlier, the Federal Circuit has interpreted the language of the patent statute's nonobviousness standard to allow for patentability where an invention is "obvious to try" but nonetheless has only a limited possibility of success.<sup>146</sup> The Supreme Court has also engaged in legal interpretation of the patent statute regarding nonobviousness. It has held that courts may invoke various "secondary considerations"—"commercial success, long felt but unsolved needs, failure of others, etc." as proxies for technical nonobviousness.<sup>147</sup> Although these secondary considerations are not mentioned in the statutory language, the Supreme Court treats them as a mechanism for determining the issue of technical obviousness that is mentioned in the statute. Legal interpretation most often comes into play because patent validity determinations such as nonobviousness require the application of legal standards to underlying factual findings. Under the Supreme Court's jurisprudence, *Chevron* applies both to pure questions of legal interpretation and to the interpretation involved in applying legal standards to factual findings, and nothing in *Mead* suggests a differentiation between pure and applied interpretations.<sup>148</sup>

Thus, when the PTO makes a determination of patent validity, it engages not only in factfinding but also in legal interpretation—the application of law to fact. So how does the choice between *Chevron* and *Skidmore* play out for the PTO? In contrast to most agencies that regulate areas characterized by technical complexity, the PTO generally engages in neither of the proceedings—informal rulemaking or formal adjudication—that the *Mead* Court indicated would clearly merit deference. First, unlike most significant agencies, the PTO does not have any significant substantive rulemaking authority. Federal statutes give the PTO authority to make rules on a variety of procedural matters (for example, how

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144. As many commentators have noted, the central hurdle in *Chevron* cases is clarity—i.e., did Congress answer the relevant question, such that there is no reason to look to the agency's interpretation. See Rebecca Hanner White, *Arbitration and the Administrative State*, 38 WAKE FOREST L. REV. 1283, 1310 (2003) (discussing the importance and centrality of the determination whether the statute is clear).

145. See *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 481 (2001); *AT&T Corp. v. Iowa Utils. Bd.*, 525 U.S. 366, 392 (1999). This is not to suggest, however, that agencies always win under *Chevron*. Agencies often lose under *Chevron*'s first step, which asks whether Congress has directly spoken to the relevant issue. See, e.g., *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132–33 (2000) (rejecting the agency's interpretation at *Chevron* step one).

146. See *supra* notes 27–32 and accompanying text.

147. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

148. See *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 (1987) (applying *Chevron* to an agency's application of law to fact); *supra* note 135 (discussing *Mead*'s lack of support for a distinction between pure questions of law and applications of law to fact).

much money to charge applicants) and in a few specified substantive contexts (for instance, with respect to rejected patent applications, “[t]he Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.”)<sup>149</sup> But the statutes contain no general grant of substantive rulemaking authority, and thus the PTO lacks the power to issue binding rules setting out general requirements for patents.<sup>150</sup> Second, the PTO does not conduct adjudications that would qualify as formal adjudications for APA purposes. Formal adjudications under the APA are trial-type oral hearings conducted by an impartial presiding officer in which the parties are entitled to present evidence and cross-examine, and the officer’s decision must be based solely on the record.<sup>151</sup> The PTO does have explicit authority to administer the patent statute through adjudications of individual patents, but it has no proceedings that bear these hallmarks of formal adjudication.<sup>152</sup>

The *Mead* Court did explicitly leave open the possibility that *Chevron* deference could apply to agency actions that did not constitute either informal rulemakings or formal adjudications but nonetheless did entail a congressional “delegat[ion] [of] authority to the agency generally to make rules carrying the force of law.”<sup>153</sup> And the PTO is of course authorized to make legally binding determinations—that is, determinations of patentability—via informal adjudication. But *Mead* suggests that an agency action that lacks precedential value does not have the “force of law.”<sup>154</sup> It also indicates that decisions such as tariff rulings that are “churned out” at high frequency by low-level officials are unlikely to have the “force of law.”<sup>155</sup> The tariff rulings at issue in *Mead* bear a

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149. 35 U.S.C. § 132(b) (2000). The broadest rulemaking authority conferred on the PTO is delineated in 35 U.S.C. § 2(b)(2), and even that authority is fairly narrow, focusing on the PTO’s internal procedures. *See* 35 U.S.C. § 2(b)(2) (2000) (providing that the PTO may establish regulations “govern[ing] the conduct of proceedings in the Office, . . . facilitat[ing] and expedit[ing] the processing of patent applications, . . . govern[ing] the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office, . . . recogniz[ing] the public interest in continuing to safeguard broad access to the United States patent system through the reduced fee structure for small entities . . . and provid[ing] for the development of a performance-based process that includes quantitative and qualitative measures and standards for evaluating cost-effectiveness and is consistent with the principles of impartiality and competitiveness.”).

150. *See* *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) (“[T]he broadest of the PTO’s rulemaking powers . . . authorizes the Commissioner to promulgate regulations directed only to ‘the conduct of proceedings in the [PTO]’; it does NOT grant the Commissioner the authority to issue substantive rules. Because Congress has not vested the Commissioner with any general substantive rulemaking power, the ‘Final Determination’ at issue in this case cannot possibly have the ‘force and effect of law.’” (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979); *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991)) (internal citations omitted)).

151. *See* 5 U.S.C. § 556 (2000). As we noted above, the APA permits some formal hearings to be based on written submissions, but none of the exceptions applies to patent decisions. *See supra* note 88.

152. *Cf.* 35 U.S.C. § 2(a)(1) (2000) (stating that the Patent and Trademark Office “shall be responsible for the granting and issuing of patents and the registration of trademarks”).

153. *United States v. Mead Corp.*, 533 U.S. 218, 226–27, 230–31 (2001).

154. *Id.* at 232–33 (emphasizing precedential value, and the importance of the challenged adjudications’ lack of precedential value, in determining that *Chevron* deference did not apply to them).

155. *Id.* at 233.

striking resemblance to patent grants by PTO examiners. PTO patent grants lack precedential value, and the four thousand examiners who work at the PTO grant almost 150,000 of them per year.<sup>156</sup> Thus PTO legal interpretations issued in the context of grants are probably subject to the sliding scale of *Skidmore* deference.

With respect to legal interpretations issued in patent denials, the issue is less clear. Unlike patent grants, patent denials have to go through several layers of internal agency review—internal review at the BPAI as well as a decision by the PTO's Solicitor General to defend an appeal to the Federal Circuit. So patent denials might be entitled to *Chevron* deference. But even if *Skidmore* is the correct approach, it would mandate more deference in the case of a denial, where the PTO's decisionmaking has gone through several layers of internal agency review, and less deference in the case of a grant, where such internal processes do not exist.

The Federal Circuit's actual decisions with respect to PTO legal determinations tell an interesting story. In 1997, the Federal Circuit concluded that *Chevron* did not apply to PTO patent denials.<sup>157</sup> Perhaps this demonstrated acumen: the Supreme Court never held that the sort of informal adjudications implemented by the PTO—with some elements of formality but clearly falling short of the requirements of a formal adjudication under sections 556 and 557—would in fact receive *Chevron* deference. Commentators, and other circuits, widely believed that *Chevron* deference applied in such situations, but maybe they were not as careful as the Federal Circuit.<sup>158</sup> The alternative explanation is that the Federal Circuit was not prescient but lucky: it did not apply *Chevron*, as it did not apply the APA, because it mistakenly believed that ordinary principles of administrative law did not govern its review of the PTO. On this theory, *Zurko* disabused the Federal Circuit of that notion, but *Mead* allowed it to avoid the strong form of deference delineated in *Chevron*. We cannot know, of course, which explanation is the correct one, but the latter seems more consistent with the Federal Circuit's actions with respect to other aspects of administrative law.

The latter explanation is also more consistent with the Federal Circuit's behavior regarding PTO legal determinations. Both before and after *Zurko*, the Federal Circuit has repeatedly stated that it grants no deference whatsoever to PTO legal interpretations. Prior to *Zurko*, many Federal Circuit cases simply

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156. U.S. Patent & Trademark Office, Calendar Year 2005 Patent Counts, [http://www.uspto.gov/go/taf/st\\_co\\_05.htm](http://www.uspto.gov/go/taf/st_co_05.htm) (last visited Nov. 2, 2006) (143,806 utility patents granted in 2005).

157. *In re Portola Packaging, Inc.*, 110 F.3d 786, 788 (Fed. Cir. 1997) (stating, without any analysis, that it would review a patent rejection claim “without deference to the Commissioner’s interpretation”). The Federal Circuit had held earlier (consistent with Supreme Court precedent) that because the PTO did not have substantive rulemaking authority, *Chevron* deference did not apply to PTO regulations. *See Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996).

158. *See supra* notes 126–29 and accompanying text.

stated flatly that they reviewed PTO legal determinations de novo.<sup>159</sup> *Zurko* did little to change this pattern: even after *Zurko*, the Federal Circuit frequently states that it owes no deference to PTO legal determinations.<sup>160</sup> Although the Federal Circuit does apply *Skidmore* deference to the actions of *other* agencies that it reviews,<sup>161</sup> it rarely cites to *Skidmore* itself (or to *Skidmore*'s progeny in the Supreme Court) when it reviews PTO actions. Instead the court relies on its own pre-*Mead* cases, which it then construes as providing for no deference whatsoever.<sup>162</sup>

Thus far, we have discussed the Federal Circuit's refusal to apply *Skidmore* deference to PTO interpretations of the statute it administers. What about the PTO's interpretation of its regulations, which are entitled to very strong deference under the Supreme Court decision in *Bowles v. Seminole Rock & Sand Co.*?<sup>163</sup> Before *Zurko*, the Federal Circuit had similarly stated that it granted no deference to PTO interpretations of its own regulations. After *Zurko*, the Federal Circuit confronted this question again in *Dethmers Manufacturing Co. v. Automatic Equipment Manufacturing Co.*, and the court decided that it would continue to grant no deference.<sup>164</sup> Judge Dyk issued a dissent cogently arguing that *Zurko* changed the analysis by reminding the Federal Circuit that ordinary principles of administrative law applied to its review of the PTO.<sup>165</sup> As he noted

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159. See, e.g., *DH Tech., Inc. v. Synergystex Int'l, Inc.*, 154 F.3d 1333, 1339 (Fed. Cir. 1998) ("Statutory interpretation is a question of law, which we review de novo."); *In re Portola Packaging, Inc.*, 110 F.3d at 788 ("Whether the rejection based on the combined teachings of the Faulstich and Hunter patents was permissible under the reexamination statute raises an issue of statutory interpretation, a question of law which we review de novo, without deference to the Commissioner's interpretation." (citation omitted)).

160. See, e.g., *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1341 (Fed. Cir. 2004) ("This court reviews statutory interpretation, the central issue in this case, without deference." (citing *Merck*, 80 F.3d at 1549–50)).

161. See, e.g., *Warner-Lambert Co. v. United States*, 425 F.3d 1381, 1384–86 (Fed. Cir. 2005) (holding that a United States Customs Service classification was entitled to *Skidmore* deference); *Cathedral Candle Co. v. U.S. Int'l Trade Comm'n*, 400 F.3d 1352, 1365–66, 1370–72 (Fed. Cir. 2005) (discussing the potential application of *Skidmore* to an International Trade Commission interpretation and finding that the interpretation was entitled to *Skidmore* deference); *infra* note 162.

162. There are two post-*Zurko* cases in which the Federal Circuit has applied *Skidmore* deference to PTO actions. See generally *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377 (Fed. Cir. 2002); *BlackLight Power, Inc. v. Rogan*, 295 F.3d 1269 (Fed. Cir. 2002). In *Bayer*, the Federal Circuit stated that "[t]he district court properly accorded deference to the PTO's implementing regulations and to the PTO's interpretative 'Decision,'" and cited *Skidmore*, *Merck*, and, strikingly, Judge Dyk's dissent in *Dethmers Manufacturing Co. v. Automatic Equipment Manufacturing Co.*, 272 F.3d 1365, 1379 (Fed. Cir. 2001), treating the dissent as if it were the majority. See *Bayer*, 298 F.3d at 1381. We discuss *Dethmers* in the text.

163. 325 U.S. 410, 414 (1945) (holding that "the ultimate criterion" for judicial construction of an unclear agency regulation "is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation"); see *Pauley v. Bethenergy Mines, Inc.*, 501 U.S. 680, 702 (1991) (stating that "the Secretary's view [of the agency regulation] need only be reasonable to warrant deference"); *Ehlert v. United States*, 402 U.S. 99, 105 (1971) (deferring to the agency's "plausible construction of the language of the actual regulation").

164. 272 F.3d at 1370 (giving no deference to the PTO's interpretation of its own regulation).

165. *Id.* at 1378–79 (Dyk, J., dissenting).



in his dissent from the Federal Circuit's denial of the petition for rehearing en banc, "[o]ur decision . . . declining to give deference to the PTO interpretation, is directly inconsistent with Supreme Court decisions concerning other agencies and with our own decisions concerning other agencies."<sup>166</sup> Strikingly, the majority's only response was to rely on its pre-*Zurko* opinions refusing to defer.<sup>167</sup> For the majority of the Federal Circuit, *Zurko* apparently changed fairly little, and the administrative law rules that apply to every other agency still do not apply to the PTO.

Of course, given the broad language of patent law's central statutory provisions, many important determinations in patent law will turn on factfinding and policy rather than law. Nonetheless, the Federal Circuit's failure to mention *Skidmore* deference in its review of PTO decisions, and to adopt de novo review instead, is important. This is because the court tends to turn facts and policy into law.<sup>168</sup> For example, the court has, in a variety of important cases, reviewed de novo, as questions of law, technical (and factual) claims about what constitutes prior art and level of ordinary skill in the art.<sup>169</sup> By turning facts into law, and then ignoring *Skidmore*, the court is able to avoid deferential review altogether. As for policy, the Federal Circuit's position (discussed in the next section) is that the PTO does not make such determinations. The upshot is that the Federal Circuit often reviews PTO policy determinations de novo.

### 3. Policy Decisions and Exercises of Discretion

As we noted above, all agency decisions are divided into a few categories: findings of fact, legal interpretations, and policy determinations (which include exercises of discretion). Policy and discretion are sometimes treated separately, but more often are put together in one category. After all, all policy choices are, by definition, discretionary choices. The basis for a differentiation between the two is that some discretionary decisions have the effect of making policy for the agency, and other decisions are specific determinations whose effect is limited to the particular case.<sup>170</sup> There can be a blurring of the categories at the margins (if a specific decision is consistently applied in all cases, it may reflect—or become—agency policy), but we can usually differentiate narrow implementations from broader, legislative-like policy choices.

