ARTICLE

GROWING PAINS IN THE ADMINISTRATIVE STATE: THE PATENT OFFICE'S TROUBLED QUEST FOR MANAGERIAL CONTROL

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INTRODUCTION

In the last ten years of our "information age," the workload of the Patent and Trademark Office (PTO) has grown dramatically, increasing from 238,850 utility-patent applications in 1998 to over 460,000 in 2008. The flood of recent applications has thrust this previously obscure agency into the spotlight. The PTO faces an unenviable task. The volume of patent applications is obviously extremely large. At the same time, evaluating whether a patent should be granted is often a highly complex endeavor. Proper evaluation requires understanding not only the science in the area in which the patent is sought but also the manner in which the patent statute applies to the science. The patent statute itself sets out only a relatively skeletal set of standards regarding how patentability should be determined.

¹ U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT, FISCAL YEAR 2008, at 116 tbl.2, *available at* http://www.uspto.gov/web/offices/com/annual/2008/2008annualreport.pdf [hereinafter PTO, PAR REPORT].

² Because of the technical complexity of the task involved, the analogy made by Professors Abramowicz and Duffy to the Post Office, *see* Michael Abramowicz & John F. Duffy, *Ending the Patenting Monopoly*, 157 U. PA. L. REV. 1541 (2009), is not entirely apposite. Even the analogy to the Social Security Administration understates the technical complexity involved. *See id.* at 1558-64.

³ See Arti K. Rai, Building a Better Innovation System: Combining Facially Neutral Patent Standards with Therapeutics Regulation, 45 HOUS. L. REV. 1037, 1053-56 (2008) (discussing how scientifically oriented patentability standards promote the goal of innovation). To be sure, the diligence with which this complex task is performed might vary depending on the patent application. For discussions of alternative application tracks, such as accelerated and deferred examination, see *infra* notes 44-46, 109 and accompanying text.

⁴ For example, the nonobviousness requirement for securing a patent gives substantial discretion to the decision maker applying the requirement:

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art 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 to which said subject matter pertains.

³⁵ U.S.C. § 103(a) (2006). Moreover, recent case law from the Supreme Court has made it clear that the Court views nonobviousness and other patent determinations to be standards rather than rules. See Rai, supra note 3, at 1038-39. In contrast, the Court of Appeals for the Federal Circuit has tended to take a more formalist approach. See, e.g., Arti K. Rai, Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform, 103 COLUM. L. REV. 1035, 1102-03 (2003) (criticizing the formalist approach to patent law then being taken by the Federal Circuit and concluding that a standards-based approach is both formally and functionally justified); John R. Thomas, Formalism

For all of these reasons, one might expect Congress to have established a highly muscular patent agency. This has not happened. Not only does the PTO lack substantive rulemaking authority, but the PTO's reviewing court, the Court of Appeals for the Federal Circuit, does not give any formal deference to legal decisions made by the agency in its statutorily authorized case-by-case adjudication.

Even in the face of all of these obstacles, the PTO has had some success in reforming substantive law in a manner that gives it more power in the decision-making process. The courts appear to have accepted, at least implicitly, the PTO's argument that these substantive reforms will help the agency manage its workload and improve the quality of the patents that it issues. In the 2005 case In re Fisher, the PTO succeeded in convincing the Federal Circuit of the validity of its heightened standard for evaluating the utility of patent applications. As a consequence, patentees cannot file applications until they have a "specific" and "substantial" use for their inventions. In 2006, the PTO worked with the Justice Department's Office of the Solicitor General to shape Supreme Court interest in and reform of the core patentability standard of nonobviousness.9 The result was the Su-

at the Federal Circuit, 52 AM. U. L. REV. 771, 774-75 (2003) (disapproving of the Federal Circuit's formalist approach).

See Stuart Minor Benjamin & Arti K. Rai, Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law, 95 GEO. L.J. 269, 293-301 (2007) (discussing the Federal Circuit's failure to give either Chevron or Skidmore deference to the legal determinations that the PTO makes in individual patent cases).

⁶ Whether the PTO is *correct* in its views is ultimately an empirical question. Given the recent vintage of these cases, an empirical verdict cannot yet be rendered. But the argument that, relative to the prior state of affairs, the new case law will result in efficiency and quality improvements is not implausible on its face.

⁴²¹ F.3d 1365 (Fed. Cir. 2005).

⁸ See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1097 (Jan. 5, 2001).

⁹ In KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007), the PTO and the Office of the Solicitor General filed an influential amicus brief opposing the Federal Circuit's "teaching, suggestion, or motivation" (TSM) requirement for proving nonobviousness. See Brief for the United States as Amicus Curiae Supporting Petitioner at 16-24, KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007) (No. 04-1350), available at http:// www.usdoj.gov/osg/briefs/2006/3mer/1ami/2004-1350.mer.ami.pdf. The PTO and the Solicitor General were also heavily involved with the effort to persuade the Supreme Court to take the case in the first instance. See Brief for the United States as Amicus Curiae Supporting Petitioner, KSR, 127 S. Ct. 1727 (No. 04-1350), available at http:// www.usdoj.gov/osg/briefs/2005/2pet/6invit/2004-1350.pet.ami.inv.pdf. At least in certain cases, the Federal Circuit had interpreted the TSM requirement to mean that, in situations where several prior art references had to be combined to show nonobviousness, the patent examiner (or challenger, if the patent had already been granted) was required to identify written documentation suggesting that the references should be

preme Court's 2007 decision in *KSR International Co. v. Teleflex Inc.*, ¹⁰ which has made it easier for the PTO to deny arguably "obvious" patents. In October 2008, the PTO was successful in leveraging the threat of Supreme Court intervention on the issue of patentable subject matter ¹¹ to secure from the Federal Circuit an en banc decision, *In re Bilski*, upholding the PTO policy of excluding from patentability processes that are not tied to a physical transformation or machine. ¹² Most recently, the PTO was able to rely on *KSR* and an earlier Supreme Court decision, *Dickinson v. Zurko*, ¹³ which mandated significant deference to factual findings made by the PTO in the context of patent denials, to secure an April 2009 Federal Circuit victory with respect to the PTO's application of nonobviousness to DNA-sequence claims. ¹⁴

In addition, for the first time, the PTO will soon have in-house professional economic assistance to help it make decisions about substantive examination criteria. As one of its final moves, the George W. Bush administration spearheaded the establishment of an Office of the Chief Economist within the PTO Director's Office. ¹⁵ If filled properly, with a respected economist who is perceived as being objective, this Chief Economist position could serve as an institutional locus for data-driven thinking about how the patent law's legal standards could best serve innovation-policy goals. Moreover, because the position is set up under the Intergovernmental Personnel Act (IPA), it could attract academic economists in the same manner as similar positions at the FTC and the FCC. ¹⁶ While these somewhat jury-rigged

combined. The briefs filed by the PTO and the Solicitor General focused on the significant burdens that a TSM requirement placed on patent examiners.

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¹⁰ 127 S. Ct. 1727.

