

ALLOCATING POWER OVER FACT-FINDING IN THE PATENT SYSTEM

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I. INTRODUCTION

Under well-settled patent law, the decision regarding whether to grant or deny a patent turns on technical fact-finding. The decision maker must assess both the relevant written knowledge in a particular art at a given time and the general level of skill in the art at that time.¹ For example, patents are supposed to be granted only when, against the background of the knowledge that existed at the time of invention, the invention would not have been obvious to the person having ordinary skill in the art (PHOSITA).² Although this nonobviousness determination is ultimately considered a question of law, the Supreme Court has repeatedly emphasized that it involves inquiry into technical facts.³ Thus, a key question to consider in evaluating proposals to improve the patent system is how such proposals allocate fact-finding power.⁴

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1. *See, e.g.*, *Graham v. John Deere Co.*, 383 U.S. 1 (1966) (holding that the nonobviousness standard enunciated in Section 103 of the patent statute requires factual inquiry into “scope and content of the prior art” and into “ordinary skill in the pertinent art”).

2. *Id.*

3. *Id.* at 17; *see also* *Dennison Mfg. v. Panduit Corp.*, 475 U.S. 809 (1986) (remanding to the Federal Circuit with specific instructions on deference to the trial court’s factual determinations regarding nonobviousness).

4. Some might argue that, case law notwithstanding, technical fact-finding should not be particularly relevant because the PHOSITA is a policy construct designed to achieve the economic goal of promoting invention and further develop-

The recommendations that the Federal Trade Commission (FTC) and the National Academy of Sciences (NAS) make in their reports could have a substantial impact on which patent institution has power over fact-finding. This is particularly true with respect to the recommendations that one or more reports makes in the following three arenas: judicial deference to the ordinary U.S. Patent and Trademark Office (USPTO) decision to issue a patent; USPTO and Court of Appeals for the Federal Circuit (Federal Circuit) application of the nonobviousness standard; and judicial deference to USPTO findings in proposed post-grant review proceedings.

ment/commercialization of the invention. *Cf.* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 1, at 10 (2003) [hereinafter FTC REPORT] (“Competition policy and economic perspectives would ask a somewhat different question, one that focuses on whether and how the patent is necessary to encourage innovation.”), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>. Thus, for example, whether an invention is nonobvious to a PHOSITA is a policy question, not a technical one. This argument misses the mark, however. Although the PHOSITA is undoubtedly a policy construct, the central policy question of whether an invention is likely to arise absent a patent incentive is closely linked to technical issues. In particular, if the ordinary technician in a given art could readily formulate a particular invention from knowledge of what has come before, that invention will likely arise without the need for patent-related output restrictions and deadweight loss. Moreover, although technically difficult inventions may well arise without a patent (especially if the research is, for example, federally funded), the technical difficulty of an invention often serves as a reasonably transparent and reliable proxy for determining the extent to which a patent incentive may be important. *Id.* at 11 (noting that the “more manageable standards of the patent system” help to address the less administrable policy question). Of course, there may be cases where other policy reasons favor granting a patent. For example, an invention such as a therapeutic drug could be technically obvious but expensive to commercialize. In that case, a patent on the prototype drug could provide the monopoly security necessary for such commercialization. Alternatively, it is conceivable an invention could be technically obvious but nonetheless expensive to generate. In each of these cases, purely economic considerations might weigh in favor of granting a patent. For an argument along these lines, see, for example, Dan Burk & Mark Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1660-62 (2003) (arguing that purely economic factors should be a secondary consideration used in the nonobvious analysis). More generally, as various commentators, including the FTC, NAS, and this author, have recognized, the Federal Circuit can, and should, explicitly enunciate interpretations of the patent law that take into account the expanding economic literature on patents, including literature that illustrates the different role patents play in different industries. See FTC REPORT, *supra*, EXECUTIVE SUMMARY, at 17, reprinted in 19 BERKELEY TECH. L.J. 861, 880-81 (2004) [hereinafter FTC EXECUTIVE SUMMARY]; NAT'L ACAD. OF SCIS., A PATENT SYSTEM FOR THE 21ST CENTURY 4-5 (Stephen A. Merrill et al. eds., forthcoming 2004) [hereinafter NAS STUDY], available at <http://www.nap.edu/books/0309089107.html>; Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1102-1134 (2003). These sorts of arguments do not, however, obviate the need for technical fact-finding.