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166. *Dethmers Mfg. Co., Inc. v. Automatic Equip. Mfg. Co.*, 293 F.3d 1364, 1366–67 (Fed. Cir. 2002) (Dyk, J., dissenting from denial of rehearing en banc).

167. See *Dethmers*, 272 F.3d at 1370 (relying on pre-*Zurko* cases).

168. See *infra* notes 191–201; see also Rai, *Engaging Facts and Policy*, *supra* note 4, at 1052–65 (reviewing cases).

169. See, e.g., *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995) (reviewing de novo, and reversing, the PTO's determination that methods routinely used by biotechnologists are appropriate prior art for claims to gene sequences).

170. See, e.g., GARY C. BRYNER, *BUREAUCRATIC DISCRETION: LAW AND POLICY IN FEDERAL REGULATORY AGENCIES* 6 (1987) (defining “two basic kinds of discretionary authority given to administrative agencies: (1) authority to make legislative-like policy decisions, and (2) authority to decide how general policies apply to specific cases”).

When do policy and discretionary decisions arise? There has probably never been a statutory scheme that left no room for discretion. An agency that is directed to issue a particular regulation still has to decide on what date to issue it.<sup>171</sup> To pick an example from a case involving the PTO, a law that permits an agency to impose sanctions against someone who fails to comply with the agency's procedural regulations<sup>172</sup> leaves the agency's decisionmakers with some discretion to determine whether a particular action constitutes such a failure.<sup>173</sup> Policy decisions are less obviously inevitable. In reality, though, legislatures generally give agencies room to make their own judgments about how best to advance Congress's goals.<sup>174</sup> In such situations, the question for a reviewing court is that of the limits (if any) on the agency's exercise of its policymaking authority.

This last point highlights the difference between legal determinations and policy decisions. Although there is no clear distinction between the two categories,<sup>175</sup> law and policy do tend to fall on opposite sides of a spectrum. Sometimes a statute is ambiguous, and the job of an interpreter (in the first instance, the administering agency) is to put forward its best reading of the statute. On other occasions a statute uses terms that are so broad that rules of statutory construction provide limited guidance and leave the agency with a wide range of choices. So the agency does not engage in statutory construction but instead makes value judgments in light of the overall policy goals animating the statute. Agency actions often incorporate some such policy decisions. For example, when Congress directs an agency to regulate consistent with the public interest, convenience, or necessity, it is giving the agency broad policy discretion to implement those goals.<sup>176</sup> Even when a statute is more specific and directs an

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171. Even if the agency is directed to issue regulations by a certain date, it still has the discretion to decide whether to issue them on that date or at some earlier point. We are aware of no statute specifying the exact date (no later, no earlier) on which a regulation must be issued.

172. The PTO does have authority to issue regulations governing its own procedures. *See supra* note 149 and accompanying text.

173. *See Gerritsen v. Shirai*, 979 F.2d 1524, 1532 (Fed. Cir. 1992) (reviewing such a determination by the BPAI for abuse of discretion and finding that the determination was not an abuse).

174. *See, e.g.*, Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1676–78, 1711–12 (1975) (noting that there is a “large degree of agency discretion arising from the inability of Congress . . . to fashion precise directives”).

175. Indeed, some have argued that *Chevron* deference at step two is defensible precisely on the grounds that the resolution of legal ambiguities can involve determinations of policy that should be made by political actors, not courts. *See* Sunstein, *supra* note 126, at 2086; *see also* *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 845, 865 (1984) (noting that the EPA had made a “reasonable policy choice” and that it was “entirely appropriate for this political branch of the Government to make such policy choices”).

176. *See, e.g.*, 47 U.S.C. § 303 (2000) (empowering the FCC to regulate consistent with “public convenience, interest, or necessity”).

This is not to suggest that these statutes impose no limits on the agency. Even broad terms like “public interest” rule out some agency actions. *See, e.g.*, *NAACP v. Fed. Power Comm’n*, 425 U.S. 662, 671 (1976) (holding that a statutory mandate to advance the “public interest” did not enable the Federal Power Commission to prohibit employment discrimination by regulated firms because such a

agency to regulate to protect the public health, the agency still must decide how to construct a dose-response curve and where to draw the line, consistent with the public health tradeoffs in doing so.<sup>177</sup> In the case of the patent statute, a number of provisions arguably allow for some policymaking.<sup>178</sup> For example, one of the criteria for patenting in the Patent Act is that an invention be “useful.”<sup>179</sup> But the statute does not explain in any way what “useful” means. Courts, including the Supreme Court, have long interpreted utility in light of policy concerns—specifically, concerns that patents on basic research might hinder cumulative innovation.<sup>180</sup> In 2001, in response to concerns that patents over certain types of upstream genetic information could lead to transaction cost-heavy patent thickets, the PTO issued guidelines stating that utility should be given a relatively rigorous interpretation, particularly in cases involving upstream genetic information.<sup>181</sup> In so doing, it was making a policy determination.

As with findings of fact and legal interpretations, administrative law creates a scheme for review of agency policy decisions and exercises of discretion. If the organic statute provides a standard of review, then it controls. Otherwise, the APA serves as a gap-filler. Specifically, section 706(2)(A) is a catch-all provision that applies not only to challenges to agency factfinding but also to challenges to agency policy decisions and exercises of discretion.<sup>182</sup>

How do the standards of section 706(2)(A) apply in these contexts? For exercises of discretion, section 706(2)(A) specifically provides for invalidation

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regulation was beyond the purposes of the authorizing legislation). But a term like “public interest” is still quite capacious, and an agency will have many policy options within its ambit.

177. *See, e.g., Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214–15 (5th Cir. 1991) (discussing the policy determinations entailed in the EPA’s application of a statute authorizing “regulation necessary to protect adequately against . . . risk using the least burdensome requirement” (emphasis omitted) (quoting 15 U.S.C. § 2601(c) as previously codified)). Note that the current version of this statute provides: “It is the intent of Congress that the Administrator shall carry out this chapter in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this chapter.” 15 U.S.C. § 2601(c) (2000).

178. Rai, *Engaging Facts and Policy*, *supra* note 4, at 1118–19, 1126–27 (discussing provisions regarding patent scope that could be used in a manner sensitive to the need for follow-on research); *see Burk & Lemley, supra* note 14, at 1580 (discussing patent standards that the authors argue could be interpreted in a manner sensitive to policy and thus encourage innovation).

179. 35 U.S.C. § 101 (2000).

180. *See Brenner v. Manson*, 383 U.S. 519, 534–35 (1966) (“Unless and until a process is refined and developed to this point—where specific benefits exist in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”).

181. *See Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1097–99 (Jan. 5, 2001). *See generally Burk & Lemley, supra* note 14 (discussing the use of the utility standard as a policy tool). Although the PTO guidelines do not specifically state that they apply to upstream genetic information only, the responses to comments in the guidelines are drawn from this category of information. *See Utility Examination Guidelines*, 66 Fed. Reg. at 1092–98.

182. *See* 5 U.S.C. § 706(2)(A) (2000) (“[T]he reviewing court shall . . . (2) hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . .”).

based on “an abuse of discretion.” The standard that courts of appeals use in implementing this provision with respect to agency action is very lenient and very familiar to courts of appeals, because it is the standard that they routinely use in evaluating discretionary decisions of a lower court.<sup>183</sup>

Section 706(2)(A) does not include a distinct provision for review of “policy.” But courts have found that its provision for setting aside actions that are “arbitrary [or] capricious” is applicable to review of policy decisions.<sup>184</sup> How is the “arbitrary [or] capricious” standard of section 706(2)(A) applied? Under settled principles of administrative law, the answer is what is known as “hard look” review.<sup>185</sup> Under such review, a court will invalidate an agency action if the court determines that the agency failed to take a hard look at the significant considerations against its position.<sup>186</sup> If an agency fails to offer an adequate explanation for its rejection of such countervailing considerations, or promulgates a regulation that fails to take into account relevant factors, a court will invalidate the action.<sup>187</sup> Thus, to return to the example above, if a reviewing court applying ordinary administrative law were to decide that the PTO’s utility guidelines did not adequately consider arguments that there may be mechanisms for working around thickets created by patents on upstream information, the

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183. *Compare* *Interstate Commerce Comm’n v. Bhd. of Locomotive Eng’rs*, 482 U.S. 270, 278–79 (1987) (applying the abuse of discretion standard under section 706(2)(A) to review an agency’s decision), *with* *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141–43 (1997) (applying the abuse of discretion standard to a district court’s decisions to exclude evidence).

184. *See* *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983) (finding that the “arbitrary [or] capricious” standard of section 706(2)(A) applies to agency policy determinations).

185. *See id.* (adopting what is known as hard look review); *El Conejo Americano of Texas, Inc. v. Dep’t of Transp.*, 278 F.3d 17, 19–20 (D.C. Cir. 2002) (applying hard look); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 851 (D.C. Cir. 1970) (“Its supervisory function calls on the court to intervene not merely in case of procedural inadequacies, or bypassing of the mandate in the legislative charter, but more broadly if the court becomes aware, especially from a combination of danger signals, that the agency has not really taken a ‘hard look’ at the salient problems, and has not genuinely engaged in reasoned decision-making.”).

186. As the Supreme Court elaborated in *State Farm*,

The scope of review under the ‘arbitrary and capricious’ standard is narrow and a court is not to substitute its judgment for that of the agency. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’ . . . An agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). Thus, an agency’s failure to respond to alternatives to its regulation or arguments that undercut its action is “arbitrary [or] capricious” within the meaning of 5 U.S.C. § 706(2)(A).

187. *Sierra Club v. EPA*, 356 F.3d 296, 305–07 (D.C. Cir. 2004), provides a useful instantiation (and discussion) of the differences between *Chevron* and hard look review.

court might reject the PTO action.<sup>188</sup>

Just as deference to factual and legal determinations is not complete, so, too, deference to policy determinations leaves a court with room to reach its own conclusions about the agency's handling of the policy decisions. Indeed, of the three forms of review, hard look review has proved to have the most bite in the ordinary administrative law context (that is, outside of the world of Federal Circuit review of the PTO). Invalidations based on faulty factfinding are fairly uncommon. And when *Chevron* applies to an agency's legal interpretation, courts very rarely invalidate agency action on the grounds that the agency's interpretation of an unclear statute was unreasonable.<sup>189</sup> Actions entitled to *Skidmore* deference receive less deference, but most agencies (though not the PTO) are entitled to *Chevron* deference and generally receive such deference for their key actions (because they are embodied in informal rulemaking). The most common basis courts invoke to strike down agency actions is that the agency failed to take a hard look at the arguments for it to act otherwise.<sup>190</sup>

How does the Federal Circuit treat PTO policy decisions and exercises of discretion? The court does recognize that the PTO exercises discretion.<sup>191</sup> However, with few exceptions, the court has not merely failed to apply the well-established principles of hard look review to PTO policy decisions. More fundamentally, in contrast to the court's treatment of other agencies that it reviews, it has failed to recognize policy decisions as a separate category of PTO behavior.<sup>192</sup> Rather, it treats PTO decisions as encompassing fact and law,

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188. Cf. John Walsh et al., *Working Through the Patent Problem*, 299 Sci. 1021, 1021 (2003) (arguing that researchers are reasonably successful in using various strategies for addressing patent thickets).

189. See *supra* note 145 and accompanying text (noting that the Supreme Court has rejected an agency's legal interpretation at *Chevron*'s second step on only two occasions).

190. See MURRAY J. HORN, *THE POLITICAL ECONOMY OF PUBLIC ADMINISTRATION* 64 (James E. Alt & Douglass C. North eds., 1995) (reporting that "most agency decisions are reversed because of inadequate reasoning from the facts"); Frank B. Cross, *Shattering the Fragile Case for Judicial Review of Rulemaking*, 85 VA. L. REV. 1243, 1265 (1999) (stating that the most common basis for rejecting agency action is "judicial second-guessing of the policy wisdom of administrative decisions"); Patricia M. Wald, *Judicial Review in Midpassage: The Uneasy Partnership Between Courts and Agencies Plays On*, 32 TULSA L.J. 221, 234 (1996) (stating that the D.C. Circuit's most frequent cause for overturning agency action is that the agency did not give adequate reasons for its policy decisions).

191. See, e.g., *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). In that case, the Federal Circuit identified the relevant question as whether the PTO abused its discretion. Most of its analysis, however, addressed questions of law (specifically, whether a regulation permitted the PTO to require submission of certain information, whether the PTO's interpretation was entitled to substantial deference, and whether a different regulation allowed a regulated power to refuse the PTO's request for information). See *id.* at 1284. Only at the end of the opinion did the court consider whether the PTO had abused its discretion. See *id.* at 1284–85.

192. In its review of PTO decisions, the Federal Circuit rarely cites to the foundational Supreme Court case on hard look review—*State Farm*—or refers to its language delineating the sort of review in which appellate courts are supposed to engage. Interestingly, in the case involving the PTO in which the Federal Circuit most squarely appears to rely on *State Farm* (and thus apparently recognizes the existence of policy decisions), the Federal Circuit applies the doctrine incorrectly. See *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002). In that case, the Federal Circuit reviewed, and rejected, the PTO's decision

or sometimes fact, law, and discretion.<sup>193</sup>

In a recent case, *In re Fisher*,<sup>194</sup> the Federal Circuit provided a telling example of the court's extreme discomfort with a policy category as applied to PTO decisions. In that case, the court reviewed the PTO's decision to apply its 2001 utility guidelines in a manner that rejected a patent application for a gene fragment of unknown function. The *Fisher* court viewed the PTO's utility determination as a simple factual finding that it reviewed for substantial evidence.<sup>195</sup> The court was highly dismissive of policy arguments advanced by the PTO and its supporting amici to the effect that allowing patents on gene fragments without demonstrated utility would delay scientific progress by creating patent thickets.<sup>196</sup> Ignoring the reality that the Patent Act and administrative law permit agencies to make policy decisions, the court viewed these arguments as "public policy considerations which are more appropriately directed to Congress as the legislative branch of government."<sup>197</sup> Moreover, the court determined that the PTO's Utility Guidelines were simply advisory and that they could "be given judicial notice to the extent they do not conflict with the statute."<sup>198</sup>

Interestingly, the PTO would not have needed to draft utility guidelines driven by policy concerns if the Federal Circuit had allowed it to conduct its

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(through the BPAI) to combine two references to find obviousness. Specifically, the court rejected the BPAI's statement that "[t]he conclusion of obviousness may be made from common knowledge and common sense of a person of ordinary skill in the art without any specific hint or suggestion in a particular reference." *Id.* at 1341 (quoting the BPAI's opinion in the case). Although the Federal Circuit did not explicitly state that the BPAI's statement was a policy decision (indeed, as we discussed above, see *supra* notes 101–04 and accompanying text, motivation to combine in any particular case is a factual question, and the court treated motivation partly in that way), the court did invoke *State Farm*. See *id.* at 1344 (citing *State Farm* for the proposition that an agency must have an evidentiary basis for its findings—even under deferential review). But to the extent that the *Lee* court invoked hard look to reject reliance on common sense, its decision squarely contradicts the well-settled doctrine of official notice. See *supra* note 105 and accompanying text.