In the recent case of Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., 126 S. Ct. 2921 (2006), the Supreme Court originally granted certiorari to address the issue of patentable subject matter. Notably, the Court itself raised the issue, even though it had not been argued below. Although the Court ultimately dismissed the certiorari petition as improvidently granted, three Justices dissented from the Court's decision. In the view of Justices Breyer, Souter, and Stevens, the issue was highly compelling and had been adequately briefed. Id. at 2921-29 (Breyer, J., dissenting).

¹² 545 F.3d 943, 961 (Fed. Cir. 2008).

¹³ 527 U.S. 150 (1999).

¹⁴ *In re* Kubin, 561 F.3d 1351 (Fed. Cir. 2009).

¹⁵ Job Announcement, U.S. Patent & Trademark Office, Chief Economist, Office of the Under Secretary and Director (on file with author) (detailing the responsibilities of the Chief Economist).

¹⁶ 5 U.S.C. §§ 3371–3376 (2006); *see also* Int'l Trade Admin., Dep't of Commerce, Intergovernmental Personnel Act (IPA) Fact Sheet (2006), http://

mechanisms to influence substantive patent law are hardly a substitute for the power conferred by substantive rulemaking authority, ¹⁷ they nonetheless represent a significant win for the PTO.

By contrast, the PTO's efforts to regulate the manner in which patent applications are processed, where Congress has explicitly given the PTO rulemaking authority under section 2(b)(2) of the Patent Act, ¹⁸ could be viewed as less successful. Perhaps most notably, the PTO rules package that limits the number of "repeat" applications patentees can file and places additional requirements on applications that contain large numbers of claims was the subject of a sweeping judicial challenge that succeeded in the district court. ¹⁹ The district court's opinion in this litigation threatened to limit the PTO's rulemaking authority on questions of procedure to relatively narrow concerns. Although the Federal Circuit's March 2009 panel opinion in the case takes a more expansive view of PTO authority, ²⁰ the opinion includes a dissent and may not ultimately persuade the majority of the Federal Circuit.

On first examination, then, it would appear that the agency has enjoyed some success in areas where it has limited authority, and is operating on tenuous ground in areas where it has been delegated explicit authority. More generally, from the perspective of administrative law, the idea that an agency would have circumscribed control over the manner in which it processes its workload is anomalous. An important line of Supreme Court case law stresses that agencies are generally in the best position to articulate their own procedural requirements.²¹ And when the agency in question has over 9000 em-

www.ita.doc.gov/ooms/ohrml7.htm (discussing requirements of the Intergovernmental Personnel Act, including the possibility of hiring from the academic sector).

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¹⁷ While substantive rulemaking authority means that an agency makes substantive "law" at the point that it promulgates a rule, the PTO must wait for a private party to bring an appropriate test case and then wait for a decision by the Court of Appeals for the Federal Circuit or even the Supreme Court.

¹⁸ 35 U.S.C. § 2(b)(2) (2006) (stating that the PTO "may establish regulations" to "govern the conduct of proceedings in the Office").

See infra Section II.D (describing the district court's decision in Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008), vacated in part sub nom. Tafas v. Doll, 559 F.3d 1345 (Fed. Cir. 2009), to strike down the PTO's proposed rules).

²⁰ Tafas, 559 F.3d 1345.

See Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc., 435 U.S. 519, 525 (1978) ("[A]dministrative agencies and administrators will be familiar with the industries which they regulate and will be in a better position than federal courts or Congress itself to design procedural rules adapted to the peculiarities of the indus-

ployees (including over 6000 patent examiners), the need for significant managerial control would appear quite pressing.

Perhaps unsurprisingly, on second examination one sees more complexity and nuance. The PTO faces a set of mutually reinforcing challenges that substantially weaken its control over procedure. First, even where reform does not directly involve external interest groups, and thus is unlikely to be the subject of a court challenge, the PTO has limited room for maneuvering. Most notably, the complexities of collective bargaining with a union that represents over 6000 examiners pose a formidable challenge.

Once external interest groups get involved, the challenges grow even larger. Because substance and procedure exist on a spectrum, separated by no bright dividing line, the PTO's lack of substantive rulemaking authority makes it quite vulnerable to interest-group charges that it has overstepped its bounds. Relatedly, as administrative law scholars have long discussed, any attempt to implement significant reform through rulemaking poses a challenge. Perhaps because of the PTO's limited history with rulemaking, it has not shown great aptitude in implementing the interest-group outreach that is often necessary (though hardly sufficient) to meet this challenge. Moreover, although the PTO has procedural-rulemaking authority, it has not been given fee-setting authority, an important concomitant power for an agency with operations that are entirely fee based.

Finally, there is the anomaly of review by a court, the Federal Circuit, that itself can lay claim to specialization and expertise—two characteristics that administrative law scholars typically see as the exclusive attributes of agencies. The Federal Circuit's desire to formulate its own procedural rules for the PTO—perhaps most notably in the area of inequitable conduct—substantially weakens the agency's ability to regulate interactions with applicants.

But the fact that anomalies can be explained does not mean that they should persist. In the case of the PTO, ameliorating the difficult situation is likely to require making it less of an outlier among administrative agencies. Although dramatic changes may be undesirable—and are, in any event, likely to be politically infeasible—a few relatively narrow tweaks affording the PTO some power over procedure could produce significant improvements. ²²

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try and the tasks of the agency involved." (quoting FCC v. Schreiber, 381 U.S. 279, 290 (1965))).

²² A caveat on the normative scope of this Article bears emphasis. Because transi-

This Article proceeds in three parts. Part I reviews the evidence of dysfunction and discusses the extent to which difficulties have emerged as a consequence of both exogenous forces and problems in substantive legal doctrine. As that Part notes, for better or for worse (perhaps better in the case of substantive legal doctrine, worse in the case of exogenous forces), both exogenous forces and substantive legal doctrine will, at least in the near term, be considerably different than in the recent past. Part II discusses the area of procedure, where little has changed in recent years. It elaborates on the factors, noted above, that limit the PTO's latitude in the area of procedure. Part III outlines realistic near-term possibilities for the path forward, focusing on ways in which the current trend toward tying the PTO more closely to the administrative state in the area of substantive patent law could be mirrored in the area of procedure.

I. CURRENT DYSFUNCTION: THE ROLE OF EXOGENOUS FORCES AND SUBSTANTIVE LAW

A. Increased Workload and Backlog

In the last ten years, the PTO has been confronted with a significant increase in numbers of patent applications. As noted earlier, the number of utility-patent filings nearly doubled between 1998 and 2008, going from about 239,000 in fiscal year (FY) 1998 to over 460,000 in FY 2008.23 The George W. Bush administration, buoyed by a 2005 decision by congressional appropriators to let the PTO retain all of the fees that it charged,²⁴ attempted to address this increasing workload by hiring approximately 1200 new examiners each year in FY 2006 through FY

tion costs and political feasibility are key background considerations in the Article, it does not purport to examine how an ideal system built from scratch would allocate power between the PTO, Congress, and the courts.

³ PTO, PAR REPORT, *supra* note 1, at 116 tbl.2.