The FTC's approach to power allocation is relatively explicit: the USPTO's factual findings should be accorded a low level of deference when made in the context of an ordinary patent grant; significant deference when made in the context of a patent denial; and perhaps the highest level of deference when made in a post-grant review.⁵ While the NAS Study does not focus as explicitly on how courts should treat USPTO fact-finding, its recommendations also have significant implications for power allocation.

In this Article, I evaluate the power allocation that would emerge from each report's recommendations. I argue that, in their areas of overlap, both the FTC and NAS reports properly account for the fact-finding competence—or lack thereof—of the USPTO. Where the reports diverge, however, the FTC report may do a better job of accurately diagnosing, and suggesting remedies for, the relevant fact-finding problem. In contrast with the NAS, which would treat the USPTO's fact-finding role as minimal, at least outside the context of post-grant review, the FTC's recommendations account for one context—the patent denial—where USPTO fact-finding could be accurate.

This Article is organized around the three contexts in which the reports' recommendations have an impact on the allocation of fact-finding power. Part II evaluates the recommendation made explicitly by the FTC and somewhat more implicitly by the NAS, that the fact-finding associated with USPTO patent grants be accorded a relatively low level of deference. This recommendation appears appropriate: even though patent examiners, and the USPTO more generally, probably possess more technical expertise than other government actors, reducing the burden associated with challenging patent validity also takes into account the institutional pressures that are likely to cause examiners to grant questionable patents. Part III discusses why raising the nonobviousness standard in the manner the FTC advocates effectively asks the Federal Circuit to be more deferential to USPTO patent denials. The FTC's recommendation is apt: unlike USPTO patent grants, USPTO patent denials are likely to invoke usefully its technical expertise. In contrast, the NAS recommendations regarding nonobvi-

5. FTC EXECUTIVE SUMMARY, *supra* note 4, at 8 (post-grant review), *reprinted in* 19 BERKELEY TECH. L.J. 861, 869-70 (2004); *id.* at 8-10 (ordinary patent grants), *reprinted in* 19 BERKELEY TECH. L.J. 861, 870-72; *id.* at 11-12 (nonobviousness-based patent denials), *reprinted in* 19 BERKELEY TECH. L.J. 861, 873-75. For a somewhat similar point, see Rai, *supra* note 4, at 1077, which discusses the Federal Circuit's deferential view of USPTO fact-finding in the context of patent grants but not in the context of patent denials and arguing that the Federal Circuit has gotten the asymmetry "precisely backwards."

ousness may not take sufficient account of the USPTO's technical expertise. Part IV discusses the reports' recommendations on how courts should view the results of post-grant review proceedings. While the FTC explicitly, and correctly, urges a high level of deference to USPTO fact-finding in the post-grant review, the NAS does not address the issue. There are, however, good reasons for the Federal Circuit to give significant deference to findings made by the USPTO in post-grant review proceedings.

As noted, the FTC Report, and to a lesser extent the NAS Study, recommend changes in levels of deference. While tweaking of deference levels is a hallmark of our legal system, the issue of whether such alteration actually affects judicial behavior remains open: for a variety of reasons, effects on judicial behavior may be difficult to discern empirically. The Article therefore concludes with a section, Part V, discussing mechanisms for empirical evaluation of altered deference levels.

II. CHALLENGES TO FACT-FINDING IN USPTO PATENT GRANTS

The FTC Report recommends altering the burden of proof associated with challenging the ordinary patent grant.⁶ According to the FTC, overcoming the presumption of patent validity enunciated in the patent statute should require only a preponderance of the evidence, not the clear and convincing evidence Federal Circuit case law currently requires.⁷ Although the NAS does not explicitly recommend altering the burden of proof, it reaches a somewhat similar conclusion through its recommendations on post-grant review. First, the NAS recommends that third party patent challenges in a post-grant review proceeding be subject to a preponderance of the evidence standard.⁸ Second, the NAS recommends that federal district courts be able to refer questions of patent validity to a post-grant review proceeding, thus confining themselves to issues of infringement.⁹ The effect of these recommendations would be the application of a preponderance of the evidence standard to a significant percentage of proceedings.¹⁰

6. FTC REPORT, *supra* note 4, ch. 5, at 28 (“[T]here is no persuasive reason why the level of that burden should be clear and convincing evidence.”).

7. *Id.*

8. NAS STUDY, *supra* note 4, at 79.

9. *Id.*

10. One difficulty with the NAS approach is that it would appear to lead to a situation where its recommended preponderance of the evidence standard was applied to certain validity challenges and the Federal Circuit's recommended clear and convincing evidence standard to other validity challenges.