Also striking is the fact that the Federal Circuit has straightforwardly applied *State Farm* in reviewing agencies other than the PTO. See, e.g., *Timken U.S. Corp. v. United States*, 421 F.3d 1350, 1355 (Fed. Cir. 2005) (applying *State Farm* to a policy decision made by the International Trade Commission).

193. See, e.g., *In re Bogese*, 303 F.3d 1362, 1366 (Fed. Cir. 2002) ("Our review of a decision of the Board is governed by the Administrative Procedure Act, 5 U.S.C. § 706. Under that statutory provision, we will set aside legal actions of the Board that are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,' and set aside factual findings that are 'unsupported by substantial evidence.'" (citations omitted)); *In re McDaniel*, 293 F.3d 1379, 1382 (Fed. Cir. 2002) (relying on identical language). Note that the quotation uses the odd phrase "legal actions." We assume that "legal action[]" means "legal interpretation," as that sets up the parallelism with "factual findings" in the same sentence; if so, then the courts are, indeed, talking only about legal interpretations and factual findings. If, however, "legal action" means "final agency action" as that term is used in administrative law, then "legal action" might encompass policy decisions as well as discretionary actions.

194. 421 F.3d 1365 (Fed. Cir. 2005).

195. *Id.* at 1369.

196. See *id.* at 1378.

197. *Id.*

198. *Id.* at 1372 (citing prior Federal Circuit cases).

ordinary, nonobviousness-related factfinding. As Judge Rader pointed out in his *Fisher* dissent, the utility guidelines arose in large part because Federal Circuit cases in the area of genetic information have disabled the PTO.<sup>199</sup> Specifically, the Federal Circuit has overturned PTO determinations that routine methods for generating genetic information constitute relevant prior art.<sup>200</sup> Judge Rader's dissent underscores a point we made earlier—that, done properly, the type of technical factfinding required by the patent statute often serves economic policy goals reasonably well.<sup>201</sup>

Nonetheless, it bears emphasis that there will be some situations where technical standards will not comport with considerations of economic policy. For example, given the rapid advance of biotechnology, it might be technically obvious to identify a gene that could be used therapeutically. In this case, a patent right might be useful for development purposes—without a patent no one would have the incentive to develop the potential therapeutic product through the expensive clinical trial process. Indeed, the Federal Circuit's decision essentially to eliminate the nonobviousness standard in the area of gene sequencing (by stating that methods do not count as prior art for gene sequence patents) could be rationalized as a response to the fear of such a scenario.<sup>202</sup> The problem with the Federal Circuit's approach is that it does not, and cannot, distinguish between situations in which elimination of the nonobviousness standard is likely to create patent thickets and those in which such elimination may be useful for promoting drug development. Moreover, as a matter of patent doctrine, the Federal Circuit's approach to nonobviousness leads inexorably to the conclusion that such patents must be unusually narrow.<sup>203</sup> Consequently, in the therapeutic context, the Federal Circuit's approach would not provide the sort of protection necessary for further clinical development.<sup>204</sup> Only explicit consideration of policy allows for distinctions that provide the requisite level of protection at the appropriate stage of research.

Some commentators have argued that the nonobviousness requirement—and particularly the doctrine of secondary considerations—could be expanded to

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199. *Id.* at 1382 (asserting that “this court has deprived the Patent Office of the obviousness requirement for genomic inventions”).

200. *See, e.g., In re Deuel*, 51 F.3d 1552, 1557–59 (Fed. Cir. 1995).

201. *See supra* notes 33–34 and accompanying text.

202. Although they do not use this particular example, some commentators have argued that the Federal Circuit decision effectively to eliminate the obviousness standard in the area of gene sequencing may have been a *sub rosa* attempt to incorporate economic considerations. *See, e.g.,* Karen I. Boyd, *Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness*, 12 BERKELEY TECH. L.J. 311, 337–43 (1997); *see also* Burk & Lemley, *supra* note 14.

203. *See Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568–69 (Fed. Cir. 1997) (noting that “[i]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass”). A full discussion of the reasons for this link between a low nonobviousness standard and narrow patent scope is beyond the purview of this Article. Briefly, however, when the nonobviousness standard is low because the field is purportedly uncertain or risky, the scope of the inventive terrain the patent applicant can claim will be correspondingly narrow.

204. *See* Rai, *Engaging Facts and Policy*, *supra* note 4, at 1072–73.

take explicit account of economic policy arguments.<sup>205</sup> As we discussed earlier, the current secondary considerations doctrine aims to assist with the inquiry into technical nonobviousness set out in the statute.<sup>206</sup> Thus this doctrine is best seen as a legal interpretation of the statute. An economic nonobviousness criterion, by contrast, would be driven entirely by policy—it would have no clear statutory hook. But the language of the nonobviousness requirement is arguably sufficiently capacious to allow for an economic nonobviousness criterion driven entirely by policy. Thus, for example, if the PTO were faced with a grant application on a therapeutic gene that was technically obvious, it could determine, as a matter of policy, that the patent was necessary to promote development. As many commentators have noted, the cost and risk associated with taking a therapy through the clinical trials mandated by the Food and Drug Administration is substantial.<sup>207</sup> The PTO might also point out that such a patent grant would be unlikely to lead to patent thickets. Indeed, one of the reasons that the patent would be necessary in the first instance was that the likelihood of additional downstream patents was small. The Federal Circuit would (or should) then review the PTO's policy determination using the “hard look” approach—did the PTO (ideally assisted by economic advisors) consider all of the economic arguments for and against the need for such a patent?

### III. COMPARATIVE INSTITUTIONAL ANALYSIS AND JUDICIAL REVIEW

The prior two Parts have discussed the existing structure for judicial review of PTO decisionmaking (or at least what, as a matter of formal legal analysis, such judicial review should look like). The discussion so far thus answers the descriptive question of how existing administrative principles apply to the Federal Circuit's review of the PTO. That answer is sufficient to guide courts and is valuable in its own right, but it does not answer the normative question of how we would want the relationship between courts (particularly the Federal Circuit) and the PTO to be structured. In this section, we turn to normative concerns. In keeping with our discussion in Part I, our normative baseline is innovation. Thus we ask what type of judicial review is most likely to promote innovation.<sup>208</sup>

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205. See generally Merges, *supra* note 32.

206. See *supra* notes 147–48 and accompanying text.

207. See, e.g., Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003).

208. See Einer R. Elhauge, *Does Interest Group Theory Justify More Intrusive Judicial Review?*, 101 YALE L.J. 31, 48–59 (1991) (arguing for the importance of a normative baseline in institutional analysis). Because of our normative baseline, we focus here on functional normative considerations—for example, tradeoffs between expertise and capture as well as values of deliberation and accountability—as contrasted with formal structural considerations (e.g., a formal perspective on separation of powers). It bears mentioning, however, that some concerns about how administrative law doctrine, particularly the *Chevron* doctrine, may contravene formal constitutional values are arguably addressed by cases like *Mead*, which attempt to limit the domain of *Chevron* to situations where it would appear that Congress has “delegated” authority to make law to the administrative agency.



This entails a comparative analysis of the PTO and the Federal Circuit. After all, the question is what role we want each institution to play—and that is a comparative question between institutions. If we conclude, for example, that both agencies and courts do a good (or bad) job of making some set of decisions, that still leaves us with the question of how much authority we want each to have relative to the other. In what follows, we address this question through a pragmatic lens. There is an allure to concocting a *deus ex machina*—in this case, an ideal court (or courts) and agency—but that would elide the harder task of making comparative institutional choices among realistic alternatives.

#### A. JUDICIAL REVIEW GENERALLY

A fair amount has been written on the broad topic of comparative institutional analysis, providing a foundation for consideration of the relative strengths and weaknesses of administrative agencies and federal courts.<sup>209</sup> In broad outline, agencies generally have an advantage over courts in terms of institutional competence. One of the central rationales for creating administrative agencies was that they would have greater expertise and focus than generalist legislatures or courts.<sup>210</sup> The idea was to create expert agencies that would concentrate on a particular area, and thereby bring technocratic rigor to the decisionmaking process.<sup>211</sup> Even if the head (or heads) of an agency is not an expert, agencies usually have large staffs and significant research capabilities. And the agencies can request information from third parties (for example, think tanks and academic societies) to supplement their internal expertise. In contrast, courts have modest staffs, and the vast majority of the information judges receive is from

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209. A major recent commentator on comparative institutional analysis is Neil Komesar. See NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* (1994). His work does not focus on administrative agencies, but he includes them among the institutions he considers. Others have focused more specifically on legislatures versus courts. See generally GUIDO CALABRESI, *A COMMON LAW FOR THE AGE OF STATUTES* (1982); HENRY M. HART JR. & ALBERT M. SACKS, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW* (William N. Eskridge Jr. & Philip P. Frickey eds., 1994); DONALD L. HOROWITZ, *THE COURTS AND SOCIAL POLICY* 22–67 (1977); Stuart Minor Benjamin, *Proactive Legislation and the First Amendment*, 99 MICH. L. REV. 281, 332–43 (1999); Christopher L. Eisgruber, *The Most Competent Branches*, 83 GEO. L.J. 347 (1994); Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885 (2003).

210. See, e.g., Felix Frankfurter, *The Task of Administrative Law*, 75 U. PA. L. REV. 614, 621 (1927) (“[T]he inquirer [into administrative law] must have a sympathetic understanding of the major causes which led to the emergence of modern administrative law, and must be able to move freely in the world of social and economic facts with which administrative law is largely concerned.”).

211. See, e.g., JAMES M. LANDIS, *THE ADMINISTRATIVE PROCESS* 6–46 (Greenwood Press 1974) (1938) (discussing the ideas behind the development of the administrative state in the United States); Louis L. Jaffe, *James Landis and the Administrative Process*, 78 HARV. L. REV. 319 (1964); Sunstein, *supra* note 126, at 2079 (1990) (“For the twentieth century reformers, courts lacked the flexibility, powers of coordination, initiative, democratic accountability, and expertise necessary to deal with complex social problems.”).

self-selected interested parties.<sup>212</sup> As one of us has previously noted, “Judges can seek information from disinterested parties, but such procedures are ad hoc and, in part for that reason, fairly cumbersome.”<sup>213</sup> Agencies thus generally have a greater ability than courts to amass expertise and make decisions on complex, data-intensive matters.<sup>214</sup>

The advantages in competence that flow from specialization may have other drawbacks, however. The agency might be so narrowly focused that it develops tunnel vision—that is, it focuses on benefiting its own sector of the economy even though the costs imposed on society more broadly may outweigh those benefits.<sup>215</sup> More disturbingly, it may be biased, as a result of capture by narrow interests. This latter concern flows in significant part from the logic of collective action:<sup>216</sup> small groups of players with concentrated interests will have an easier time organizing, and influencing, decisionmakers than will large, diffuse groups. Concentrated costs (or benefits) make for more effective action than do diffuse costs (or benefits).<sup>217</sup>

This concern about capture is not limited to agencies, however. Although many early capture theorists saw agencies as particularly prone to capture by narrow interests, the rise of public choice theory—which assumes that all government actors maximize, at least in part, private goals to which narrow interests can cater—extends concerns about the power of narrow interests to all government actors.<sup>218</sup> The idea is that powerful interests will do a good job of supplying whatever it is that government actors seek (for example, incumbency protection in the case of representatives), and so we would expect those interests to prevail in whatever forum they appear. On this theory, all government actors—including courts—will be subject to capture, at least to some

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212. See Frederick K. Beutel, *Some Implications of Experimental Jurisprudence*, 48 HARV. L. REV. 169, 180–81 (1934); Kenneth Culp Davis, *Judicial, Legislative, and Administrative Lawmaking: A Proposed Research Service for the Supreme Court*, 71 MINN. L. REV. 1, 10–17 (1987).

213. See Benjamin, *supra* note 209, at 333–34.

214. See Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 972–75 (1992) (“[C]ourts are generalists, whereas agencies are specialists. Specialists usually have a better grasp of technical terms or the practical consequences of a decision, and thus their views should be given deference by generalists.”).

215. See, e.g., STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 11 (3d prtg. 1994) (“Tunnel vision, a classic administrative disease, arises when an agency so organizes or subdivides its tasks that each employee’s individual conscientious performance effectively carries single-minded pursuit of a single goal too far, to the point where it brings about more harm than good.”).

216. The phrase comes from the book of the same title. See MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS* (1965).

217. *Id.* at 53–57, 132–34.

218. Some suggest that public actors are motivated solely (or at least very heavily) by their private interests. See, e.g., Terry M. Moe, *The Positive Theory of Public Bureaucracy*, in *PERSPECTIVES ON PUBLIC CHOICE: A HANDBOOK* 455, 456–58 (Dennis C. Mueller ed., 1997); Roger G. Noll, *Economic Perspectives on the Politics of Regulation*, in 2 *HANDBOOK OF INDUSTRIAL ORGANIZATION* 1253, 1262–63 (Richard Schmalensee & Robert D. Willig eds., 1989).

degree.<sup>219</sup>

As the work of Neil Komesar among others illustrates, concerns about government actors being captured by narrow interests are not limited to those who accept the motivational presuppositions of public choice.<sup>220</sup> Even for those who are agnostic about motivation, or believe that government actors pursue public-regarding objectives,<sup>221</sup> capture by narrow interests seems a plausible account of the result that will occur if these interests are the most vigorous participants in the processes of governance. In the case of courts, this translates into the unexceptional proposition, long noted in the legal literature, that those repeat players with the strongest interest in the precedential or preclusive effects of a case will have a significant advantage in judicial proceedings.<sup>222</sup>

But just as the degree of competence is a comparative one between courts and agencies, so too is the likelihood of bias (in the form of capture). Saying that courts may be subject to capture does not mean that the danger of capture is as great for courts as it is for agencies. Although a few commentators have suggested that courts are more easily controlled by factions than are agencies,<sup>223</sup> the more widely held view is that courts are less likely to be captured.<sup>224</sup> This conclusion flows in significant part from the facts that agencies usually have a somewhat narrow focus; that agency officials often come from, and plan to return to, the industry that they regulate; and that powerful interest groups can help to provide agency members with benefits that they prize (budgetary clout on Capitol Hill and future employment are the two most often cited).<sup>225</sup> By contrast, judges have life tenure and thus less concern about their future employment, have salaries and budgets that are largely free from congressional

219. See Noll, *supra* note 218, at 1263.

220. See KOMESAR, *supra* note 209, at 54–58, 172–73, 192.

221. See Cynthia R. Farina & Jeffrey J. Rachlinski, *Foreword: Post-Public Choice?*, 87 CORNELL L. REV. 267, 268–70 (2002) (noting that behavioral research portrays people as less self-centered than public choice suggests); cf. Jerry L. Mashaw, *The Economics of Politics and the Understanding of Public Law*, 65 CHI.-KENT L. REV. 123, 146 (1989) (noting that critics of public choice have shown only that ideology plays some role in legislative behavior; critics “merely limit[] the appropriate claims that can be made for an economic theory of politics”).