²⁴ As discussed further below, the PTO is an entirely fee-funded organization. However, it has not always been able to keep all of the fees that it collects. See infra notes 48-52 and accompanying text. In the 1990s, for instance, Congress diverted hundreds of millions of dollars in fee revenues from PTO coffers. See, e.g., Figueroa v. United States, 66 Fed. Cl. 139, 143 (2005) (analyzing a challenge to the constitutional authority of Congress to divert fees in which the plaintiff asserted that \$422.5 million had been diverted); Press Release, Am. Bar Ass'n, PTO Fee Diversion Costs Jobs: Bar, Industry United Against Diversion 1 (Apr. 2003), available at http://www.abanet.org/ intelprop/feediversion.pdf (estimating that "nearly \$750 million dollars have been withheld from the USPTO in the past decade").

2008.25 However, because examiner attrition rates were also high, net growth in the workforce between the end of 2005 and the end of 2008 was only 1946 employees (about fifty-four percent of total hiring). 26

Additionally, end results did not improve. To the contrary, according to the PTO's own statistics, the elapsed time before an applicant receives an initial response from the PTO increased from 21.1 months in 2005 to 25.6 months in 2008.27 At the end of FY 2008, the PTO had not even begun review of over 770,000 applications.²⁸ A total of 1,276,028 were listed as pending—that is, either awaiting initial review or in the review process.²⁵

In the areas of information and communications technology (ICT), delays were particularly acute. For example, in Technology Center 2100, which covers computer architecture, software, and information security, the elapsed time before a first office action was 30.8 months; in Technology Center 2600, which covers communications, the elapsed time was 32.5 months.³⁰

Delays in patent examination can be a challenge for all firms seeking patents. However, such delays are particularly problematic for startups that rely on issued patents to attract venture capital. ³¹ To the extent that startup-driven innovation will be an important component of any plan to move the U.S. economy out of severe recession, addressing backlog should be a high priority.

Delays in patent examination can also adversely affect the ability of cash-constrained startups to seek patent protection in other countries.³² Under the Patent Cooperation Treaty (PCT), a U.S. applicant can specify other countries in which it wants to preserve its U.S. filing date but then delay the significant expense associated with actually

²⁵ U.S. PATENT & TRADEMARK OFFICE, PATENT DATA UPDATE: FY 08, at 4 tbl. (on file with author) [hereinafter PTO, PATENT DATA UPDATE] (stating that 1211 examiners were hired in 2008, 1215 in 2007, and 1193 in 2006).

 $^{^{26}}$ Id. For a discussion of the problem of employee attrition, see infra notes 58-59 and accompanying text.

PTO, PAR REPORT, supra note 1, at 16 fig.

²⁸ *Id.* at 118 tbl.5.

²⁹ *Id*.

³⁰ *Id.* at 118 tbl.4.

 $^{^{31}}$ The empirical data indicate that most biotech firms that receive venture-capital backing have issued patents. See Ronald J. Mann & Thomas W. Sager, Patents, Venture Capital, and Software Start-ups, 36 RES. POL'Y 193, 197 (2007). Because the Mann and Sager data are from the late 1990s, an era of robust venture-capital availability, it may actually understate the desirability of patents for life-sciences firms seeking venturecapital funding.

³² Thanks to Steven Spinner for noting this point.

prosecuting the application in those countries for as long as thirty months.³³ Thus, at least in theory, a firm that has filed a PCT application can save money by waiting to see whether the PTO thinks that the invention is likely to be patentable before deciding whether to incur the expense of seeking protection in other jurisdictions. But if there are long delays before a patent is examined, the time window for seeking international protection may close.

Slow examination has not necessarily meant careful and deliberate examination. Given the large volume of applications, examiners still have an average of only about twenty hours to examine applications. Moreover, although patent-grant rates appear to have decreased somewhat over the last six years, it is not clear whether this decrease targets "bad" patent applications (as the PTO argues) or represents an across-the-board decision to reject patent applications (as some patent applicants argue).

B. Causes: Exogenous and Endogenous

Some of the PTO's increased workload can be traced to exogenous causes that would generally be considered positive. Perhaps most notably, because the conceptual distance between basic and applied research in existing fields, such as biotechnology, is relatively narrow, and because certain new fields, such as nanotechnology, have immediate commercial application, a significant percentage of current academic and industrial research is patentable.³⁶

Substantive patent law doctrine that developed in the 1990s has also contributed to the growth in patent applications. This contribu-

³³ Patent Cooperation Treaty art. 22, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231. While the treaty originally provided for only a twenty-month period, that period was subsequently increased to thirty months. *See* Revision of the Time Limit for National Stage Commencement in the United States for Patent Cooperation Treaty Applications, 67 Fed. Reg. 520, 520 (Jan. 4, 2002) (providing notice of extension of the time period by the World Intellectual Property Organization).

³⁴ The precise amount of time available to an examiner depends on her General Schedule (GS) pay grade and the technology center in which she works. U.S. GOV'T ACCOUNTABILITY OFFICE, U.S. PATENT AND TRADEMARK OFFICE: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG 7 (2007), available at http://www.gao.gov/new.items/d071102.pdf [hereinafter GAO REPORT]. For further discussion of the examiner incentive and compensation system, see *infra* notes 53-54 and accompanying text.

³⁵ See infra note 52.

³⁶ See, e.g., Arti K. Rai & Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 LAW & CONTEMP. PROBS. 289, 289-91 (2003) (discussing the narrowing of the conceptual gap between basic and applied research in the biomedical arena).

tion has arguably been less positive. The doctrine (overruled by *KSR*) that patent examiners show documentary evidence of a prior art suggestion to combine or modify prior art references in order to use those references to prove obviousness³⁷ made it quite difficult for the PTO to deny patent applications. Federal Circuit decisions expanding patentable subject matter³⁸ created an opportunity for the filing of large numbers of patents with vague claims, particularly in the ICT area.³⁹

The patent-application figure achieved in 2008 may represent a peak, at least in the short and medium term. Exogenous forces in the form of a dramatically weakened economy (national and global) are likely to contribute to a diminution in application filings, at least for the short to medium term. ⁴⁰ The decisions in *KSR* and *Bilski* may also lead to downward pressure on filings.

On the other hand, backlog and poor quality are linked not simply to exogenous forces and substantive patent law but also to problems falling on the procedural side of the substance versus procedure spectrum. Part II reviews these problems and presents five mutually reinforcing reasons why they may prove difficult to fix.

II. THE MANAGERIAL CONUNDRUM

A. The Current State of Play

From the perspective of efficient workflow management, the current U.S. system of patent filing and examination is quite peculiar. The U.S. system is unique in allowing applicants who have been denied the coverage they seek to file "repeat" applications as many times as they want. Repeat applications fall into two distinct categories: continuations and requests for continued examination (RCEs). Although continuations can share the same priority filing date as their

 $^{^{\}rm 37}$ See supra note 9 and accompanying text.

See, e.g., State St. Bank & Trust Co. v. Signature Fin. Group, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (stating that, to establish patentable subject matter, an applicant need only show that her invention is "useful").

JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 9 (2008) (arguing that because patent claims in the ICT industries fail to provide notice of patent boundaries, both publicly traded and smaller firms in these industries incur large costs associated with actual and potential infringement).

⁴⁰ See Timothy K. Wilson, Patent Demand—A Simple Path to Patent Reform, 2 INT'L IN-HOUSE COUNS. J. 806, 810 (2008) (indicating that, at least from 1982 onwards, GDP growth and growth in patent filings have been highly correlated).

⁴¹ See 35 U.S.C. § 120 (2006) (continuations); id. § 132 (RCEs).

"parent" application, they are technically considered new applications. In contrast, RCEs represent continued examination of the same application. Continuations also have a much longer history than RCEs—continuations have existed for decades, while RCEs were only established in 1999. 42

Notwithstanding these distinctions, the two types of repeat applications now tend to be used in similar ways. Both continuations and RCEs are typically used to adjust the scope of the initial patent application so that it yields the patent, or set of patents, that is most commercially useful to the applicant. For at least certain segments of the biopharmaceutical industry, continuations appear to serve as a mechanism for claiming the particular molecule within a genus of compounds that ultimately proves successful in clinical trials.⁴³ For all applicants, continuations (though not RCEs) can serve as a mechanism for securing narrower coverage in an initial patent while holding out for broader coverage in a continuation.⁴⁴

One might argue that an applicant determined to secure optimal coverage (within the bounds of the relevant substantive patent law) should be able to use repeat filings for that purpose. On this view, repeat filings would represent a second-best option when the first-best option—either a fully reliable initial examination or the ability to defer examination pending a determination of precisely what claim scope the applicant needs (or whether the applicant ultimately needs patent protection at all)—is not available. For reasons discussed further below, the first-best option of a reliable initial examination may not currently be available. Deferred examination is currently available in limited form, ⁴⁵ but this limited form is suboptimal because appli-

 $^{^{42}}$ RCEs were established as part of the American Inventors Protection Act of 1999, Pub. L. No. 106-113, sec. 4403(2), § 132(b), 113 Stat. 1501A-552, 1501A-560 (codified as amended at 35 U.S.C. § 132(b) (2006)).

⁴³ See, e.g., Brief of Plaintiffs-Appellees GlaxoSmithKline at 8, Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008) (Nos. 07-1008, 07-0846).

⁴⁴ Interestingly, although the biopharmaceutical industry is most adamant in opposing the limitations the PTO has attempted to place on continuation and RCE filing (and is the lead plaintiff in the case challenging these limits), Technology Center 2100—computer architecture, software, and information security—currently receives the most RCEs. In FY 2008, thirty-six percent of total filings in Technology Center 2100 were RCE filings. John J. Doll, Deputy Under Sec'y of Commerce for Intellectual Prop. and Deputy Dir. of the USPTO (Acting), U.S. Patent & Trademark Office, Slide Presentation: Patents Business Unit 17 (on file with author) [hereinafter John Doll, Slide Presentation].

⁴⁵ 37 C.F.R. § 1.103(d) (2008); U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 709 (8th ed., 7th rev. 2008) [hereinafter PTO, MPEP], available at http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r6_0700.pdf. Ap-

cants have to determine at the outset the precise time period for which they want to defer examination. 46

But even if repeat filings can be justified, we might expect that the cost that any filing—repeat or, for that matter, initial—imposes on the system would be borne by the applicant. 47 This does not happen. As noted, the PTO is an entirely fee-based organization. However, under the current fee structure, a large percentage of the front-end examination cost is recouped through back-end issuance fees as well as maintenance fees, which are considerably higher than front-end filing fees. 48 Specific numbers from recent years illustrate the magnitude of the cross-subsidy. The PTO estimates that in fiscal years 2005 to 2008, the average examination cost per patent has ranged between \$3773 and \$3961. 49 By contrast, the initial filing fee, which is supposed to cover filing, search, and examination, is \$1090. Issuance fees are seventy-four percent higher (\$1480), and maintenance fees (due at 3.5, 7.5, and 11.5 years) are \$1020, \$2320, and \$3580, respectively.

Not only do applicants who secure and maintain patents dramatically subsidize those whose patents are denied, but the current fee structure also sets up an obvious financial incentive for the PTO to grant patents. The skewed incentive structure may be based on a policy judgment that patent applications, even those that ultimately end up being nonmeritorious, should be encouraged. Relatedly, it could be based on the supposition that false positives, in the form of patent applications that are improperly granted, are better than false negatives, in the form of patents that are not applied for in the first instance. But

plicants can also defer examination de facto in various ways. For example, they can use the availability of a thirty-month delay under the PCT application process to defer examination. The benefits of improving current methods for deferring examination are well articulated in Steven Bennett & David Kappos, Deferred Examination: A Solution Whose Time Has Come, IP WATCH, Mar. 12, 2009, http://www.ip-watch.org/weblog/ 2009/03/12/inside-views-deferred-examination-a-solution-whose-time-has-come. tably, an improved system of deferred examination could in all likelihood be implemented through PTO regulation, so long as the PTO's procedural-rulemaking authority is not interpreted in an unduly cramped fashion. See infra subsection III.A.1.

Revision of Patent Fees for Fiscal Year 2009, 73 Fed. Reg. 47,534, 47,535 (Aug. 18, 2008) (to be codified at 37 C.F.R. $\S 1.20(e)-(g)$).

Bennett & Kappos, *supra* note 45.

As discussed further in the text, requiring appropriate payment for the filing of patent applications may be particularly desirable to the extent that, even after they are issued, patents impose significant deadweight loss and transaction costs. See infra Section II.C.

For FY 2008, maintenance fees were the PTO's largest source of earned revenue. PTO, PAR REPORT, supra note 1, at 56 fig.

⁴⁹ *Id*. at 43 fig.

the case for such a policy judgment has not been made.⁵¹ Meanwhile, the skewed structure creates additional patent applications that add to backlog. Additionally, in contexts where quality concerns counsel in favor of granting a relatively small percentage of applications, the structure creates the potential for significant revenue shortfalls.⁵²

On the examiner side of the equation, incentives are also peculiar. The compensation system for examiners awards credits, or "counts," for only two specific actions taken during the examination period: "first office actions" and "disposals." The examiner receives a first-office-action count by making a preliminary communication to the applicant as to whether the application is allowable (thereby permitting the applicant to amend claims as necessary or to contest the examiner's conclusion). A variety of actions on the part of either the examiner or the applicant can produce a disposal count. Such actions include allowance of the application, abandonment (which can occur not only when the applicant entirely drops an application but also when she files a continuation), and an RCE.

Counts must be achieved within an allotted period of time that is calculated based on the experience level of the examiner and on the complexity of the technology at issue. A recent report by the Government Accountability Office (GAO) explains that

Interestingly, some economists have argued against self-funding of patent offices on the grounds that such self-funding will cause offices to set initial application fees too high. See Joshua S. Gans et al., Patent Renewal Fees and Self-Funding Patent Offices, TOPICS IN THEORETICAL ECON., 2004, at 1. But these economists work within a line of economic theory that assumes policymakers cannot measure the social value of invention, and therefore the socially optimal approach is to encourage the maximal number of patent applications, grant such applications, and then cull ex post through renewal fees. Id. at 1-3 (discussing theoretical literature). Under this line of theory, it is not clear why a patent office (or litigation system) with validity criteria would exist in the first instance. Any patent for which an entity was willing to pay renewal fees would be a patent worth having from a social standpoint. Presumably this could include patents on public domain information.