The FTC's recommendation—and that of the NAS, to the extent it is similar—makes sense. Although the patent examiner may come closer than any other actor within the government system to having the relevant “ordinary skill in the art,” the examiner’s decision to grant a patent should nonetheless be viewed with caution. For a number of reasons, examiners are unlikely to deny even questionable applications.¹¹ Most notably, because the application process is *ex parte*, and the applicants themselves have less than optimal incentives to disclose relevant prior art, the examiner must herself find such art.¹² Because of the volume of patent applications, the examiner typically conducts this search in a very short period of time (approximately eighteen hours, according to one estimate).¹³ The time pressure faced by the examiner is especially acute in areas like software and business methods where the art is diffuse.¹⁴ Additionally, examiners are biased in favor of granting patents. This bias emerges because they are evaluated according to the number of final dispositions they record, and it is much easier to secure a final disposition by granting a patent than by denying one.¹⁵

Of course, substantially greater levels of funding for the USPTO would allow examiners to spend more time finding prior art on each patent. However, because most patents are neither litigated nor licensed, it may be inefficient for examiners to conduct an exhaustive search for prior art on each patent.¹⁶ A discussion of the level of scrutiny each patent

11. See FTC REPORT, *supra* note 4, ch. 5, at 4-6 (discussing why patent grants may be questionable, such as increase in the number of patent applications and decrease in amount of time spent evaluating a patent application). A partial list of recent publications pointing out the deficiencies of the examination process includes: Shubha Ghosh & Jay Kesan, *What Do Patents Purchase: In Search of Optimal Ignorance in the Patent Office*, 40 HOUS. L. REV. 1219 (2004); Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495 (2001); Cecil D. Quillen, Jr. & Ogden H. Webster, *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office*, 11 FED. CIR. B.J. 1 (2001); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305.

12. FTC REPORT, *supra* note 3, ch.5, at 7, 8 (stating that a patent applicant has not duty to search for prior art and that a patent examiner is “largely on his or her own in conducting prior art searches”).

13. Lemley, *supra* note 11, at 1500; see FTC REPORT, *supra* note 4, ch. 5, at 5 (giving estimates of time to examine a patent application from start to finish to range from eight hours up to twenty-five hours).

14. FTC REPORT, *supra* note 4, ch. 5, at 7.

15. Thomas, *supra* note 11, at 324.

16. See Lemley, *supra* note 11, at 1501 (“Of the roughly two million patents currently in force [as of 2001], only a tiny number are the basis for lawsuits each year.”) (internal footnote omitted).

should optimally receive is beyond the scope of this Article.¹⁷ One point is clear, however: absent substantial change in the USPTO examination process for ordinary patent grants, the significant institutional bias in favor of grants should overcome any strong presumption in favor of agency competence in the fact-finding associated with such grants.¹⁸

In contrast, when the USPTO denies a patent, the fact-finding associated with the USPTO's analysis is much more likely to be accurate. This is because the patent examiner has the burden of demonstrating the unpatentability of the applicant's assertions, and thus the examiner is required to assemble evidence supporting the rejection.¹⁹ It is therefore appropriate for the Federal Circuit to treat a denial different than a grant. Differential treatment is particularly appropriate because, before the denial ever reaches the Federal Circuit, the denial will have gone through review at the Board of Patent Appeals and Interferences (BPAI).²⁰ The three-member review board of the BPAI, which is composed of judges skilled in the relevant law and frequently even in the relevant science, is hardly a rubber stamp for examiner decisions to deny a patent. To the contrary, in fiscal year 2002, the BPAI squarely affirmed examiner denials in only 29.9% of cases; it reversed such denials in 37.4% of cases.²¹

III. NONOBVIOUSNESS: THE ROLE OF DEFERENCE TO USPTO PATENT DENIALS

Both reports' recommendations on nonobviousness underscore the validity of USPTO fact-finding in the context of patent denials. In at least

17. The issue is hard to decide because many of the possible costs of "bad" patents are so difficult to quantify. In particular, it is very difficult to quantify the costs associated with bad patents that are neither licensed nor litigated. For example, although there is some evidence that small firms avoid research and development in areas where larger firms have a significant patent presence, see Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J.L. & ECON. 463 (1995), the full extent of such behavior is not known. Even if it were known, moreover, the loss to social welfare would be difficult to quantify. For a discussion of these and other problems associated with quantifying the cost of bad patents, see Rai, *supra* note 4, at 1081-83.