222. See Marc Galanter, *Why the “Haves” Come Out Ahead: Speculations on the Limits of Legal Change*, 9 LAW & SOC’Y REV. 95, 97–104 (1974) (stating that “repeat players” have advantages that give them a greater chance of success than “one-shotters”); Daniel Kessler, Thomas Meites & Geoffrey Miller, *Explaining Deviations from the Fifty-Percent Rule: A Multimodal Approach to the Selection of Cases for Litigation*, 25 J. LEGAL STUD. 233, 242 (1996).

223. See Frank B. Cross, *Shattering the Fragile Case for Judicial Review of Rulemaking*, 85 VA. L. REV. 1243, 1323 (1999) (suggesting that agencies are less likely to be controlled by factions because they are guided by the President, and “the President’s broad and heterogeneous constituency renders the Executive relatively less vulnerable and creates greater concern for the broad public interest”).

224. See Robert D. Cooter, *The Objectives of Private and Public Judges*, 41 PUB. CHOICE 107, 129 (1983) (suggesting that judges tend to seek to maximize their prestige among litigants and thus are less subject to capture). See generally KOMESAR, *supra* note 209, at 10 (arguing that the courts have some comparative advantages when compared to other institutions).

225. See WILLIAM A. NISKANEN JR., BUREAUCRACY AND REPRESENTATIVE GOVERNMENT 114 (1971) (“[T]he coterminous relation of a bureaucrat’s rewards and his position implies that bureaucrat will maximize the total budget of his bureau . . .”).

meddling, and may have a greater desire for prestige (which powerful interest groups cannot easily provide).<sup>226</sup> It thus seems that, as a comparative matter, agencies have greater competence but are more likely to be subject to the blandishments of well-funded interest groups. This is not a huge surprise, of course. The theory of capture grew out of studies of agency behavior in the first place.<sup>227</sup>

What does this suggest for administrative law? The standard answer is that courts should give great deference to agencies' findings of fact and less deference to their legal interpretations and policy determinations. As to facts, the idea is that accurate factfinding in complex areas requires specialized knowledge and intimate familiarity with the underlying circumstances, so competence looms particularly large.<sup>228</sup> The advantage that courts have in terms of capture is outweighed by their difficulty in sifting through complicated technical information. The possibility of an agency's bias affecting its factfinding suggests that deference should not be complete, but the agency's great advantage in competence suggests that deference should be very great.

As contrasted with agency factfinding, an agency's legal interpretations and its policy decisions are not as dependent on the understanding of technical data. Accordingly, they can be more effectively reviewed by courts. In addition, legal and policy determinations that sweep broadly are likely to be the subject of the most intensive lobbying and thus may be the determinations we most want to insulate from the possibility of capture. These considerations suggest less judicial deference for agencies' legal and policy determinations than for their findings of fact.

The deference scheme suggested by this comparative institutional analysis is close to the system we have. As we discussed earlier, courts give very great deference to agency factfinding and less deference to policy decisions and many legal determinations.<sup>229</sup> An exception to this general conformity with comparative institutional analysis is *Chevron* deference.<sup>230</sup> As cabined by *Mead*, however, *Chevron* deference clearly applies to legal interpretations made in informal rulemakings or formal adjudications.<sup>231</sup> Although commentators have fairly criticized this emphasis on procedure as perhaps contributing unduly to ossifica-

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226. See RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 530–31 (6th ed. 2003) (noting the value of judges' "aloof disinterest" in the outcome of cases). This does not necessarily mean that judges are insulated from their private interests. Rather, it means that their private interests may more closely comport with public interests. Assuming, for example, that their private interest is in their reputation and esteem among their colleagues and litigants, those interests might be fairly closely aligned with the public interest.

227. See MARVER H. BERNSTEIN, *REGULATING BUSINESS BY INDEPENDENT COMMISSION* 79–87 (Greenwood Press 1977) (1955).

228. See, e.g., Benjamin, *supra* note 209, at 332–35.

229. See *supra* Part II.B.

230. See *supra* Part II.B.2.

231. See *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001); *supra* notes 136–39 and accompanying text (indicating that a significant level of procedural formality is sufficient, if not always necessary).

tion,<sup>232</sup> procedure can sometimes provide a defense against capture and promote normative values of deliberation and accountability. For example, the trial-type context of formal adjudications, with the parties presenting evidence and rebutting their opponents' evidence and with the hearing officer's decision based solely on the material presented at the hearing, alleviates the fear of powerful interests presenting arguments privately to the decisionmaker and more generally reduces concerns about bias affecting the agency's decision.<sup>233</sup> Informal rulemaking, by contrast, allows for precisely this sort of private communication. Because the agency's decision need not be based on the record, the result has been that the most important decisions are made by the agency outside of the routinized comment process—all of which raises serious concerns about the influence of powerful interest groups.<sup>234</sup> In sum, with the significant exception of deference to legal determinations in the context of informal rulemaking, the current regime is close to the one suggested by normative considerations.<sup>235</sup>

#### B. JUDICIAL REVIEW IN THE EXISTING PATENT SYSTEM

The PTO does not engage in informal rulemaking, so the exception noted immediately above is not an issue. But that still leaves the larger question: Does this comparative institutional analysis play out differently in the specific context of the Federal Circuit and the PTO? The short answer is a qualified “yes.” Is the Federal Circuit's specialization, and the PTO's relative weakness, sufficiently anomalous that the PTO should be subject to a special deference regime? The short answer is, quite emphatically, “no.” Although there might be reasons for the relationship between the PTO and the courts to diverge somewhat from the traditional agency/court relationship, there is no reason for major departures. In what follows, we consider what judicial review of the PTO should look like.

We begin with law and policy. The repeated exposure of Federal Circuit judges to appeals from the PTO—and appeals in patent cases more generally—

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232. Barron & Kagan, *supra* note 56, at 204 (discussing costs of APA procedures).

233. See Richard Delgado et al., *Fairness and Formality: Minimizing the Risk of Prejudice in Alternative Dispute Resolution*, 1985 WIS. L. REV. 1359, 1375–91 (finding that the rules and structure of formal adjudication tend to reduce bias, whereas informality tends to increase it).

234. See Stuart Minor Benjamin, *Evaluating E-Rulemaking: Public Participation and Political Institutions*, *Thirty-Fifth Administrative Law Issue*, 55 DUKE L.J. 893 (2006); E. Donald Elliott, *Re-inventing Rulemaking*, 41 DUKE L.J. 1490, 1492–93 (1992) (“Notice and comment rulemaking is to public participation as Japanese Kabuki theater is to human passions—a highly stylized process for displaying in a formal way the essence of something which in real life takes place in other venues.”).

235. For present purposes, we do not need to address the problem of whether, over the broad range of administrative decisionmaking, the approach set out by *Mead* will be too difficult for courts to apply. With the possible exception of patent denials, see *supra* p. 299, the domain of *Chevron* in the patent context is quite clear. Moreover, although many commentators have argued that the standard set out by *Mead* is too difficult for lower courts to apply, and that a brightline rule might be preferable, see, e.g., Merrill, *supra* note 133, at 808–09 (arguing for a “meta-rule”); Sunstein, *supra* note 133, at 194 (asserting that *Chevron* deference can be applied in “much simpler and better ways”); Vermeule, *supra* note 133, at 347 (criticizing the “increasing complexity” caused by *Mead*), *Mead* does attempt to mediate the long-standing debate over the relative attractiveness of rules versus standards by adopting a rule that procedural rigor is sufficient.

means that they have greater familiarity with the underlying statutory regime and the PTO's implementation of its authority under that regime than a generalist judge would with a typical agency that she reviews. As a result, Federal Circuit judges probably have greater-than-average expertise with respect to the PTO's legal interpretations and policy decisions.

However, concerns about bias and tunnel vision are also quite salient in the context of legal and policy determinations. Because of specialization, the possibility of bias is greater for the Federal Circuit than for the regional United States Courts of Appeals. Just as agencies can suffer from bias, so too can specialized courts.<sup>236</sup> In particular, unlike generalist courts of appeals, the Federal Circuit is closely connected with a particular bar, the patent bar. Although the patent bar has members who represent both plaintiffs and defendants in patent cases, patent lawyers generally have an interest in a patent system that is relatively robust.<sup>237</sup> Thus, the Federal Circuit is not likely to hear many arguments that raise fundamental legal and policy questions about the system. Notably, various empirical studies indicate that the Federal Circuit is substantially less likely to find patents invalid than its predecessor regional courts of appeals.<sup>238</sup> While this is hardly definitive evidence of capture—the regional courts of appeals may well have been too demanding in their validity standards, and some empirical studies also suggest that the Federal Circuit may be more likely than its predecessors to read patents narrowly and hence find them not infringed<sup>239</sup>—it is suggestive of capture.

This is not to suggest that the PTO is unbiased. To the contrary, the problem of capture arises with respect to the PTO as well. It is favorably disposed to patent holders. Not only is the incentive system of individual examiners strongly tilted towards granting patents, but the agency as a whole is funded by applicant fees.<sup>240</sup>

The point is simply that just as expertise is relative, so too is bias. In this

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236. See, e.g., Richard L. Revesz, *Specialized Courts and the Administrative Lawmaking System*, 138 U. PA. L. REV. 1111, 1146, 1153 (1990) (arguing that specialized courts tend to control administrative action less effectively than generalist courts); Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 3–4 (1989) (noting that specialized judges may be susceptible to capture).

237. See generally ADAM JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS* (2004) (noting that the proliferation of patents has led to a proliferation of patent litigation, rendering lawyers the “key players” in patent struggles).

238. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205–06 (1998); Matthew D. Henry & John L. Turner, *The Court of Appeals for the Federal Circuit's Impact on Patent Litigation*, 35 J. LEGAL STUD. 85 (2006); Glynn S. Lunney, *E-Obviousness*, 7 MICH. TELECOMM. & TECH. L. REV. 363, 365 (2001); Glynn S. Lunney, *Patent Law, the Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 SUP. CT. ECON. REV. 1, 1–2 (2004).

239. Lunney, *supra* note 238; Henry & Turner, *supra* note 238.

240. See *infra* notes 247–53 and accompanying text (discussing the PTO's incentives to grant patents); Joseph Scott Miller, *This Bitter Has Some Sweet: Potential Antitrust Enforcement Benefits From Patent Law's Procedural Rules*, 70 ANTITRUST L.J. 875, 893 n.48 (2003) (noting that the sole funding source for the PTO is applicant fees).

case, it appears that having a specialized court that reviews PTO decisions has produced in the Federal Circuit—relative to the regional courts of appeals—both greater bias and greater expertise about the statutory scheme and PTO processes.

So how, if at all, should the Federal Circuit's somewhat greater bias, and somewhat greater expertise, about legal and policy determinations change the deference calculus outlined in the previous section? The problem with answering that question is that expertise and capture pull in opposite directions, and it is difficult to determine whether one outweighs the other. What seems clear, though, is that the change from the deference template discussed in Part III.A would be fairly small. That is, given that bias and expertise counteract one another, it seems unlikely that either would be so much greater than the other that it would change significantly the normatively attractive standard of review.<sup>241</sup>

What about factfinding? As we discussed above, the expertise factor is most important in the area of factfinding. In the context of nonobviousness, for example, expertise is necessary not only for purposes of applying the so-called *Graham* considerations (for example, the relationship of the invention to the prior art and the ordinary skill in the field),<sup>242</sup> but it also may be important in guarding against hindsight bias.<sup>243</sup> The judges of the Federal Circuit are certainly more steeped in patent jurisprudence than generalist judges, and the Federal Circuit does have a small technical staff. But it is not clear that Federal Circuit judges know more about any given technology than a generalist judge would. The specialization required to understand the underlying technologies is so great that a background in patent law—or even a general science background—will provide little advantage when a judge is dealing with factual findings on a complex technological matter.<sup>244</sup> Thus, the few Federal Circuit judges with technical training likely will find that training relevant in relatively few cases (and the Federal Circuit judges without such training will not have even that modest benefit).<sup>245</sup>

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241. We discuss the desirability of very small changes to the level of deference in Part IV.C.

242. See *supra* note 147 and accompanying text.

243. See Gregory Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. (forthcoming 2006) (arguing, based on experiment with law students, that hindsight bias is pervasive, but noting studies indicating that it may be less pervasive among experts).

244. See Rai, *Engaging Facts and Policy*, *supra* note 4, at 1069 (“[B]ecause scientific knowledge is highly localized, training in one area of science or technology simply does not transfer into other areas.”); see also Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 766 (2002). Technical training may be particularly relevant to factfinding in patent law because there is reason to believe that individuals with technical training may be less likely than laypersons to suffer from hindsight bias in their determinations of whether an invention is obvious. See Mandel, *supra* note 243.

245. Judges Linn, Gajarsa, Newman, and Lourie have technical backgrounds. See U.S. Court of Appeals for the Federal Circuit, *Judicial Biographies*, <http://www.fedcir.gov/judgbios.html> (last visited Sept. 22, 2006).