⁵² As noted earlier, in recent years the PTO has reduced the percentage of patents that it grants during the first round of examination. See John Doll, Slide Presentation, supra note 44, at 12 (showing an allowance rate of 44.2% in 2008, a drop from rates of about 70% in 2002). Although the grant rate is higher once continuations and RCEs are taken into account, a downward trend can be discerned. See Mark A. Lemley & Bhaven Sampat, Essay, Is the Patent Office a Rubber Stamp?, 58 EMORY L.J. 181, 182-89 (2008) (discussing recent data, including figures regarding continuations and RCEs). Of course, percentages tell us very little about whether the PTO grant rate is too high, too low, or just right. This is particularly the case because patent scope can be modified substantially in prosecution. Indeed, a strong argument can be made that the relevant concern is not grant rates, but appropriate incentive structures for both applicants and examiners.

⁵³ GAO REPORT, *supra* note 34, at 7.

a GS-12 patent examiner working on data processing applications is expected to achieve two counts in 31.6 hours, whereas a GS-12 patent examiner working on plastic molding applications is expected to do so in 20.1 hours. In contrast, GS-7 examiners working on these two types of applications are expected to achieve two counts in 45.1 and 28.7 hours, respectively. 54

This production framework has not changed since 1976.⁵⁵

Various analysts have argued that the framework no longer reflects the work required to consider patent applications. In certain cases, as a consequence of improvements in automation of the prior art search, the time allotted may be too high. In other cases, the increasing complexity of a particular scientific or technological area (and the associated patent applications) creates a situation in which the time allotted may be too small. The mismatch has an obvious impact on examiner morale. Indeed, the GAO report discussed above concluded that high rates of patent-examiner attrition were largely a function of overly demanding, or at least outdated, production goals. Attrition creates inefficiencies for all organizations. For the PTO, however, the inefficiency may be particularly costly—those who leave tend to do so after only three to five years, precisely the point at which the PTO's investment in training is beginning to pay off in terms of output. The series of the prior of output.

The production framework may also create incentives for examiners to prolong patent examination by "forcing" repeat applications. Specifically, to the extent that examiners determine that they cannot do an adequate job in the time allotted for an examination, they can use various tactics to encourage applicants to file continuations or RCE applications. Even though examination of a continuation should be easier since the examiner has seen the application before, examiners

⁵⁵ *Id*. at 8

⁵⁴ *Id*.

⁵⁶ See, e.g., id. at 5 (stating that sixty-seven percent of surveyed patent examiners cited production goals as "among the primary reasons they would consider leaving the USPTO").

⁵⁷ In general, the total number of claims per issued patent appears to have increased almost one-hundred percent since 1976. Posting of Dennis Crouch to Patent Law Blog (Patently-O), Rising Claim Counts, http://www.patentlyo.com/patent/2007/12/rising-claim-co.html (Dec. 23, 2007). Most of this increase has occurred in dependent claims. *See* Ron D. Katznelson, *Bad Science in Search of "Bad" Patents*, 17 FED. CIR. B.J. 1, 26 fig.3 (2007) (reporting that the average number of total claims rose from approximately fourteen in 1990 to twenty-four in 2002).

⁵⁸ GAO REPORT, *supra* note 34, at 5-6.

⁵⁹ See id. at 5 (stating that seventy percent of those patent examiners who left the PTO between 2002 and 2006 worked there for less than five years).

receive the same amount of credit for conducting a first office action on a continuation as on an original application. Meanwhile, as noted earlier, continuations and RCEs also redound to the benefit of applicants, as they are subsidized for pursuit of optimal claim coverage.

As noted above (and discussed further below), the PTO's attempt to limit patentee use of repeat applications is currently the subject of litigation that threatens the agency's power to manage its workload. A more direct alternative, which would not have required rulemaking or perhaps even negotiations with outside interest groups, might have been reform of the scheme that establishes incentives and compensation for examiners. Indeed, at least two prominent reports issued in the last five years—both the GAO report discussed above and a report by the Department of Commerce's Inspector General —have recommended such internal reforms. The next Section considers why such reform, though highly appealing in theory, may be difficult to achieve in practice.

B. Internal Reforms: Examiner Incentives and Prior Art Searching

Presumably, the goal of internal reform would be to ensure that, at least on the examiner side, delaying behavior is not rewarded and time allocated better corresponds to the time required for any given application. But such complex recalibration may be difficult to implement in a work environment where the patent examiners' union tends to view management-proposed changes as attempts to squeeze examiners further with respect to the time that they have to examine applications.⁶¹

Union resistance to management-proposed changes may also pose an impediment to longstanding hopes that greater examination efficiency and quality could be achieved either through outsourcing prior art searches or through reliance on the prior art searches of foreign patent offices. Proponents of the outsourcing scenario argue that separating the prior art search function from the examination function could yield specialization-related efficiencies. Proponents of the inter-

OFFICE OF INSPECTOR GEN., U.S. DEP'T OF COMMERCE, FINAL INSPECTION REPORT NO. IPE-15722, USPTO SHOULD REASSESS HOW EXAMINER GOALS, PERFORMANCE APPRAISAL PLANS, AND THE AWARD SYSTEM STIMULATE AND REWARD EXAMINER PRODUCTION 30 (2004), available at http://www.oig.doc.gov/oig/reports/2004/USPTO-IPE-15722-09-04.pdf.

⁶¹ See Press Release, Patent Office Prof'l Ass'n (POPA), Fixing the USPTO: Doing the Job Right the First Time (Aug. 2008) (on file with author) [hereinafter POPA, Fixing] (discussing the current "culture of conflict" at the PTO and stating that examiners need more time to do their job correctly).

national work-sharing scenario note the very significant inefficiency of having U.S. examiners do prior art searches on the many foreign applications that another patent office has already searched thoroughly. ⁶²

Although these arguments are compelling, ⁶³ realizing efficiencies would require examiner assent to a reduction of counts achieved on applications for which a prior art search has already been done. Such assent may be difficult to achieve. Indeed, although the PTO has vigorously pursued various work-sharing programs with other offices, ⁶⁴ it has not, at least thus far, attempted to translate this work sharing into a restructuring of the count system.

Union arguments about examiner workload are buttressed by the reality of high attrition rates among patent examiners. Particularly during times of economic growth (precisely the times when patent applications tend to grow), ⁶⁵ examiners often have lucrative alternative opportunities in the private sector. Thus, PTO management has limited latitude to undertake change that makes (or is perceived as making) additional demands on examiners. At a minimum, it cannot undertake such change without offering significant compensatory benefits.