18. Notably, changing the burden placed upon the entity challenging patent validity would not require building the complex coalitions necessary for legislative action. Rather, the Federal Circuit would merely have to alter its requirement that "clear and convincing evidence" is needed to overcome the presumption of patent validity.

19. See FTC REPORT, *supra* note 4, ch. 5, at 8.

20. 35 U.S.C. § 134 (2000).

21. See Bd. of Patent Appeals & Interferences, USPTO, Receipts and Dispositions by Technology Centers for *Ex Parte* Appeals, available at <http://www.uspto.gov/web/offices/dcom/bpai/docs/receipts/fy2002.htm> (last modified Nov. 16, 2003) (listing statistics).

three of the areas where the reports make nonobviousness-related recommendations—combining prior art references, business method patents, and DNA patents—one key problem has been the Federal Circuit’s failure to recognize that the USPTO can, and should, be allowed to insert its knowledge of the art into the patent examination process. While the FTC directly addresses this problem, the NAS analysis is less clear, particularly with respect to business method patents.

The FTC Report recommends that the Federal Circuit relax application of its so-called “suggestion” test for combining references to show obviousness.²² Although this recommendation applies to all cases before the Federal Circuit, whether based on appeals from a district court or from the USPTO, the FTC rightly focuses on some recent Federal Circuit opinions in which the court has forbidden the USPTO from combining references based on common knowledge in the art.²³ The examiner instead must point to a specific written reference that suggests the combination is obvious.²⁴ Because skilled scientists and engineers have little motivation to publish what is already well known, this requirement may make the examiner’s task virtually impossible.

A similar lack of deference to USPTO fact-finding, in this case fact-finding regarding what constitutes appropriate prior art, is the root cause of the problem in one of the nonobviousness contexts on which the NAS Study focuses—the context of gene patents.²⁵ As I have argued at length elsewhere,²⁶ the Federal Circuit’s refusal to engage USPTO arguments that DNA isolation methods routinely used by genomic scientists should be considered appropriate prior art in sequence patentability determinations has effectively eliminated the nonobviousness standard as a bar to patentability in sequence cases.²⁷ The NAS Study recognizes the Federal

22. FTC REPORT, *supra* note 4, ch. 4, at 15.

23. *Id.* at 10-11.

24. *Id.* at 10; *see, e.g., In re Sang-Su Lee*, 277 F.3d 1338 (Fed. Cir. 2002) (noting that a suggestion to combine *cannot* rely on “common knowledge and common sense”); *see also In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999) (overturning, on improper combination of prior art grounds, a USPTO determination that a patent application for a plastic garbage bag decorated to look like a jack-o-lantern when filled with trash or leaves was obvious).

25. NAS STUDY, *supra* note 4, at 75-78 (discussing in particular *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995)).

26. Rai, *supra* note 4, at 1069.

27. Some have argued that the *Deuel* case may have represented an attempt by the Federal Circuit to preserve patentability of DNA sequences that the court (like the USPTO) knew were technically obvious on the grounds that such sequences are nonetheless expensive to generate. *See, e.g., Karen Boyd, Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness*, 12 BERKELEY TECH.

Circuit's failure to examine whether gene sequence patents are technically inventive,²⁸ but it does not note the extent to which the problem has resulted from the Federal Circuit's rejection of the USPTO's technically accurate factual findings regarding appropriate prior art.

Similarly, in the context of discussing business methods, the NAS Study recognizes but does not fully diagnose the problem. The NAS observes that many obvious business method patents may have been granted because of the difficulty examiners face in finding written references stating common knowledge in the art.²⁹ Rather than suggesting that the Federal Circuit allow some role for the knowledge and skill of the examiner, however, the NAS recommends that expert testimony be used.³⁰ Moreover, because testimony by a USPTO-chosen expert during the *ex parte* proceeding might be inappropriately biased against the applicant,³¹ expert testimony should come in during the post-grant review, where experts on both sides could testify.³²

Thus, the NAS approach, like that of certain Federal Circuit opinions, forbids examiners from relying on their ordinary knowledge. Indeed, because the NAS considers *ex parte* expert testimony to be inappropriate as well,³³ no patent could be denied based upon ordinary knowledge unless it happened to be challenged in a post-grant review proceeding.