Moreover, even if Federal Circuit judges did, on average, have more factfinding expertise than generalist judges, that expertise still pales in comparison to that of the PTO. In contrast to the judges' limited technical backgrounds and small staffs, the PTO has thousands of patent examiners with training in multiple different fields of technology. Any increase in expertise of the Federal Circuit over a generalist court is so marginal, in light of the greater resources of the PTO, that such specialization should make little, if any, difference in the deference accorded to the PTO on factfinding.<sup>246</sup>

There is a different consideration, though, that suggests a bigger relative change from the generic deference template outlined above—the context for PTO patent denials versus patent grants.<sup>247</sup> The current structure of patent examination makes PTO denials sufficiently difficult that there is strong reason to believe that false positives (patent grants that should be denials) are much more common than false negatives (denials that should be grants). Under the patent statute, the patent examiner has the burden of demonstrating lack of patentability.<sup>248</sup> Moreover, because of the severe resource constraints under which the patent office operates, the examiner must typically meet this burden in about eighteen hours.<sup>249</sup> The nature of patent procedure also militates in favor of patent grants. Specifically, because an applicant can always file a continuation application if her initial application is denied, there need be no such thing as a “final” rejection of an application. Determined applicants can “wear down” the examiner through the filing of multiple continuations.<sup>250</sup> Most importantly, a patent denial diverges from a patent grant in that it goes through significant appellate review even before it reaches the Federal Circuit. Such review is conducted by three-judge panels of the BPAI. Notably, review by BPAI judges, who are familiar with the relevant law and frequently have some skill in the relevant science, is far from a rubber stamp for examiner denials. To the contrary, in fiscal year 2004, the BPAI affirmed examiner denials in only

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246. And, as we discuss in Part IV.C, those small changes are likely not worth the trouble.

247. See Jay P. Kesan & Andres A. Gallo, *Why “Bad” Patents Survive in the Market and How Should We Change?—The Private and Social Costs Of Patents*, 55 EMORY L.J. 61, 76 (2006) (“The Patent Office has an incentive to grant patents without being unduly concerned about the quality of its examination process.”).

248. See 35 U.S.C. § 102 (2000 & Supp. II 2002) (stating that “[a] person shall be entitled to a patent unless” the examiner shows that she has failed to meet certain requirements of patentability).

249. See Lemley, *supra* note 38, at 1500 (stating that a patent examiner spends an average of eighteen hours on a patent application); see also FTC REPORT, *supra* note 2, ch. 5, at 5 (giving estimates of the total amount of time available to examine a patent application that range from eight to twenty-five hours).

250. See Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 75 (2004) (stating that “an examiner faced with a determined applicant has every incentive to give in and allow the patent”). Of course, to the extent that continuation proceedings were curtailed considerably (as is the current PTO plan), this argument would no longer militate in favor of accuracy in patent denial. Even with reform of continuations, however, the other arguments in the text supporting accuracy of patent denials would still counsel in favor of significant deference.



37.1% of cases.<sup>251</sup> Moreover, even those denials that were actually reviewed by the BPAI represent only a very select subset of all patent denials. In fiscal year 2003, examiners from most technology classes reopened the case, or simply allowed the application, more than 50% of the time after an appeal brief to the BPAI had been filed.<sup>252</sup>

The flip side of the costs of denial is that decisions to grant patents should be subject to less deference. That is, the greater likelihood of false positives than false negatives counsels courts to treat grants more warily than would an ordinary court reviewing an ordinary agency. The disincentives for PTO patent denials are sufficiently great that bifurcated, or asymmetric, review would be attractive—with patent denials subject to more deference than patent grants.<sup>253</sup>

#### IV. BRINGING ADMINISTRATIVE LAW DOCTRINE AND NORMATIVELY ATTRACTIVE STANDARDS TOGETHER

A comparative institutional analysis of the Federal Circuit and the PTO suggests that a normatively attractive level of deference could differ in certain ways from the deference provided by administrative law doctrine. Thus, the last remaining questions are how (if at all) the normatively attractive answer might converge with the doctrine, and whether such convergence is worth the trouble.

##### A. STATUTORY OR JUDICIAL ALTERATION OF THE STANDARDS OF REVIEW

The most straightforward and safest way to create particular levels of deference is for Congress to change the statutory scheme. The degree of deference courts should accord to agency decisions is subject to congressional control, and Congress can exercise this control by specifying the standards of review that the Federal Circuit should apply when considering various kinds of PTO actions. The APA, after all, is just a set of default rules, and agencies' organic acts often

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251. See United States Patent & Trademark Office, Fiscal Year 2004, <http://www.uspto.gov/web/offices/dcom/bpai/docs/receipts/fy2004.htm> (last visited Oct. 22, 2006) (showing that 37.1% of denials were affirmed by the BPAI).

252. In total, 59.4% of appeals resulted in either allowance or reopening of the case. Examiner Actions after Submission of Appeal Brief (on file with authors). In Part IV, we discuss trends in BPAI reversals and appeals to the BPAI as a function of changing standards of review by the Federal Circuit.

253. One might favor a policy of deference to PTO factfinding in an ordinary patent denial but nonetheless ask whether such a policy will have much impact. After all, only about 1% of patent dispositions ultimately get appealed to the BPAI. Approximately 1% of BPAI dispositions then get appealed to the Federal Circuit. Interview with James Toupin, USPTO General Counsel (Oct. 13, 2004) (on file with authors). The small numbers notwithstanding, direct appeals from the BPAI to the Federal Circuit appear to be the cases that are most "visible" to patent examiners, as well as to the higher level PTO administration. Unlike appeals from district court litigation, which tend to be decided many years after the original patent decision, appeals from the BPAI are decided soon after the patent decision is made. Indeed, they may be decided within the tenure of the average patent examiner. Additionally, these appeals represent the most direct evaluation of the PTO. By contrast, in cases appealed from district courts, the factfinding that is at issue is generally that of the district court. And our review of the cases emphasized by the Manual of Patent Examining Procedure fortifies the argument that the PTO pays disproportionate attention to direct appeals.

contain their own specific rules that govern.<sup>254</sup> So Congress could amend the Patent Act to create whatever particular rules for review of the PTO that it desired.

In fact, the statutory tweaks could be fairly minor. The default APA-level deference for PTO factfinding mandated by *Dickinson v. Zurko*, if applied properly by the Federal Circuit, would work well as a normative matter for patent denials. As for deference on questions of law, the analysis in *Mead* suggests that *Chevron* may be the appropriate standard for patent denials.<sup>255</sup> Under *Chevron*, the PTO's patent denial would receive substantial deference—it would be upheld if reasonable. But even if *Skidmore* were the appropriate standard, a normatively attractive result likely would occur. *Skidmore* explicitly provides for a sliding scale of deference. As we noted above, ordinary patent denials occur only after significant and careful agency internal review.<sup>256</sup> This is important under *Skidmore*, which looks first to “the thoroughness evident in [the agency’s] consideration” in determining how much deference to grant to the agency’s decision.<sup>257</sup> As *Mead* elaborated, under *Skidmore* courts look to “the degree of the agency’s care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency’s position.”<sup>258</sup> The level of care and thoroughness entailed in patent denials is considerable (as is the PTO’s relative expertness).<sup>259</sup> As a result, *Skidmore* suggests a fair amount of deference to agency legal determinations made in the course of such denials—and less deference in the context of patent grants, which do not entail significant internal review. As for policy determinations, a “hard look” approach would favor patent denials over patent grants. To the extent the PTO engages in economic reasoning, it is much more likely to do so comprehensively in the context of the fairly extensive procedures involved in patent denials than in its routine patent grants.

Only the level of deference accorded to factfinding in patent grants would have to be altered. Indeed, the FTC report specifically argued that the factfinding in ordinary patent grants should be subject to being overturned under a relatively low-threshold “preponderance of the evidence” standard.<sup>260</sup>

A legislative reduction of the evidentiary burden for patent invalidation is a straightforward solution. But current patent reform bills in Congress do not so propose (at least outside the context of post-grant review discussed below). Absent statutory change, could the Federal Circuit (if it were so inclined) adopt the analysis of this

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254. See *supra* note 60 and accompanying text.

255. See *supra* p. 299.

256. See *supra* notes 120–21 and accompanying text and p. 299.

257. See *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (“The weight [accorded to an administrative] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”); *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (quoting this language).

258. *Mead*, 533 U.S. at 228.

259. See *supra* notes 247–52 and accompanying text.

260. FTC REPORT, *supra* note 2, ch. 5, at 28.

Article and announce that, henceforth, it would increase or decrease the deference it accorded to PTO actions (or instructed lower courts to accord to PTO actions) based on normative considerations of comparative institutional analysis? As we have discussed in this Article, the Federal Circuit's review of the PTO should be guided by administrative law doctrine. One of the central points of our Article, and of *Dickinson v. Zurko*, is that ordinary rules of administrative law apply to the Federal Circuit and the PTO.<sup>261</sup> So the real question is whether, as a matter of administrative law doctrine, a court can take into account considerations of institutional analysis in deciding what standards of review to apply.

Neither the Supreme Court nor any circuit court has explicitly stated that courts should calibrate the level of deference to agency factfinding based on an agency's likelihood of capture or the thoroughness of its evaluation.<sup>262</sup> But there is some judicial support for the proposition that courts take into account an agency's expertise and the structure of an agency's processes in determining how much deference is owed to a particular decision. Interestingly, the clearest such statement from the Supreme Court appears in *Dickinson v. Zurko* itself. There the Court noted the "importance of case-specific factors, such as a finding's dependence upon agency expertise or the presence of internal agency review, which factors will often prove more influential in respect to outcome than will the applicable standard of review."<sup>263</sup> Given the structure of PTO incentives, factfinding in denials is much more likely to take advantage of PTO expertise than is factfinding in grants.<sup>264</sup> Moreover, unlike a grant, a denial goes through precisely the type of internal agency review to which the *Zurko* Court refers. Thus, if the *Zurko* language were taken seriously, that would mean that judicial deference to PTO factfinding would be asymmetric: factfinding in patent denials would be given more deference than factfinding in patent grants.

There is another quite practical reason that proper application of administrative law principles would entail substantially greater overall deference to factfinding in patent denials than in patent grants. The empirical literature suggests that when patent grants are challenged in litigation, it is often at least in part on the basis of prior art that the PTO never reviewed.<sup>265</sup> Under boilerplate administrative law, a court cannot defer to agency factfinding if the agency has not even passed on the factual question—the agency has not considered the factual question, so there is nothing for the court to defer to. In contrast, when a patent applicant appeals a patent denial, the appeal is unlikely to introduce new prior art. Instead, like appellate decisionmakers generally, the Federal Circuit decides

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261. 527 U.S. 150, 165 (1999).

262. Some commentators have argued in favor of a similar approach. See, e.g., Sidney A. Shapiro, *Administrative Law After the Counter-Reformation: Restoring Faith in Pragmatic Government*, 48 U. KAN. L. REV. 689, 746 (2000) (arguing in favor of judicial "[p]ragmatism").

263. *Dickinson*, 527 U.S. at 163.

264. See *supra* notes 247–53 and accompanying text.

265. See Allison & Lemley, *supra* note 238, at 231.

the case on the basis of the factual record put forward by the PTO.<sup>266</sup>

#### B. COMBINING NEW PROCEDURES WITH EXISTING ADMINISTRATIVE LAW PRINCIPLES

As we noted at the outset of this Article, our aim is not to describe the relationship between an idealized court and agency. But we do want to consider realistic changes. We noted in the previous section that judicial application of existing administrative law principles, without any action by Congress, could bring review of PTO decisions closer to a normatively attractive position. As we also noted above, Congress could pass legislation specifying normatively attractive standards of review. Another important possibility would be for Congress to create new PTO procedures and then either specify the review applicable to those procedures or, more simply, let the application of existing administrative law principles complete the move to more normatively attractive standards of review.

##### 1. Post-Grant Review and Deference

There are two modest changes to PTO procedures that fit the bill. The first is post-grant opposition proceedings. As various commentators have noted, such proceedings have been used successfully in most patent offices outside the U.S. and would probably improve patent quality.<sup>267</sup> What others have failed to recognize, however, is that the collective action problem that might chill use of such proceedings can be mitigated through the application of existing administrative law doctrines. Indeed, only through administrative review can these proceedings approximate the advantages of the European system of post-grant review.

*a. Cost-Effective Post-Grant Review.* We noted earlier in this Article the widespread belief that the large number of poor quality patents currently being issued by the PTO is imposing substantial costs.<sup>268</sup> There is some uncertainty about the extent of such costs, but most commentators believe that they are considerable, at least with respect to patents that are economically significant.<sup>269</sup> Thus, despite some uncertainty about the costs, many commentators (including the Federal Trade Commission, the National Academy of Sciences,

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266. The Federal Circuit does, however, sometimes step out of its appellate role and supplement the PTO record. See William C. Rooklidge & Matthew F. Weil, *Judicial Hyperactivity: The Federal Circuit's Discomfort with Its Appellate Role*, 15 BERKELEY TECH. L.J. 725, 739–47 (2000) (discussing cases in which the Federal Circuit appeared to supplement the factual record).

267. See *infra* notes 268–70 and accompanying text.

268. See FTC REPORT, *supra* note 2, ch. 5, at 1–4 (finding that poor quality patents that are nonetheless commercially significant slow innovation by discouraging firms from conducting research, necessitate unnecessary licenses and royalty payments, and impose unnecessary litigation costs in challenges to their validity); Ghosh & Kesan, *supra* note 38, at 227–34 (discussing social costs of bad patents); Kesan & Gallo, *supra* note 247, at 87–90 (discussing litigation costs of bad patents); Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FLA. ST. U. L. REV. 119, 126–27 (2005) (presenting costs of poor quality patents).

269. See FTC REPORT, *supra* note 2, ch. 3, at 22 (noting that patent litigation can cost between five and seven million dollars and take years to litigate); Allison & Lemley, *supra* note 238, at 187 (discussing exceptionally high costs of patent litigation).

and the American Intellectual Property Law Association) have argued in favor of the cost-effectiveness of post-grant opposition proceedings—that is, trial-type proceedings before an administrative patent judge where competitors of the patentee could bring prior art to bear, other types of written and oral evidence could be taken, and the administrative judge would make a decision based on the evidence presented.<sup>270</sup> Like ordinary patent denials, denials in post-grant review would be subject to immediate appeal to the Federal Circuit. Absent such appeal, or if the patent denial was upheld on appeal, the patent would be taken out of the system.

To the extent that post-grant opposition proceedings are used on a regular basis to target those patents that are economically important (and evidence from the European experience suggests that post-grant review indeed targets such patents),<sup>271</sup> such opposition proceedings are likely to be cost-effective.<sup>272</sup> More specifically, post-grant review proceedings could be valuable if two conditions obtain: (1) these proceedings are actually used on a reasonably regular basis; and (2) the proceedings thereby address the deleterious consequences imposed by patents of uncertain validity, such as the need for expensive litigation before a trial court decisionmaker (a lay judge and jury) of questionable competence, unnecessary licensing, wasteful “inventing around,” chilling effects, and races to accumulate defensive portfolios.