Compensatory benefits in the form of higher salaries or substantially improved information-technology tools (the information-technology infrastructure at the PTO is notoriously poor and better tools are a prominent demand of the examiners' union⁶⁶) might be possible. However, in order for such benefits to be offered, the PTO's budget would have to grow. At a minimum, the PTO would need

⁶² See, e.g., Gerald J. Mossinghoff & Stephen G. Kunin, *Improving the Effectiveness of the U.S. Patent and Trademark Office*, SCIENCE PROGRESS, Fall-Winter 2008/2009, at 72, 76, *available at* http://www.scienceprogress.org/2009/01/improving-the-effectiveness-of-uspto (noting the "debilitating redundancy" of the current patent search and examination system).

⁶³ In the case of outsourcing, one could argue, however, that greater segmentation might produce transaction costs that exceeded efficiencies. This argument parallels the literature on the comparative advantages of markets and firms. *See generally* OLIVER HART, FIRMS, CONTRACTS, AND FINANCIAL STRUCTURE 5-6, 23-28 (1995) (explaining how transaction costs compel a frequent user to seek ownership, thereby avoiding the costs of ambiguous contracts).

⁶⁴ See John Doll, Slide Presentation, *supra* note 44, at 39 (discussing implementation of pilot programs with the United Kingdom, the European Patent Office, and the Korean Patent Office, as well as full implementation as of January 4, 2008, of work sharing with the Japanese Patent Office).

⁶⁵ In the last fifteen years, examiner attrition rates have been highest when the economy is strongest. In FY 2000, for example, the attrition rate peaked at 13.77%. In FY 1999, it was 12.52%. PTO, PATENT DATA UPDATE, *supra* note 25, at 4.

⁶⁶ See POPA, Fixing, supra note 61 (stating the need for updates to the U.S. classification system so that examiners can find the best prior art).

greater control over its budget. In contrast with the purely internal reforms discussed thus far, reforms involving fees obviously require some level of assent from external interest groups. The next Section turns to the critical, but hotly contested, question of fees.

C. Limits on Authority over Fees

Although the PTO has authority to set a few fees by regulation, any significant change in the major fees that it charges—filing fees, issuance fees, and maintenance fees—currently requires congressional action. The generally modest pace of congressional action in the patent arena does not afford the PTO the flexibility over fees that it needs to manage its workload. In addition, although Congress has in recent years allowed the PTO to keep all of its fees, the patent statute currently requires that this decision be made annually by congressional appropriators. 68

Patent-reform legislation proposed in the 111th Congress gives the PTO authority to set most major fees so long as the "fee amounts are set to reasonably compensate the Office for the services performed." Giving the PTO permanent regulatory power to impose on applicants a "pay as you go" strategy and ensuring a permanent end to fee diversion would be a significant improvement over the current system of cross-subsidy and year-by-year assessment of the fee-diversion question. Such a system would stabilize the PTO's budget and allow for long-term planning.

Securing this regulatory power—or even a one-time fee restructuring—may prove difficult, however. For the last few years, legislation on fees has been bundled with other, more contentious provisions (perhaps most saliently, provisions concerning damages apportionment in litigated cases). Whether Congress would entertain fee legislation divorced from such highly contentious provisions is unclear. In addition, even such stand-alone legislation would not necessarily pass easily. For example, the February 2003 Strategic Plan for the PTO announced by then-Director James Rogan would have raised and re-

⁶⁷ See 35 U.S.C. § 41(d) (2006) (limiting the PTO's discretion in setting fees to minor issues such as "processing, services, or materials").

⁶⁸ *Id.* § 42(e).

S. 610, 111th Cong. § 9(a)(1) (2009). The legislation sets up a fairly elaborate consultation-and-comment scheme that the PTO must follow before any fee change can become effective. The PTO must consult with the Advisory Committees (the Patent Public Advisory Committee and the Trademark Public Advisory Committee) and also seek comments from the general public and Congress.

structured fees considerably.⁷⁰ Various patent interest groups rebelled against these proposed fee increases, and the PTO ultimately withdrew its request for legislation to implement the increases.

To be sure, in the case of the fee increases proposed by Director Rogan, interest groups protested most vigorously provisions that would have imposed claim fees that increased in a nonlinear fashion for more than three independent claims and more than twenty total claims. As the PTO admitted, this nonlinear escalation was not necessary to compensate the Office for services performed. This element of the reform package (as well as certain other elements) took a good idea with some political feasibility—fee increases and restructuring—and expanded it into a proposal that was highly objectionable to interest groups. The efforts by Director Rogan suggested a lack of political sensitivity that would (as discussed further below 12) be a persistent feature of the PTO's reform agenda.

In fairness to the PTO, a fee structure that does more than "reasonably compensate" the PTO for services performed is not necessarily a bad idea. Such a fee structure might be put into place to deter filing behavior that imposes costs not only on the PTO but also on society as a whole. Whether patents with large numbers of claims impose larger social costs, however, is not clear. These large numbers of claims may reflect an effort to seek appropriate patent scope against a background law that imposes significant sanctions on applicants who file a small number of broad claims that they are then asked to narrow. ⁷³

A better use of fees to achieve deterrence might take aim at the "patent portfolio" approaches used by many ICT firms. As has now been well documented, ICT firms often amass large patent portfolios on the grounds that they need defensive patents as protection against

⁷⁰ See U.S. PATENT & TRADEMARK OFFICE, THE 21ST CENTURY STRATEGIC PLAN 3 (2003) ("This strategic plan cannot succeed without... changing the USPTO's current fee schedule and access to revenue generated...." (italics omitted)).

See U.S. PATENT & TRADEMARK OFFICE, THE 21ST CENTURY STRATEGIC PLAN: FEE PROPOSAL COMPARISON CHART, http://www.uspto.gov/web/offices/com/strat21/feeproposalcomparison.htm (last visited Apr. 15, 2009) (showing proposed charges).

⁷² See infra notes 97-100 and accompanying text (describing continuation and claims rules).

⁷³ The sanctions in question emerge from the doctrine of prosecution history estoppel. Under the Federal Circuit's interpretation of this doctrine, patentees who narrow broad claims during prosecution in response to an examiner's objection are severely limited in their ability to assert in subsequent litigation that a defendant infringes by utilizing an invention substantially equivalent to the patented invention. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1366-67 (Fed. Cir. 2003).

lawsuits from their competitors.⁷⁴ This strategy of mutually assured destruction (MAD) appears to be socially wasteful,⁷⁵ especially if one takes into account the possibility that some of these ICT patents will fall into the hands of nonpracticing entities that are not subject to the logic of MAD and instead use the patents for holdup purposes.

Moving ICT firms away from the socially wasteful MAD strategy represents a significant collective action problem, however. Moreover, increasing fees to a level that merely allowed for reasonable compensation for services performed is not likely to do enough to address the collective-action problem. Although the data on the question are limited, several recent studies have suggested that at low fee levels, patent demand is relatively inelastic. In fact, an intellectual property attorney at one of these large ICT firms recently argued that a filing fee as high as \$50,000 (applicable, he would suggest, only to large firms) might be necessary to curb filing significantly.