The argument in favor of the NAS approach is that it would ensure that the system produced fewer false negatives—denials of patents that should have been granted. The NAS Study hints at this rationale by em-

L.J. 311 (1997). This rationale seems dubious since DNA isolation techniques are relatively inexpensive. A better "economic nonobviousness" argument might rest on the need for expensive follow-on development. Presumably this rationale would be particularly persuasive when the sequence patent covers what is effectively a therapeutic. However, the doctrinal mechanism by which the *Deuel* case reduces the nonobviousness standard for DNA patents—eliminating DNA isolation methods as relevant prior art—also leads to a situation where DNA patent scope is quite narrow. Although narrow scope is not necessarily problematic when such DNA patents represent research tools (and, indeed, may be affirmatively useful in reducing the transaction costs associated with licensing), narrow scope may be quite problematic for DNA patents that are effectively therapeutic products and hence need significant protection to induce follow-on development.

28. NAS STUDY, *supra* note 4, at 68.

29. *Id.* at 74 (noting that "scientists, artisans, and creative people generally speaking strive to publish *non-obvious* information") (emphasis original).

30. *Id.* at 68.

31. *Id.* at 74.

32. *Id.*

33. The NAS does not explain why, given the pressure on examiners to grant patents, the examiner would pick an expert biased against granting the patent.

phasizing the problem of hindsight bias.³⁴ Although hindsight bias is a legitimate concern, the NAS approach would probably result in a large number of false positives—grants of patents that should have been denied. Because the USPTO's ordinary role in evaluating patents would be greatly diminished, numerous cases would turn on the use of post-grant review proceedings. Given that such proceedings might not be used, and would also be quite a bit more expensive than ordinary patent review, placing so much emphasis for weeding out bad patents on these proceedings is probably unwise. Thus, the FTC's approach, which uses post-grant review but also capitalizes on the USPTO's relative competence in issuing patent denials, is preferable.

Indeed, we might consider taking the FTC's emphasis on the initial patent denial one step further. Insuring that examiners do in fact have a minimum level of skill in the art is one mechanism for channeling more questionable patents into the initial denial category. Although examiner skill is not especially problematic in areas like biotechnology, where the USPTO has scores of Ph.D.s, it may be problematic in areas like software and business methods. As contrasted with requiring each patent application to be scrutinized exhaustively for prior art, insuring a minimum level of skill in the art should be relatively inexpensive.

Arguably, the 1999 Supreme Court decision in *Dickinson v. Zurko* admonishes the Federal Circuit on the very question of deference to USPTO fact-finding in the context of a patent denial.³⁵ In *Zurko*, the Court held that USPTO fact-finding should be reviewed under the highly deferential standard of review established under the Administrative Procedure Act (APA).³⁶ The Court squarely rejected the Federal Circuit's contention that the less deferential clearly erroneous standard applied.³⁷

34. Hindsight bias is the tendency of decision makers to view inventions as obvious in retrospect.

35. 527 U.S. 150 (1999).

36. *Id.*

37. *Id.* In the case below, the Federal Circuit had held that clearly erroneous review applied and that such review was more rigorous than the Administrative Procedure Act (APA) standard. *In re Zurko*, 142 F.3d 1447, 1454 (Fed. Cir. 1998), *rev'd sub nom.* *Dickinson v. Zurko*, 527 U.S. 150 (1999). In a recent article, administrative law scholar Paul Verkuil suggests that the clearly erroneous standard might be thought of as resulting in affirmance 70-80% of the time. Verkuil believes the two APA-based standards of review, substantial evidence review and arbitrary and capricious review, would respectively result in affirmance 75-85% and 85-90% of the time. Paul R. Verkuil, *An Outcomes Analysis of Scope of Review Standards*, 44 WM. & MARY L. REV. 679, 689 (2002). I discuss the differences, if any, between substantial evidence and arbitrary and capricious review further in the text.

So, one might be puzzled at the Federal Circuit's decision making. With respect to gene patents, one could argue that *In re Deuel*, which rejected the USPTO's factual determinations regarding appropriate prior art and thereby virtually eliminated the nonobviousness standard for DNA patents,³⁸ was decided in 1995 and thus would perhaps be decided differently in the post-*Zurko* landscape. Yet, even more puzzling is the 2002 *In re Lee* decision, a case involving electronic video display technology, in which the court specifically directed the examiner to refrain from combining prior art references based on common sense or general knowledge in the field.³⁹

In part the Federal Circuit has been able to resist the natural implications of *Zurko* because the Supreme Court was not presented with, and hence did not decide, the specific question of whether the appropriate standard of APA-based review was "substantial evidence" or "arbitrary and capricious."⁴⁰ Substantial evidence review, which focuses on evidence within the four corners of the agency record, applies to formal agency proceedings;⁴¹ arbitrary and capricious review applies to informal proceedings.⁴² Although several of the Justices, including Justice Breyer, indicated at oral argument that arbitrary and capricious review might be most appropriate given the *ex parte*, informal nature of the USPTO proceedings,⁴³ Justice Breyer's opinion for the majority squarely addressed only the threshold issue of APA applicability briefed by the parties. The opinion did suggest in passing, however, that the degree of appellate intrusiveness allowed by the two APA standards was similar.⁴⁴

38. 51 F.3d 1552 (Fed. Cir. 1995).