The most readily quantifiable of these costs is the actual out-of-pocket expense of litigation. The obvious category of cases where litigation will be avoided is those cases in which the patents are invalidated during the opposition

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270. See *supra* note 2 and accompanying text. The NAS proposal, which suggests that district courts could also refer validity questions to an administrative “Open Review” process, would take us even further towards a fully administrative determination of validity. See NAS PROPOSAL, *supra* note 2, at 96. In addition to the FTC, the NAS, and AIPLA, the academic commentary in favor of post-grant review has been overwhelming. See, e.g., Joseph Farrell & Robert P. Merges, *Incentives To Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Review Might Help*, 19 BERKELEY TECH. L.J. 943, 967–68 (2004); Janis, *supra* note 63; Kesan & Gallo, *supra* note 247, at 76–95; Rai, *Engaging Facts and Policy*, *supra* note 4, at 1040; John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 731–37 (2002). Notably, Professor Mark Lemley, perhaps the chief proponent of using litigation to address poor-quality patents, has recently endorsed improved administrative procedures. See Mark Lemley et al., *What to Do About Bad Patents?*, REGULATION, Winter 2005–2006, at 10–12.

Currently, the primary impediment to enactment of post-grant review involves a dispute over whether such review should be available throughout the life of the patent or only for a specified time period after the patent is granted. Firms that rely heavily on patents and thus want early certainty about their rights favor time limits on the availability of post-grant review. However, because some patents are worth opposing only when they are actually asserted, such time limits would reduce considerably the usefulness of an opposition process. Moreover, firms that require early certainty would be better served by voluntarily opting into the system of rigorous review proposed in Part IV.B.2.

271. See Hall & Harhoff, *supra* note 42, at 1002–07.

272. Some commentators have argued that post-grant oppositions might be less effective than pre-grant oppositions to the extent that the PTO may be reluctant to question the validity of a patent that it has already approved. See Kesan, *supra* note 244, at 778. As Kesan notes, however, this concern can be addressed by clearly separating the post-grant review function from the examination function. See Kesan & Gallo, *supra* note 247, at 111. As we noted earlier, the BPAI, which has a function clearly separate from the examination process, has been quite aggressive in its review of patent denials by examiners. See *supra* notes 251–52 and accompanying text.

proceeding. In a recent benefit-cost analysis, Bronwyn Hall and Dietmar Harhoff focus on this ability of post-grant proceedings to eliminate litigation over dubious patents.<sup>273</sup> In their analysis, they point out that if we assume a relatively high revocation rate, and we further assume that revoked patents would otherwise be litigated, the benefit-cost analysis weighs heavily in favor of having post-grant review.<sup>274</sup> Perhaps needless to say, however, much turns on the cost of the review and the revocation rate. For example, assuming a revocation rate of 35% (the rate of revocation under the European Opposition Office process), a post-grant review cost of \$100,000, and a trial cost of \$2 million, the benefit-cost ratio is 7:1.<sup>275</sup> On the other hand, if we assume a revocation rate of 11% (the rate under the PTO's existing patent re-examination process) and a post-grant review cost of \$500,000, the benefit-cost ratio is unfavorable (0.44:1).<sup>276</sup> Table 1 summarizes these calculations.

Cost of Post-Grant Review	Revocation Probability	Non-Revocation Probability	Cost of Litigation	Benefit of Litigation Avoided Through Revocation	Benefit of Litigation Avoided (Non-Revocation)	Benefit-Cost Ratio
\$100,000	.35	.65	\$2,000,000	\$700,000	\$0	7:1
\$500,000	.11	.89	\$2,000,000	\$220,000	\$0	0.44:1

As indicated by the table, Professors Hall and Harhoff do not focus on additional cost savings that might be generated by the avoidance of litigation on patents that survive the examination process.<sup>277</sup> But cost savings from such patents may also prove important, particularly to the extent that the cost of post-grant review is high, and the PTO revocation rate low (a plausible scenario to the extent, for example, that opposed patents are generally solid but sufficiently commercially valuable that they merit challenge). Thus, even if we assumed a revocation rate of 11% and a post-grant review cost of \$500,000, the benefit-cost ratio might become favorable if in the other 89% of cases the post-grant review would render a patent that otherwise would have been challenged in litigation less likely to be challenged. If, for example, post-grant

273. See Hall & Harhoff, *supra* note 42.

274. *Id.* at 1010–14.

275. *Id.* at 1012–13 tbl.3. Although we use the two million dollar figure cited by Hall and Harhoff for purposes of consistency with their analysis, we note that the average figure for litigation that goes through a full trial is higher. See *supra* note 269 (FTC report giving figures of five to seven million dollars).

276. Hall & Harhoff, *supra* note 42, at 1012–13 tbl.3.

277. Indeed, for reasons that are unclear, they suggest that patents that survive the examination process might, in certain scenarios, *increase* litigation costs. *Id.* at 1012–13. They do include, in several scenarios, possible benefits from averted litigation in cases where the patent has been amended. See *id.*

review reduced by even 25% the chances of the patent being challenged, then benefits from litigation avoided would increase to \$665,000.<sup>278</sup> With a low cost of post-grant review, and relatively high revocation probability, benefits would increase to \$1,025,000.<sup>279</sup> Table 2 summarizes these calculations.

<b>Cost of Post-Grant Review</b>	<b>Revocation Probability</b>	<b>Non-Revocation Probability</b>	<b>Cost of Litigation</b>	<b>Benefit of Litigation Avoided Through Revocation</b>	<b>Benefit of Litigation Avoided (Non-Revocation Yields 25% Reduction in Litigation)</b>	<b>Benefit-Cost Ratio</b>
\$100,000	.35	.65	\$2,000,000	\$700,000	\$325,000	10.25:1
\$500,000	.11	.89	\$2,000,000	\$220,000	\$445,000	1.33:1

Not surprisingly, then, many of the current proposals for post-grant review attempt to obviate trial court litigation on patents that survive examination. Generally speaking, these proposals use estoppel-based approaches. In other words, if an opponent loses a particular issue of fact or law in the post-grant review, it is estopped from raising the issue in subsequent litigation. For example, patent reform legislation introduced in the House in 2005 specifically provides that when the decision of a panel in an opposition proceeding becomes final (and finality can be achieved whether or not the patentee chooses to appeal),

the determination with respect to an issue of invalidity raised by an opposer shall bar the opposer from asserting, in any subsequent proceeding . . . involving that opposer under this title, that any claim of that patent addressed in the opposition proceeding is invalid on the basis of any issue of fact or law actually decided by the panel and necessary to the determination of that issue.<sup>280</sup>

The problem with estoppel is that it exacerbates the collective action problem that already lurks in the post-grant review proceeding. In litigation, collective action problems exist because the rules on non-mutual defensive issue preclusion enunciated by the Supreme Court<sup>281</sup> effectively cause the challenger who successfully invalidates a patent to provide a public good. Under the issue

278. This result is reached by the following:  $\$220,000 + (.25)(.89)(\$2,000,000) = \$665,000$ .

279.  $\$700,000 + (.25)(.65)(\$2,000,000) = \$1,025,000$ .

280. Patent Reform Act, H.R. 2795, 109th Cong. § 9(f) (2005).

281. See *Blonder-Tongue Lab., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971).

preclusion doctrine, the challenger invalidates the patent not only for itself but for the world at large. Thus, in the litigation context, patent challenges are likely to be brought much less often than is socially optimal.<sup>282</sup> As Professor Jay Thomas has cogently argued, the inability of a patent challenger fully to appropriate the benefits of an invalidity ruling creates the same disincentive to bring an opposition challenge as it poses in the litigation context.<sup>283</sup> Although the lower cost of an opposition proceeding reduces the scale of the disincentive, the disincentive is still there. Meanwhile, estoppel against an unsuccessful challenger (which is also a feature of litigation under the Supreme Court's approach) significantly exacerbates the disincentive. Not only does the challenger provide a public good if it wins, but the challenger is uniquely disadvantaged if it loses—only the challenger is barred from raising again questions of invalidity. In patent litigation, victory has a hundred fathers, but defeat is an orphan. The addition of estoppel transfers all of the problems of litigation into the administrative context.

Indeed, many patent lawyers argue that the estoppel provision in the existing *inter partes* reexamination proceedings represents a major reason that such proceedings have not been used.<sup>284</sup> To be sure, current proposals for estoppel emerging from post-grant review limit such estoppel to issues actually decided; in contrast, the *inter partes* reexamination estoppel provision embraces all issues that the reexamination requester raised or could have raised.<sup>285</sup> Even so,

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282. See Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 688–95 (2004) (discussing collective action problems raised by *Blonder-Tongue* but also noting that the problem can sometimes be mitigated if the accused infringer has blocking patents); see also Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237, 246 (2006) (comprehensive empirical study of cases brought in 1995, 1997, and 2000 that finds there are “very few rulings of [patent] invalidity by the courts”). Joseph Farrell and Robert Merges point out that the public good aspects of a patent challenge do not represent the only reason that such challenges are likely to be brought less frequently than is socially optimal. As they note, in certain situations involving oligopolistic competition between licensees that pay sales-based royalties to the patentee, the potential for pass-through of such royalties may make the licensees' combined loss from paying royalties smaller than the patentee's gain from the patent. See Farrell & Merges, *supra* note 270, at 953–54. Administrative law cannot address the latter problem. However, while the public good problem is likely to arise in most potential validity challenges, the pass-through problem may arise in only a subset of such challenges.

283. John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 333–34.

284. See, e.g., M. Patricia Thayer et al., *Examining Reexamination: Not Yet an Antidote to Litigation*, 5 SEDONA CONF. J. 23, 24 (2004) (noting that estoppel makes “*inter partes* reexamination something of a double-or-nothing gamble”). Recently, there has been a slight rise in the use of *inter partes* proceedings. Communication from Stephen B. Maebius to Arti K. Rai, April 11, 2006 (use of such proceedings rose from 27 actions in 2004 to 59 in 2005) (on file with authors).

285. Section 315(c) of the Patent Act provides: “A third party requester whose request for an *inter partes* reexamination results in [an order for such reexamination] is estopped from asserting at a later time, in any civil action . . . the invalidity of any claim finally determined to be valid and patentable on any ground which the third-party requester raised or could have raised during the *inter partes* reexamination proceedings.” 35 U.S.C. § 315(c) (2000 & Supp. II 2002). Legislation currently pending in the House would delete the “could have raised” language, thus bringing the *inter partes* reexamina-



for reasons discussed above, an estoppel-focused approach is likely to restrict the attractiveness of post-grant review proceedings.

A second problem with an estoppel-based approach is that, if the patent survives post-grant review, estoppel obviates the need for only a limited amount of litigation—litigation against the party who brought the opposition. Other competitors are free to challenge the patent unhindered.<sup>286</sup>

The reform proposal by the National Academy of Sciences attempts to reduce the impact of estoppel by proposing that it become operative only if appeal is taken to the Federal Circuit.<sup>287</sup> This proposal makes some sense: if the challenger that loses the opposition wants to avoid estoppel effects, it can simply refrain from appealing to the Federal Circuit. Indeed, as a matter of doctrine, estoppel is appropriate only after an appeal to the Federal Circuit: estoppel is a rule of civil procedure and it should presumptively apply only to results that emerge from actual litigation. But low-cost review without estoppel merely reduces the scope of the collective action problem. The successful opposer still provides a public good.

One mechanism for addressing the lingering collective action problem would be through some type of reward or bounty system. For example, the current system under which generics challenge pharmaceutical patents has an exclusivity reward (the successful generic challenger is allowed to market its generic exclusively for a 180-day period).<sup>288</sup> Recognizing the collective action problem, Professor Thomas has proposed a bounty, charged against patent applicants, for those who bring successful administrative oppositions.<sup>289</sup> However, rewards and bounties are subject to problems of collusion and are also notoriously difficult to calibrate appropriately.<sup>290</sup> The social cost that would have been imposed by the invalidated patent is an obvious criterion to use in calculating rewards. At the post-grant review stage, however, the patent might be early in its life cycle. Thus while potential third-party opposers may be able to guess that the patent has some commercial significance, the patent's precise social impact might be difficult to assess.<sup>291</sup>

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tion language into conformity with the language on the proposed post-grant opposition proceeding. *See* Patent Reform Act, H.R. 2795, 109th Cong. § 9 (2005).

286. It is possible that courts and/or juries might give some weight to the fact that the patent survived an adversarial examination. But what weight they will give to this fact is unclear.

287. *See* NAS PROPOSAL, *supra* note 2, at 101. In a somewhat similar vein, Joseph Farrell and Robert Merges contend that an administrative opponent who loses should not be precluded from raising the same arguments in litigation. *See* Farrell & Merges, *supra* note 270, at 967.

288. 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003).

289. *See* Thomas, *supra* note 38, at 340–53. Thomas sets up his bounty system in the context of a pre-grant opposition. It could readily be adapted, however, to post-grant oppositions.

290. For discussions of such problems, see *id.* at 345–47, 349–50.

291. Professor Miller emphasizes the valuation problem in arguing against the Thomas bounty and in favor of a litigation-stage bounty calculated on the basis of the patentee's past profits. Miller, *supra* note 282, at 695–701. A bounty based on past profits does not, however, necessarily track well the social cost of a bad patent. For example, such a bounty would not work against the much-discussed problem of non-practicing patentees who assert patents for “hold-up” purposes. More generally, there

In contrast with rewards or bounties, a one-way fee shifting proposal of the type advanced by Professor Jay Kesan might provide a more administrable mechanism for addressing collective action problems. Under Kesan's proposal, opponents who successfully invalidated a patent based on prior art that should have been discovered by the patentee would recover their fees.<sup>292</sup> Fee shifting would address the collective action problem only in part, however, because fee recovery would allow the successful opposer to recover only a small portion of the public good it had provided.

*b. Improving Post-Grant Review Through Deference.* An option short of bounties that might be used in addition to one-way fee shifting is strong judicial deference. Such deference could reduce the intensity of the collective action problem. Deference to the results of post-grant review would have to operate with respect to both fact and law: although facts are particularly critical to patent validity, deference on legal determinations would also be important because patent validity has been deemed ultimately to be a question of law.<sup>293</sup> Specifically, once the PTO had ruled a patent valid in a post-grant review, the PTO's factfinding on evidence it had considered would be subject to APA-level deference, and the determination of patent validity as a whole (again, with respect to the evidence considered) would be subject to *Chevron* deference. Both deference on factfinding and *Chevron* deference would obviously apply irrespective of the identity of the party against whom it was asserted. Such deference would mean that unless the administrative opponent had pursued an appeal to the Federal Circuit (and was therefore subject to estoppel), it would be no worse off than any other potential infringer. Moreover, even if the administrative opponent were uniquely subject to estoppel, other potential infringers would also feel the negative effects of the deference. Ex ante, that would mean that all potential infringers would have an incentive to help the administrative opponent. After all, if the opponent lost, the consequences of such a loss would be visited not only upon the opponent but also upon other potential infringers. Such assistance could be provided through a variety of mechanisms. For example, even without any additional change to the patent statute, competitors might be able to use 35 U.S.C. § 301, which allows "[a]ny person at any time" to submit to the PTO prior art patents and printed publications that the person "believes to have a bearing on the patentability of any claim of a particular patent."<sup>294</sup> Better yet, post-grant review could specifically provide mechanisms

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are multiple problems, well-rehearsed by many commentators, with waiting until the litigation stage to weed out bad patents. See *supra* note 268 and accompanying text.