Even for large firms, such a dramatic increase in filing fees would be quite problematic. Moreover, imposing such a fee starting at the first application would imply that *all* filing is an activity to be deterred. This deterrence aim is squarely inconsistent with the standard argument that certain levels of patent protection are conducive to innovation for all firms, regardless of their size.

On the other hand, an argument can be made for some level of taxation in connection with patent portfolios. In this regard, a system under which firms were charged a slightly increased fee for each addi-

⁷⁴ 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, 104 (2001) (documenting defensive patenting in the semiconductor industry); see also Jean O. Lanjouw & Mark Schankerman, Protecting Intellectual Property Rights: Are Small Firms Handicapped?, 47 J.L. & ECON. 45, 45 (2004) (finding, based on a study of determinants of patent suits from 1978–1999, "that patentees with a large portfolio of patents to trade . . . are much less likely to prosecute infringement suits"); Gideon Parchomovsky & R. Polk Wagner, Patent Portfolios, 154 U. PA. L. REV. 1, 26-27, 36 (2005) (discussing defensive patent-portfolio behavior among ICT firms more generally).

⁷⁵ The argument that the MAD strategy is not socially wasteful would have to rest on the assumption that defensive patenting promotes interfirm exchanges of information that would not otherwise occur. However, there is little, if any, empirical evidence that firms in the ICT industry actually read patent disclosures (or that these disclosures provide useful information in any event).

⁷⁶ See, e.g., Wilson, supra note 40, at 810-12 (arguing, based upon a model that uses U.S. application and fee data over the last four decades, that filing fees need to be raised significantly in order to reach the elastic portion of the demand curve).

 $^{^{77}}$ Id. at 812 fig.5 (estimating that applications might fall to 100,000 if filing fees were raised to \$50,000).

tional patent application they filed in any given year is an interesting possibility.⁷⁸

A full discussion of the merits and demerits of such a "progressive" fee system is beyond the scope of this Article. One obvious demerit is that it creates the potential for gaming through the formation of shell companies or other mechanisms. More generally, regulating behavior through fees is likely to be a highly complex and politically sensitive endeavor. For present purposes, the point that bears emphasis is that such a structure would have (by far) the greatest impact on large technology firms that file thousands of applications each year. In 2008, for example, virtually all of the firms that secured more than 500 patents were large technology firms.⁷⁹

One legal difficulty with PTO implementation of a fee structure that was intended to tax applicant behavior, and not simply to compensate the PTO for examination costs, would be that Congress might explicitly have to grant the PTO taxation authority. Although the Supreme Court has stated that agencies can be authorized by Congress to impose taxes, it has also stated that if Congress wants to delegate its taxation authority to an agency, it must do so explicitly. On the other hand, as discussed further in Part III, such authorization could be part of a scheme in which Congress gives the PTO some level of authority over fee setting.

D. The Blurry Line Between Substance and Procedure

In lieu of a complex renegotiation of the incentive scheme for examiners that would have been constrained by a limited budget, and

⁷⁸ I thank Bruce Sewell for this suggestion. In fact, even if the PTO's goal were simply to charge applicants for the cost that they imposed on the Office, charging an increased fee for each additional application might be a plausible strategy. The available empirical evidence indicates that ICT firms that file significant numbers of patent applications are more likely than other firms to shift the costs of searching for prior art onto the PTO. See Juan Alcácer et al., Applicant and Examiner Citations in U.S. Patents: An Overview and Analysis (Harvard Business School, Working Paper 09-016, 2008), available at http://ssrn.com/abstract=1273016 (finding that the percentage of prior art citations added by the examiner is highest in the ICT area and among "prolific patentees").

⁷⁹ See Press Release, Wolters Kluwer Health, IFI Patent Intelligence Analysis of 2008's Top U.S.-Patent Recipients Suggests America May be Losing Dominance (Jan. 14, 2009), available at http://www.ificlaims.com/IFIPatents010909.htm (listing the "top 35" recipients of U.S. patents in 2008).

See Skinner v. Mid-Am. Pipeline Co., 490 U.S. 212, 224 (1989) ("Congress must indicate clearly its intention to delegate to the Executive the discretionary authority to recover administrative costs not inuring directly to the benefit of regulated parties ").

having failed to secure reform in the area of fees that might have helped the budgetary situation, the PTO chose a different path. The path it chose was to promulgate rules that required applicants that wanted to file more than two continuations (or continuations-in-part) and one RCE to make a showing of good cause as to why they needed another application. The PTO also required that, in cases where the applicant was seeking more than five independent claims or twenty-five total claims, the applicant provide an "examination support document" certifying the performance of a prior art search, identifying the prior art "references deemed most closely related to the subject matter of each of the claims," and discussing "how each of the independent claims is patentable over the cited references." In *Tafas v. Dudas*, a 2008 decision, a district court struck down these rules as "substantive rules that change existing law and alter the rights of applicants..."

For administrative agencies with substantive rulemaking authority, the issue of whether a rule is substantive or procedural typically arises when an agency is seeking to avoid notice-and-comment rulemaking under section 553 of the Administrative Procedure Act (APA). ⁸⁶ Under the APA, rules that are substantive (as opposed to procedural or interpretive) usually require notice-and-comment rulemaking. Thus, from the perspective of an agency that has substantive rulemaking authority, a court's disagreement with its decision regarding the substance versus procedure distinction has a limited impact. Such a disagreement simply means that, if the agency is truly committed to the rule, it will have to utilize notice-and-comment rulemaking.

In the case of the PTO, by contrast, the stakes are much higher. Indeed, the district court opinion in *Tafas v. Dudas* would have eliminated the agency's authority to make rules managing its workload in any situation where a patent applicant could perceive those rules as altering her rights in any significant manner.

To be sure, as discussed further below, there are legitimate reasons to believe the continuation and claims rules do not resolve the

 $^{^{81}}$ 37 C.F.R. \S 1.114 (2008).

⁸² *Id.* § 1.75(b)(1).

⁸³ *Id.* § 1.265(a)(2).

⁸⁴ Id. § 1.265(a)(4).

^{85 541} F. Supp. 2d 805, 814 (E.D. Va. 2008).

See, e.g., Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1050 (D.C. Cir. 1987) (discussing the distinction between procedural and substantive rules with regard to a Department of Health and Human Services peer review system).

PTO's problems. But in this case, judicial minimalism at the district court—for example, striking down the rules on the ground of impermissible retroactivity ⁸⁷—would have been preferable to a broad declaration that a rule's alteration of the rights of a patent applicant renders that rule substantive. ⁸⁸

At least for the moment, the district court's sweeping interpretation has been overturned by a panel of the Federal Circuit. On appeal, Judge Prost, writing for the majority, invoked D.C. Circuit case law to hold that a rule is not substantive within the meaning of section 553—and hence for purposes of the PTO's authority—simply because it "alter[s] the manner in which the parties present themselves or their viewpoints to the agency." 89

Although Judge Prost's opinion has considerable merit, whether it will ultimately persuade a majority of the Federal Circuit is open to question. Another recent Federal Circuit panel opinion, *Cooper Technologies v. Dudas*, ⁹⁰ appears to follow the *Tafas* district court in emphasizing the effect on "individual rights and obligations" as a touchstone of substantive rulemaking. ⁹¹ Judge Rader's dissent in *Tafas* would have affirmed the district court by emphasizing the approach taken in *Cooper Technologies*. As a consequence, even after the panel decision in

⁸⁷ Impermissible retroactivity is a ground advocated for in a Federal Circuit amicus brief filed by the American Intellectual Property Law Association. *See* Brief for American Intellectual Property Law Ass'n as Amicus Curiae Supporting Appellees, Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008) (Nos. 07-1008, 07-0846). Even a determination that the rules were arbitrary and capricious as a policy matter would have had a relatively limited impact.