39. 277 F.3d 1338 (Fed. Cir. 2002).

40. 527 U.S. 150 (1999).

41. 5 U.S.C. § 706(2)(E) (2000) (stating that a reviewing court shall "set aside agency action . . . unsupported by substantial evidence 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 . . .").

42. 5 U.S.C. § 706(2)(A).

43. Transcript of Oral Argument at *4-*8, *Dickinson v. Zurko*, 527 U.S. 150 (1999) (No. 98-377), available at 1999 WL 190969.

44. *Dickinson v. Zurko*, 527 U.S. 150, 158 (1999) (citing association of 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), for that proposition). Contrary to Justice Breyer, a few Supreme Court opinions, as well as commentary by some administrative law scholars, indicate that substantial evidence is somewhat less deferential than arbitrary and capricious review, primarily because in the former context the agency must put all of its reasoning on the record. Verkuil, *supra* note 37, at 689 (positing that arbitrary and capricious review yields a somewhat higher affirmance rate than substantial evidence review); see also *Am. Paper Inst., Inc. v. Am. Elec. Power Serv. Corp.*, 461 U.S. 402, 412-13 & n.7

The Court probably did not contemplate the liberties that the Federal Circuit would take with the legal gap left open by the *Zurko* decision. Contrary to Justice Breyer's suggestion at the *Zurko* oral argument, the Federal Circuit has determined that the relevant standard of review is substantial evidence.⁴⁵ Additionally, contrary to the suggestion of the *Zurko* majority, it has argued that this standard is considerably less deferential than the arbitrary and capricious standard.⁴⁶

Cases like *In re Lee* underscore the odd fit between stringent substantial evidence review and informal proceedings. In *Lee*, the Federal Circuit emphasized that the examiner's knowledge of the technology could not count as "evidence."⁴⁷ But since the examiner cannot call witnesses to testify about common knowledge in an industry in an *ex parte* proceeding, the examiner is forced to try to find a reference stating the common knowledge. Such a search is resource-intensive, if not futile. Either the examiner's knowledge should count as evidence or the Federal Circuit should adopt arbitrary and capricious review, which does not require that all relevant information be "on the record" and is also the more logical standard of review for informal proceedings like the USPTO examination process.

Greater deference to USPTO fact-finding in the context of nonobviousness-based patent denials, coupled with less deference to patent grants, would probably increase the number of false negatives in the system. In other words, some valid patent applications would be denied. But there is no reason to believe that false negatives are worse than false positives—that is, the granting of invalid patents. The current system appears to be tilted in favor of false positives, and these reforms would be a step towards redressing the balance.

IV. POST-GRANT REVIEW PROCEEDINGS: PRESUMPTION OF VALIDITY

The FTC Report recommends implementing a post-grant review procedure that would allow third parties to raise novelty, nonobviousness, written description, enablement, and utility questions.⁴⁸ An administrative patent judge would preside over the review, which would be a trial-type

(1983) (indicating that the arbitrary and capricious standard is more lenient than the substantial evidence standard).

45. *In re Gartside*, 203 F.3d 1305, 1312 (2000).

46. *Id.*

47. 277 F.3d 1338 (Fed. Cir. 2002).

48. FTC REPORT, *supra* note 4, ch. 5, at 23-24.

proceeding with opportunity for cross-examination and limited discovery.⁴⁹ Similarly, the NAS Study recommends that Congress create an “Open Review” procedure to enable third parties to challenge the validity of issued patents in a trial-type administrative proceeding conducted by the PTO.⁵⁰

Both reports favor such proceedings on the grounds that such proceedings would allow interested private parties to bring forward information about prior art.⁵¹ Notably, patents that are challenged in post-grant review are likely to be the ones that would otherwise be litigated.⁵² Addressing potentially invalidating information about such patents in the context of a USPTO administrative proceeding should be significantly cheaper than in the trial context.⁵³ Although important questions regarding protection against undue patentee harassment and the length of time a patent would remain subject to post-grant review would need to be addressed, the argument in favor of post-grant review proceedings is persuasive.