292. See Kesan, *supra* note 244, at 787, 795–97.

293. See, e.g., *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (noting that the "ultimate question of patent validity is one of law"). Deference with respect to legal questions would also mitigate any tendency on the part of courts to turn fact into law in order to assert more aggressive review.

294. 35 U.S.C. § 301 (2000). Under this section, if the person "explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent." *Id.* Moreover, "at the

for multiple challengers to oppose a patent.

A strongly deferential approach to review of patents that survive patent examination would address collective action problems. It would also presumably lead to diminished litigation over these patents. As we noted earlier, even a 25% percent reduction in likelihood of litigation would considerably improve the efficiency gains that could be realized through post-grant review. Moreover, to the extent that a trial-type administrative proceeding is likely to be more accurate than a judicial proceeding, a strongly deferential approach would also improve accuracy. Numerous commentators have noted the difficulties raised by the reality that complicated technical factfinding must, under conventional Seventh Amendment doctrine, be done by a lay jury.<sup>295</sup> But the Seventh Amendment does not bar a requirement of strong jury deference to an agency determination of validity.

The intuition behind a deference-based approach—taking administrative procedure seriously and not treating it simply as a subset of procedures used in litigation—is also found in the apparently successful European system of post-grant review. Under the European system, post-grant review is explicitly promoted as a major venue for challenging validity.<sup>296</sup> Deference would similarly make post-grant review the main avenue for challenging validity in the United States.

The FTC report addresses the question of judicial review of post-grant oppositions by recommending that Congress include in its legislation authorizing such oppositions a provision for *Chevron* deference to the results.<sup>297</sup> But a specific statutory provision regarding *Chevron* deference is not necessary: ordinary principles of administrative law would provide *Chevron* deference even if Congress were to omit *any* reference to a standard for judicial review.

The various post-grant review proceedings that have been proposed would be trial-type procedures on the record that bear the hallmarks of formal adjudication—most notably, a proceeding before an administrative judge at which the parties present evidence and cross-examination, with the judge's decision based

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written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential." *Id.*

295. See D.H. Kaye, *The Dynamics of Daubert: Methodology, Conclusions, and Fit in Statistical and Econometric Studies*, 87 VA. L. REV. 1933, 1939 n.27 (2001) (collecting cases and articles discussing difficulties of lay juries undertaking complicated technical factfinding); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 827 n.197 (1997) (same).

296. For example, if a party wants to challenge the validity of an EPO patent that subsequently becomes the subject of an enforcement action in a German court, it must do so through a collateral proceeding known as a nullity proceeding. See Jan J. Brinkhof, *The Revocation of European Patents*, 27 INT'L REV. INDUS. PROP. & COPYRIGHT L. 225, 231 (1996). In the Japanese system, which for a five-year period had a dual system allowing validity questions to be raised in both post-grant review at the Japanese Patent Office (JPO) and in the courts, the trial for invalidation was initiated at the JPO in ninety percent of cases. See Kesan & Gallo, *supra* note 247, at 120.

297. See FTC REPORT, *supra* note 2, ch. 5, at 23–24.

on the record.<sup>298</sup> Such proceedings would have sufficient formality to satisfy *Mead*'s test for application of *Chevron* deference.<sup>299</sup> Thus, if Congress created these procedures and said nothing more, *Chevron* deference would seem to apply to them. Congress could of course avoid any confusion by specifically so stating, but that would not be necessary.

*Chevron* deference is greater than the *Skidmore* deference that applies to other PTO actions.<sup>300</sup> Application of *Chevron* to post-grant review will thus bring about a real change in the standards applicable to PTO legal determinations. Such a change is normatively attractive for the reasons suggested in Part III.B: a decisionmaking process like post-grant review would entail sufficient rigor that we should have more confidence in it than we would other PTO actions. That makes the very great deference of *Chevron* appropriate.

## 2. Selecting Into Rigorous Examination

As we have discussed, post-grant opposition is likely to target those patents that are commercially valuable. In some cases, however, commercial value will not be apparent until well after the patent issues. Thus, for post-grant opposition to be effective, the ability to bring such an opposition should be available throughout the life of the patent. Indeed, an optimal scheme might require patents that are asserted in litigation to be referred to the PTO for a post-grant determination of validity.

For those patentees who needed early certainty about their rights, Congress could provide for the same rigorous review of patents at the examination stage, rather than after the patent has been granted. That is, in addition to creating post-grant review,<sup>301</sup> Congress could create an option for a patent applicant to have the initial consideration of its application undergo the same sort of rigorous evaluation that post-grant review would entail.<sup>302</sup> The formal adjudication envisioned as part of post-grant review would simply occur at the examination stage. And the deference accorded to formal adjudication discussed in the previous section would apply here as well.<sup>303</sup> As with post-grant review, Congress would not need to create special deference rules but instead could rely on ordinary principles of administrative law. Patent applicants would be able to opt into this formal adjudication, knowing that it would be a more searching review that would be subject to more deference as a matter of administrative

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298. See *supra* notes 88, 151 and accompanying text (discussing the requirements of 5 U.S.C. §§ 556, 557 (2000)).

299. See *supra* notes 134–39 (discussing *Mead*).

300. See *supra* notes 140–45 (discussing *Skidmore*).

301. Procedures for rigorous initial review would be in addition to procedures for post-grant review because the rationale for post-grant review would still apply to patent applications that did not go through this searching review at the initial stage.

302. Mandating rigorous review, rather than allowing applicants to choose it, would not be attractive. Our arguments would not support such a mandate, and it would not be cost-effective, given the greater costs of formal adjudication.

303. See *supra* notes 293–300 and accompanying text.

law.<sup>304</sup> For those types of invention for which firms might need early certainty about their patent rights (for example, drug inventions), this type of formal adjudication might be particularly useful. In contrast, those inventions that had not gone through formal adjudication *ex ante* would presumably be subject to such adjudication *ex post* throughout the life of the patent.

There are two obvious differences between post-grant review and rigorous examination *ex ante*. First, the former entails two steps (ordinary examination and post-grant review), and the latter entails only one. Second, rigorous examination would be initiated by the applicant, whereas post-grant review would be initiated by someone opposing the applicant. This second difference raises a question as to whether the examination will always be rigorous. Congress should allow opponents of a patent grant to participate in the rigorous examination—as they would participate in the post-grant review—and the threat of deference should attract opponents in this context as well. It might be, however, that some such examinations would not draw opponents—and that might raise concerns about a lack of rigor.

The degree of rigor is, however, something that Congress can control in creating the procedure. Congress could, for instance, place a greater evidentiary burden on the applicant (for example, mandating not only disclosure of prior art but also a statement of the relevance of the prior art)<sup>305</sup> or mandate that the PTO undertake a more extensive search for prior art if there was no opposition.

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304. Beth Noveck has recently proposed what she calls “peer to patent” review, which would attempt to foster greater rigor in the examination process by allowing applicants to “opt in” to open public review; the PTO has announced plans to experiment with a form of such review (which it calls “Patent Application Peer Review Pilot”). Beth Simone Noveck, “*Peer to Patent*”: *Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J.L. & TECH. 123 (2006); USPTO, STRATEGIC PLAN 2007–2012, at 18 (2006), available at <http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012v6.doc>. Jay Kesan has previously raised the option of selecting into more rigorous examination, Kesan, *supra* note 244, at 770–75, as have Mark Lemley, Doug Lichtman, and Bhaven Sampat. Lemley et al., *supra* note 270, at 12. None of these articles nor the PTO plan frames their proposals in administrative law terms, however. Relatedly, it is not clear whether these proposals contemplate the level of rigor necessary for *Chevron* deference.

In a recent article draft, Doug Lichtman discusses more rigorous review and does briefly make one argument related to administrative law: he suggests that the PTO might issue a regulation announcing that its patent grants should not be entitled to a strong presumption of validity. Doug Lichtman, *Aligning Patent Presumptions with the Reality of Patent Review* 14–15 (unpublished manuscript, on file with authors). There is little reason to believe that courts would give such a statement much weight, however, because the PTO’s regulations are not entitled to *Chevron* deference and because a key consideration under *Skidmore* is consistency with prior agency interpretations. See *supra* text accompanying note 140, notes 149–50 and accompanying text. Thus, even in the highly unlikely event that the PTO reversed its previous claims that its grants are entitled to a strong presumption of validity and instead “welcom[ed] the courts to revisit the question of patent validity,” Lichtman, *supra*, at 14, that reversal would have little if any legal significance.

305. Jay Kesan has suggested a rigorous examination system in which patent applicants who submitted a detailed disclosure indicating not only the prior art but also the relevance of each piece of prior art that they had submitted would receive a specific presumption of validity; the court would not invalidate the patent based on the disclosed prior art unless it was “convinced that no reasonable examiner would have allowed the patent in light of the disclosed prior art.” Kesan, *supra* note 244, at 774.

These might not be perfect substitutes for an opponent—just as there are perceived benefits to having opposing litigants in the judicial context, there may be benefits to having opponents in formal adjudications over patents—but we do not need perfect substitutes. The idea is to have a grant procedure with sufficient rigor to give us higher confidence in the outcome of the process, and that seems achievable.

Moreover, insofar as there would be a fear that patent applicants would too freely utilize this rigorous examination process—perhaps because they did not fully bear its costs—Congress could very easily adjust those costs. The most obvious mechanism would be to require that applicants reimburse the PTO for the extra costs entailed in the more searching examination process.<sup>306</sup>

In any event, the appeal of this more rigorous examination process is that it would offer significant potential benefits and require only a modest legislative change—Congress’s creation of a formal adjudication procedure as an option for patent applicants. As with post-grant review, and all other formal adjudications, Congress would not need to specify any particular levels of deference. Ordinary principles of administrative law would provide for the same normatively attractive levels of deference applicable to post-grant review, including *Chevron* deference for legal conclusions and substantial evidence review of factual findings.

#### C. ARE CHANGES TO THE STANDARDS OF REVIEW WORTH THE TROUBLE?

As we have seen, administrative law is centrally concerned with standards of review—the exact formulation of words that govern the level of deference (or lack thereof) that courts give to agencies. One might reasonably wonder whether changes in the level of deference due administrative decisionmakers actually have an effect on court decisionmaking and thus whether such changes are worth the trouble. Some might argue that a court reluctant to relinquish power would pay lip service to the relevant standard of deference but continue to review cases in the same manner, either by simply failing to apply the relevant standard or by arguing that the agency action falls into a category to which less deference was owed.<sup>307</sup> Additionally, a substantial empirical literature has found evidence of ideological or “attitudinal” models of judging.<sup>308</sup> This literature might suggest that changes in deference standards will make little difference to

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306. That said, it is not clear that there would be any reason for such a fear. Formal adjudication imposes significant costs on applicants, akin to those for litigation (which it closely resembles).

307. Cf. Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 980–84 (1992) (arguing, based on analysis of Supreme Court decisionmaking immediately after the *Chevron* decision, that Justices continued to apply the traditional (less deferential) pre-*Chevron* factors for determining case outcomes); see also Rai, *Engaging Facts and Policy*, *supra* note 4 (arguing that the Federal Circuit has assumed an aggressive and formalist appellate role in part because of its concern about the competence of inferior actors).

308. See, e.g., SAUL BRENNER & HAROLD J. SPAETH, *STARE INDECISIS: THE ALTERATION OF PRECEDENT ON THE SUPREME COURT, 1946–1992* (1995); JEFFREY A. SEGAL & HAROLD J. SPAETH, *THE SUPREME COURT AND THE ATTITUDINAL MODEL REVISITED* (2002).

the extent that case outcomes ultimately depend on the ideological disposition of judges (in this case the disposition of Federal Circuit judges towards patents).<sup>309</sup> On this view, the Federal Circuit as a whole may be “pro-patent”;<sup>310</sup> alternatively, individual judges may be either “pro-patent” or “anti-patent.”

Because of the Supreme Court’s decision in *Zurko*, we have some opportunity to test the constraining effect of legal standards in the specific context of the Federal Circuit. Cases like *In re Lee*, *In re Beasley*, and the *Zurko* case on remand, discussed in Part I, represent clear examples of the Federal Circuit straining to achieve aggressive review despite purportedly deferential standards. In the *Lee* case, aggressive review was also achieved in part by attempting to push facts into the category of policy.<sup>311</sup> Similarly, on at least four occasions following the Supreme Court’s decision in *Zurko*, the Federal Circuit has appeared to evade deference by recasting an appeal on a factual question into a determination of claim construction (which according to the court is an issue of law to be reviewed de novo).<sup>312</sup>

On the other hand, cases like *In re Lee*, or cases in which an issue of fact is transformed into a question of claim construction, do not represent the entirety of Federal Circuit decisionmaking. Post-*Gartside*, a fair number of Federal Circuit affirmances of PTO factfinding have specifically referred to the importance of deference.<sup>313</sup> In the context of the much-discussed issue of motivation to combine or modify prior art references, the efforts of some Federal Circuit panels to take deference seriously are particularly interesting. Some Federal Circuit panels have agreed with the PTO’s determination that one or more of its

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309. Cf. Thomas Miles & Cass Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of Chevron*, 73 U. CHI. L. REV. 823, 825–27 (2006) (finding evidence that, even in cases where *Chevron* is the relevant standard, political ideology (as measured by party of the appointing President) strongly affects appellate court review of agency decisions by the EPA and NLRB); Orin S. Kerr, *Shedding Light on Chevron: An Empirical Study of the Chevron Doctrine in the U.S. Courts of Appeals*, 15 YALE J. ON REG. 1, 35–40 (1998) (noting that Republican and Democratic judges reach results consistent with their political ideologies in cases citing *Chevron* that have “relatively clear ideological significance”); see also Richard L. Revesz, *Environmental Regulation, Ideology, and the D.C. Circuit*, 83 VA. L. REV. 1717 (1997) (examining 250 challenges to EPA action that were litigated in the D.C. Circuit between 1970 and 1994 and arguing that ideology influenced decisionmaking).

310. See *supra* note 238 (empirical studies indicating that the Federal Circuit has been favorably disposed towards finding patents valid).