Given the time and expense associated with post-grant review proceedings, the manner in which courts treat the conclusions reached in those proceedings is important. The FTC Report argues that Congress, in enacting legislation establishing post-grant review, should require significant judicial deference to determinations made in such proceedings.⁵⁴ Specifically, the Report suggests that courts should review deferentially not only underlying USPTO fact-finding, but also the ultimate legal conclusions regarding validity reached by the USPTO.⁵⁵ The FTC’s recommendation has merit. More so than in granting patents, or perhaps even in denying them, the USPTO is likely to be accurate in its post-grant reviews.

49. *Id.* at 24.

50. NAS STUDY, *supra* note 4, at 79.

51. *See* FTC REPORT, *supra*, note 4, ch. 5, at 19 (“Post-grant review offers substantial opportunities to improve patent quality by drawing upon the information and expertise of competitors. . . . [A] competitor engaged in an administrative challenge to a patent will be well-positioned to supply the best prior art.”); NAS STUDY, *supra* note 4, at 79.

52. Empirical study of opposition proceedings at the European Patent Office indicates that “high-value” patents tend to be opposed. Stuart Graham et al., *Patent Quality Control: A Comparison of U.S. Patent Re-examinations and European Patent Oppositions*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY (Wesley Cohen & Steve Merrill eds., 2003).

53. This assumes, of course, that the administrative process is appropriately streamlined and that the agency’s comparative technical and legal expertise will allow it to resolve validity issues more expeditiously than would a non-specialist district court. The separation of the validity issue from the question of infringement, a move that is often not possible in district courts, should also contribute to efficiency.

54. FTC REPORT, *supra* note 4, ch. 5, at 24 & n.173.

55. *Id.* at 24.

The USPTO will presumably have access not only to information about ordinary skill in the art but also to most of the relevant prior art.⁵⁶ Plenary review of the patent validity question, to the extent it turns on facts particular to the case, would not only be inefficient, but it would be likely to yield inaccurate results. Moreover, to the extent that courts, particularly the Federal Circuit, might evade deference on the factual questions underlying obviousness and other validity issues by simply asserting that validity is a legal question to be reviewed *de novo*,⁵⁷ the FTC's suggestion that Congress mandate deference on legal questions is quite prescient.⁵⁸ Conversely, the NAS Study's failure to specify the level of deference that courts should give USPTO determinations made in post-grant review proceedings is a missed opportunity.

V. A CAUTIONARY NOTE ON OUTCOMES (AND EVALUATION THEREOF)

One might reasonably ask whether tweaking deference levels by altering burdens of proof and standards of review actually affects case outcomes. Arguably, legal doctrines regarding deference are, in actual application, sufficiently indeterminate that they do not affect judicial decision-making. Indeed, the Federal Circuit's apparent resistance to the implications of *Zurko*, discussed above, is not an isolated case; rather, it parallels resistance by other appellate courts to the Supreme Court's demands of deference to agency decision making.⁵⁹

No empirical study of which I am aware specifically focuses on case outcomes as a function of modifications in deference levels. One possible

56. See *supra* note 51 and accompanying text.

57. Arguably, the Federal Circuit has made precisely this move in the area of claim construction.

58. FTC REPORT, *supra* note 4, ch. 5, at 24. (“[S]uch a post-grant proceeding [should] be declared a delegation of authority permitting the ensuing PTO conclusions of law to carry the force of law.”). One important difficulty with the FTC recommendation is that there might be cases where the court's decision to reverse a post-grant review validity determination made by the USPTO resulted not from disagreement over facts but, rather, genuine disagreement over a general principle of law or policy. Giving the USPTO primary power over legal interpretations and policy determinations is problematic. A discussion of which patent institution should have primary interpretive and policy-making power is, however, beyond the scope of this paper. For some thoughts on that question, see generally Rai, *supra* note 4.

59. See Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 984, 1027 n.114 (discussing resistance by D.C. Circuit and other lower courts of Supreme Court directives demanding deference).

study might look at the percentage of patents invalidated before and after *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, the Federal Circuit's first decision to hold that challengers prove invalidity by "clear and convincing evidence."⁶⁰

John Allison and Mark Lemley's study of judicial patent decisions between 1989 and 1996 does indicate that during this period courts held patents invalid in approximately 50% of the cases where validity was at issue and decided.⁶¹ In contrast, in the pre-Federal Circuit era, courts upheld the validity of patents in approximately 30-40% of the cases where validity was at issue.⁶² This data suggests that if the Federal Circuit were to reverse course and establish a preponderance of the evidence standard for challenging patent grants, lower courts might well invalidate patents more frequently.⁶³

However, any analysis of the effect of a change in burden of proof that is based on data from litigated cases must necessarily be quite speculative. Litigated cases represent only a small, nonrandom sample of relevant case disputes. Hence, selection bias problems are pervasive. George Priest and Benjamin Klein's "divergent expectations" model of selection bias posits that parties litigate civil disputes only when the result of litigation under the applicable set of standards is unclear.⁶⁴ When the result is unclear, each side has a 50% chance of winning.⁶⁵ Thus, in the context of patent grants, the model would predict a 50% invalidation rate irrespective of what burden of proof was employed.⁶⁶

60. 725 F.2d 1350, 1360 (Fed. Cir. 1984). A rigorous study would of course not only look at raw percentages but would also attempt to control for other factors.

61. John Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-06 (1998). In contrast, in the pre-Federal Circuit era, it appears courts upheld the validity of patents in approximately 30-40% of the cases where validity was at issue.

62. See, e.g., P.J. Federico, *Adjudicated Patents, 1948-54*, 38 J. PAT. & TRADEMARK OFF. SOC'Y 233, 236 (1956).

63. Voluntary adoption by the Federal Circuit of a preponderance of the evidence standard would of course mean that the Federal Circuit was itself serious about treating patents more skeptically.

64. See generally George Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. LEGAL STUD. 1 (1984).

65. *Id.*

66. *Id.* On the other hand, the applicability of the Priest/Klein model to patent cases is not entirely clear. The 30% validity rate common in the era before the Federal Circuit itself suggests that various assumptions that underlie the model may not apply. For a critique of these assumptions, see Daniel Kessler et al., *Explaining Deviations from the Fifty-Percent Rule: A Multimodal Approach to the Selection for Litigation*, 25 J. LEGAL STUD. 233 (1996).

The difficulty of evaluating whether alteration in a standard of review—in the case of the Federal Circuit, more lenient court review of USPTO proceedings—changes outcomes is perhaps even greater. Even assuming no selection bias of the Priest/Klein variety and assiduous judicial adherence to the lenient standard, the alteration may not lead to lower reversal rates. To the extent that the agency incorporates the liberalization of review standards into its work, it may fail to justify its conclusions as well as before the liberalization. The net result may be a similar percentage of reversals.

Perhaps not surprisingly, the few empirical studies that have examined the relationship between case outcome and standard of review yield mixed conclusions. In studying judicial review of the Social Security Administration (SSA), the Veterans Administration (VA), and agencies charged with interpreting the Freedom of Information Act (FOIA), Paul Verkuil found little connection between the standard of review purportedly employed and the judicial affirmance rate.⁶⁷ Under the purportedly lenient substantial evidence standard, courts affirmed SSA decisions only 50% of the time.⁶⁸ Under the purportedly stringent *de novo* standard, courts affirmed agency FOIA decisions 90% of the time.⁶⁹ In contrast, Peter Schuck and Donald Elliott determined that, at least in the short term, the Supreme Court decision in *Chevron*,⁷⁰ which mandated relatively deferential review of agencies, significantly affected judicial rates of affirmance, reversal, and remand.⁷¹

This is not to suggest that large-scale empirical work to gauge outcomes should not be done. To the contrary, if tweaking of deference levels is going to be effective, particularly in influencing judges, we must have quantitative—as well as qualitative—evidence on outcomes.⁷² Studying the phenomenon is necessary to guide it properly.

VI. CONCLUSION

The question of which patent institution should have primary power to make the factual determinations central to patent validity does not have a

67. Verkuil, *supra* note 37, at 719.

68. *Id.*

69. *Id.*

70. *Chevron v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

71. Schuck & Elliot, *supra* note 59, at 1030-32 (finding change in appellate dispositions that was significant at the 99% level).

72. Together with Craig Nard and David Almeling, I am currently analyzing USPTO reversal rates at the Federal Circuit before the Federal Circuit decision in *Zurko* and after its decision in *Gartside*.

single answer. Depending on the context, either the ordinary USPTO examination, a post-grant review examination, or the court system will be the most appropriate venue for accurate and efficient fact-finding. Thus attempts of the sort made in both reports, but particularly by the FTC, to allocate fact-finding power in a manner that is sensitive to institutional context make sense. The extent to which finely calibrated attempts to allocate power actually works is of course an empirical question. Much quantitative and qualitative work needs to be done on this question, not only because such work advances knowledge in the area, but also because the results may actually help to allocate power properly in the future.