311. 277 F.3d 1338, 1344–45 (Fed. Cir. 2002); see *supra* notes 102–09 and accompanying text (discussing *Lee*). To buttress its case against use of examiner “common sense,” *Lee* cited in passing to the *State Farm* line of “hard look” policy cases. 277 F.3d at 1344.

312. See, e.g., *In re Simpson*, 63 F. App’x 466, 472 (Fed. Cir. 2003) (unpublished opinion); *In re Beigel*, 7 F. App’x 959, 961 (Fed. Cir. 2001) (unpublished opinion); *In re McNeil-PPC, Inc.*, 2000 WL 426148, at \*\*1 (Fed. Cir. 2000) (unpublished opinion); *In re Baker-Hughes, Inc.*, 215 F.3d 1297, 1300–01 (Fed. Cir. 2000).

313. See, e.g., *In re Watts*, 354 F.3d 1362, 1367 (Fed. Cir. 2004); *Okajima v. Bourdeau*, 261 F.3d 1350, 1356 (Fed. Cir. 2004); *Velander v. Garner*, 348 F.3d 1359, 1378 (Fed. Cir. 2003); *In re Berg*, 320 F.3d 1310, 1315 (Fed. Cir. 2003); *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); *In re Huston*, 308 F.3d 1267, 1281 (Fed. Cir. 2002); *In re Lam*, 35 F. App’x 889, 896 (Fed. Cir. 2002) (unpublished opinion); *Singh v. Brake*, 222 F.3d 1362, 1372 (Fed. Cir. 2000) (Gajarsa, J., concurring).

cited references provided a motivation to combine.<sup>314</sup> On occasion, these panels have found this motivation in a reference that the PTO itself did not cite for that purpose.<sup>315</sup> In other cases, a panel has found the requisite motivation to combine in the “nature of the problem to be solved.”<sup>316</sup> In yet other cases, the panel has ignored the “motivation” test entirely and simply indicated it will defer to the PTO’s expert decision about what multiple references would teach a person having ordinary skill in the art.<sup>317</sup> The court has also stated that a written reference is not necessary to satisfy the motivation to combine or modify test.<sup>318</sup>

To investigate the issue more comprehensively, we collected all appeals from the PTO, decided in the five-year period immediately preceding the Supreme Court’s decision in *Zurko* and the five-year period immediately following the Federal Circuit’s decision in *Gartside*,<sup>319</sup> in which the Federal Circuit explicitly used language on fact-oriented standards of review (that is, the terms “clearly erroneous” or “substantial evidence”).<sup>320</sup> We then read these cases to identify the subset that involved at least a Federal Circuit acknowledgment that it had been called upon to review a factual question (as opposed to use of fact-oriented review language as boilerplate). With respect to this subset, we coded as a separate unit of analysis, or observation, the Federal Circuit’s resolution of each challenged PTO finding on a claim or set of claims. Thus, for example, if a case involved challenges to PTO factfinding in the areas of both written description and nonobviousness, we coded each challenge (and resolution thereof) as a separate observation. This coding sometimes involved difficult judgment calls

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314. See, e.g., *In re Morgan*, 87 F. App’x 746, 749 (Fed. Cir. 2004) (unpublished opinion); *In re Morant*, 26 F. App’x 929, 935 (Fed. Cir. 2001) (unpublished opinion); *In re Petrak*, 10 F. App’x 831, 833 (2001) (unpublished opinion); *In re Pfeiffer*, 2000 WL 1648135 (Fed. Cir. 2000) (unpublished opinion).

315. *In re Huston*, 308 F.3d at 1281.

316. *In re Pfeiffer*, 2000 WL 1648135, at \*3.

317. *In re Berg*, 320 F.3d at 1315.

318. *In re Kahn*, 441 F.3d 977, 998 (Fed. Cir. 2006). Judge Newman, the author of the *Lee* case, and Judge Lourie, the author of the *Beasley* case, lie firmly within the camp that wants to construe the Supreme Court’s deference mandate as narrowly as possible. See *In re Lee*, 274 F.3d 1338, 1344 (Fed. Cir. 2002) (“Deferential judicial review under the Administrative Procedure Act does not relieve the agency of its obligation to develop an evidentiary basis for its findings.”); *In re Beasley*, 117 F. App’x 739, 744 (Fed. Cir. 2004) (unpublished opinion) (same). Other judges, perhaps most notably Judges Dyk and Bryson, appear inclined to give substantial deference. See *In re Beasley*, 117 F. App’x at 745 (Dyk., J., dissenting) (“I see no error in the Board’s reliance on the PTO’s own specialized knowledge.”); *In re Berg*, 320 F.3d at 1315 (Bryson, J., majority) (emphasizing the “scientific competence” of patent examiners and the BPAI in affirming a BPAI finding of obviousness).

319. *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000).

320. To retrieve these cases, we searched both Westlaw and Lexis using two search algorithms. The search algorithm—“clearly /2 erroneous,” “patent,” before “6/19/99” and after “6/19/94”—extracted cases decided in the five-year period before the Supreme Court decision in *Zurko*. The search algorithm—“substantial /2 evidence,” “patent,” after “2/15/2000” and before “2/15/2005”—extracted cases decided in a five-year period after the *Gartside* decision. Of course, as we discuss further in the text, our search would not retrieve those cases that did not explicitly specify use of either clearly erroneous or substantial evidence review. David Almeling initially found and coded these cases. One of us (Rai) also coded the cases. Almeling and Rai were able to agree on all discrepancies.



with respect to whether the Federal Circuit was “really” reviewing a factual issue—for example, as we noted earlier, in some cases the Federal Circuit turns what began as an appeal of a factual issue into a question of claim construction. In order to encompass situations where the Federal Circuit was endeavoring to evade deference, we determined that if the Federal Circuit had at least initially acknowledged the existence of a factual question, we should include it within our analysis.

Upon completion of the sorting process, our pre-*Zurko* sample comprised seventy-one observations, and our post-*Gartside* sample comprised seventy-four observations. In the pre-*Zurko* sample, forty-nine of the seventy-one observations, or 67%, represented affirmances. In the post-*Gartside* sample, sixty-nine of eighty-five observations, or 81%, represented affirmances.

Because of our small sample size, this difference in affirmance percentages is not statistically significant at the .05 level traditionally used in making predictive claims based on a population.<sup>321</sup> More generally, because of small sample size; judgment calls associated with coding; the fact that our search would pull up only cases in which the Federal Circuit acknowledged it had been called upon to review facts; changes in judicial composition over the period of time we collected cases; and the significant selection bias problems that accompany analyses based on litigated cases (particularly analyses that cover long periods of time, during which parties can adjust their behavior),<sup>322</sup> we hesitate to draw any strong quantitative conclusions. Nonetheless, our analysis does suggest that at least in cases where the Federal Circuit acknowledges that it has been called upon to review PTO factfinding, *Dickinson v. Zurko* has, on balance, had some impact.

Our analysis is in accord with an early study by Peter Schuck and Donald Elliott showing that the adoption of the *Chevron* standard produced a statistically significant change in judicial behavior.<sup>323</sup> Schuck and Elliott conducted a study of 1676 appellate cases produced by sixteen appellate courts that reviewed cases from fifty different agencies in six-month periods before and after *Chevron*.<sup>324</sup> They found that appellate courts affirmed agency decisionmaking 70.9% of the time in the pre-*Chevron* period and 81.3% of the time in the

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321. Two separate tests of statistical significance failed to yield a P-value of .05 or less. Fisher's exact test yields a two-tailed P-value of .0931. A chi-square test yields a P-value of 0.1152 (chi-squared equals 2.481, 1 degree of freedom).

322. In the specific context of empirical studies that assess the impact of changes in standards of review, selection bias might result because, after a more lenient standard has been adopted, parties choose to appeal only those agency decisions that involve particularly egregious lapses. Thus, a reviewing court might be acting more deferentially but would nonetheless have the same affirmance rate as before the change in standard. This is a particular problem with studies that require examination over a relatively long period of time in order to create adequate sample size. Over this period of time, parties can adjust their decisions to the change in standard of review.

323. See Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 984, 1029–32.

324. The Schuck and Elliott sample included all cases, not just cases in which the *Chevron* doctrine was specifically invoked. See *id.* at 1032.

post-*Chevron* period.<sup>325</sup> Although the effect of *Chevron* diminished over time,<sup>326</sup> such diminution would presumably be expected as parties adjusted to the more deferential standard (and therefore challenged only agency actions that were particularly problematic).

More recent work by a number of scholars indicates that judicial ideology plays a significant role in *Chevron*-based appellate review of agencies by the D.C. Circuit and by courts that address such politically charged areas as the environment, immigration, and labor.<sup>327</sup> The relevance of this work for the Federal Circuit is unclear. As far as we are aware, no scholar has presented evidence arguing that patents represent the type of politically charged area that leads *individual judges* appointed by Presidents from different parties to view patents differently. To the contrary, empirical work by John Allison and Mark Lemley, involving appeals from district court cases, suggests that at least some judges appointed by Republican administrations (Judges Mayer and Markey) were quite likely to find patents invalid.<sup>328</sup> The more pressing question is whether the Federal Circuit as a whole is sufficiently “pro-patent” that changes in deference standards will make little difference.<sup>329</sup> Here our empirical study is at least suggestive. Even a court that is arguably “pro-patent” appears to be somewhat responsive to signals regarding deference from the Supreme Court.

Meanwhile, the costs of most of the changes discussed in this Article are fairly low. Insofar as we are suggesting that the Federal Circuit adopt existing standards from administrative law, the costs of such a move are not significant. The standards are familiar terms of art that have been fleshed out in scores of cases, so judges seeking to apply them can draw on a wealth of materials. Indeed, these standards are better established than the ones that the Federal Circuit has devised on its own. Perhaps most interesting is the reality that the Federal Circuit actually applies these standards in its review of other agencies

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325. *Id.* at 1030. This difference was significant at and above the 99% confidence level. *Id.* at 1032.

326. *Id.* at 1038; see also Sidney Shapiro and Richard Levy, *Judicial Incentives and Indeterminacy in Substantive Review of Administrative Decisions*, 44 DUKE L.J. 1051, 1071 (1995) (finding a more dramatic diminution).

327. See Kerr, *supra* note 309, at 35–40 (finding that ideology matters in areas such as immigration); Miles & Sunstein, *supra* note 309, at 823–25 (finding that ideology matters in appeals from the EPA and the NLRB); see also Frank B. Cross & Emerson H. Tiller, *Judicial Partisanship and Obedience to Legal Doctrine: Whistleblowing on the Federal Courts of Appeal*, 107 YALE L.J. 2155 (1998) (finding that ideology influenced decisionmaking by the D.C. Circuit in cases that cited *Chevron* but that this effect was tempered when a “whistleblower” from the opposite political party was on the panel).

328. John Allison & Mark Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 FLA. ST. U. L. REV. 745, 755 (2000). Our own data do suggest, however, that several judges appointed by President Clinton (Judges Bryson and Dyk) are much more assiduous in their invocation of deference than several judges (Judges Newman and Lourie) appointed by Republican presidents. This observation supports the supposition that judges appointed by Democratic Presidents (“liberal” judges in the conventional framework of attitudinal models) may be more deferential to administrative expertise and regulatory judgment than “conservative” judges. Miles & Sunstein, *supra* note 309, at 838 (calling this supposition the “bureaucratic hypothesis”).

329. See *supra* note 238 (empirical studies finding that the Federal Circuit has been favorably disposed towards finding patents valid).

under its jurisdiction.

Recall, though, that in Part III.B we suggested that a normatively attractive relationship might entail some very small changes in the level of deference that the Federal Circuit accords to PTO decisions. The discussion immediately above suggests why the costs of attempting to implement such finely calibrated changes in standards of review are probably not worth the trouble. First, the changes would be so slight that their impact (assuming full, good faith implementation) would likely be small. Second, they would move the standards of review out of the existing terms of art. The idea would be to tweak the existing categories just slightly, so that they apply a bit differently. But such a tweak means that the many cases delineating the existing standards would not apply, and instead the Federal Circuit would have to craft its own slightly modified interpretations. In light of the small probable benefits (that is, the few case outcomes that these small tweaks would be intended to change), the costs of developing a modified jurisprudence for the new categories loom large and probably outweigh the benefits.

Thus, at the end of the day, moving patent law to apply existing administrative law categories, and then modestly changing PTO practices to change how those categories actually apply to PTO actions, seems the best course of action. The costs of such an approach are low and the benefits considerable. Even without remaking patent law, we can use administrative law to push patent law in a useful direction.

#### CONCLUSION

The Federal Circuit, and many commentators, have long treated administrative law as tangential (at best) to patent law. But the PTO *is* an administrative agency, and the APA applies to the PTO and to the Federal Circuit's review of PTO decisions. Bringing the APA (and administrative law doctrine more generally) to bear on patent law regularizes patent law by applying established standards of review. Thus the APA, and the voluminous case law interpreting it, replaces ad hoc standards created by the Federal Circuit.

Application of administrative law principles also brings into focus possibilities for making realistic and normatively attractive changes to PTO procedures and to the Federal Circuit's review of the PTO. It is tempting for academics, and daunting for policymakers, to posit radical changes in existing law that would create an ideal system. Such a recasting of patent law is not necessary, however, for us to move patent law a considerable distance toward normatively attractive standards of review. First-best solutions are (by definition) the most attractive, but second-best solutions fare well if they are much more realistic and give us much of what we want. The application of administrative law principles outlined in this Article presents such a second-best solution. So, while we wait (indefinitely) for an ideal PTO and Federal Circuit to be created, principles of administrative law offer real improvement based on a huge body of experience in other areas of complex, technical regulation. To put the point more sharply,

application of administrative law is the sort of “fully enabled” improvement that the patent system is designed to foster.<sup>330</sup>

More broadly, examination of possible improvements to the patent system highlights the downside of treating an area of law as *sui generis*, and thus not subject to a general regime like administrative law. Not only is the specialized area subject to capture by powerful interests, but it also fails to benefit from well-established standards that could fairly straightforwardly be applied. Application of a broad regime like administrative law allows us to recognize, and build on, the commonalities between agencies. It also paves the way for more scrutiny of patent law. A specialized legal regime creates obstacles for non-specialists who want to understand and evaluate it; reducing that specialization reduces those barriers. Application of administrative law removes some of the mystique from patent law—but that is a feature, not a bug.

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330. See 35 U.S.C. § 112 (2000) (requiring enablement for patent to issue). The “enablement” here refers to the fact that the Federal Circuit appears to apply standard administrative principles when it reviews agencies other than the PTO. See *supra* notes 161, 192 and accompanying text.