A Federal Circuit amicus brief to which I contributed argued that the test used by the district court is incorrect. Brief for Intellectual Property and Administrative Law Professors as Amici Curiae Supporting Appellants, *Tafas*, 541 F. Supp. 2d 805 (Nos. 07-1008, 07-0846). For further discussion of the law governing the distinction between procedure and substance, see *infra* notes 112-115 and accompanying text.

⁸⁹ Tafas v. Doll, 559 F.3d 1345, 1356 (Fed. Cir. 2009) (emphasis omitted) (quoting JEM Broad. Co. v. FCC, 22 F.3d 320, 326 (D.C. Cir. 1994)).

⁹⁰ 536 F.3d 1330 (Fed. Cir. 2008).

⁹¹ *Id.* at 1136 (quoting Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 927 (Fed. Cir. 1991)). The *Tafas* court distinguished *Cooper Technologies* by arguing that in *Cooper Technologies* the panel was deciding the meaning of substantive rules relative to interpretive rules, not parsing the substance/procedure divide. *Tafas*, 559 F.3d at 1354-55. The *Tafas* majority also argued, quite correctly, that a Supreme Court decision, *Chrysler v. Brown*, 441 U.S. 281 (1979), which noted in passing that substantive rules "affect[] individual rights and obligations," *id.* at 302, was not making a determination regarding the distinction between substance and procedure. Indeed, the *Chrysler* Court addressed the issue of substance as a preliminary step in the context of a different inquiry—that of whether a particular regulation should be deemed to have the "force and effect of law." *Id.* at 301.

Tafas, how the PTO should go about managing its caseload while remaining within the limits of the law is not entirely clear.

E. Negotiating Interest-Group Arguments

As administrative law scholars have long discussed, the availability of pre-enforcement judicial review of regulation poses a challenge even for well-established agencies like the Environmental Protection Agency (EPA). One conservative estimate puts the percentage of challenged EPA rulemakings at twenty-six percent. ⁹² As a consequence, according to some scholars, many agencies have reduced their regulatory activity. ⁹³

Administrative law scholars have scrambled to find mechanisms to avert such litigation. One of the more prominent mechanisms is "negotiated rulemaking." Under a negotiated-rulemaking scheme, all affected parties (including representatives from government, the private sector, and nongovernmental organizations) are consulted prior to a notice of proposed rulemaking. The hope is that a negotiated-rulemaking committee will reach agreement on a proposed rule. If the committee reaches such an agreement, the agreement is then used as the basis for the proposed rule. ⁹⁴ Congress formally authorized the practice by passing the Negotiated Rulemaking Act of 1990. ⁹⁵ Unfortunately, however, the empirical evidence on whether this time-consuming procedure achieves positive results—whether in terms of keeping matters out of court or otherwise—is (at best) mixed. ⁹⁶

⁹² Cary Coglianese, Empirical Analysis and Administrative Law, 2002 U. ILL. L. REV.

⁹³ See id. at 1126-27 ("Administrative law scholars appear almost universally to accept that pre-enforcement judicial review of regulations at [the National Highway Traffic Safety Administration (NHTSA)], as well as at other agencies, has led to a decline in new regulations."). Coglianese himself disagrees with this perspective, however. *Id.* at 1127, 1128 & fig.1 (charting a doubling of NHTSA's cumulative pages in the Code of Federal Regulations between 1976 and 1996).

See generally Philip J. Harter, Negotiating Regulations: A Cure for Malaise, 71 GEO. L.J. 1 (1982) (describing the process and aims of negotiated rulemaking).

⁹⁵ Pub. L. No. 101-648, 104 Stat. 4969 (codified as amended at 5 U.S.C. §§ 561–570a (2006)).

⁹⁶ See Coglianese, supra note 92, at 1131-36 (finding that negotiated rules were challenged at the EPA at about the same rate as non-negotiated rules). Critics have also argued that negotiated rulemaking distorts the proper role of an agency "first, by reducing the agency to the level of a mere participant in the formulation of the rule, and second, by essentially denying that the agency has any responsibility beyond giving effect to the consensus achieved by the group." William Funk, When Smoke Gets in Your

In the case of the PTO, the usual difficulties of addressing the arguments of interest groups may be exacerbated by the agency's relative inexperience with the rulemaking process. Thus, the agency persisted in pushing for the continuation and claims rules even after it modified the continuation portion of these rules in a manner that substantially negated their effect. Specifically, by the time it issued the final continuation rules, the PTO had liberalized them to allow for a total of three additional applications as a matter of right.⁹⁷ In contrast, the original proposed rules had allowed only one additional application as a matter of right.⁹⁸ The PTO's own data suggested that, because of this liberalization, the rules would affect only a small percentage of applications.⁹⁹ At the same time, by deciding that the rules would apply not only to future applications but also to already-filed applications—with respect to which applicants may (in reliance on the old practice) have made irrevocable strategic decisions—the agency made even this small effect a flashpoint. Indeed, although a number of ICT firms and associations—including Apple, the Computer and Communications Industry Association (CCIA), the Business Software Alliance, Caterpillar, Cisco, eBay, IBM, and Intel—supported the original rules that allowed only one additional application as of right, only the CCIA supported the PTO in the judicial challenge to the rules. 100

F. Inequitable Conduct and the Federal Circuit

As noted, the continuation-and-claims-rules package contained a requirement that unusually large applications contain an examination support document (ESD) detailing the prior art and the manner in

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Eyes: Regulatory Negotiation and the Public Interest—EPA's Woodstove Standards, 18 ENVTL. L. 55, 92 (1987).

⁹⁷ 37 C.F.R. § 1.78(d) (iv) (B) (2008).

⁹⁸ See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716, 46,717-18 (Aug. 21, 2007) (codified in scattered sections of 37 C.F.R. pt. 1) (indicating the change from the proposed rule).

⁹⁹ See id. at 46,718 ("Under the proposed changes, about eleven percent of the applications and requests for continued examination filed in fiscal year 2006 would have required a justification, where under the changes being adopted in this final rule less than three percent of the applications and requests for continued examination filed in fiscal year 2006 would have required a justification.").

For a separate empirical project on rulemaking by administrative agencies, my coauthor and I collected and analyzed all of the comments filed in response to the original continuation and claims rules. This listing is taken from our analysis of those comments. *See* Stuart M. Benjamin & Arti K. Rai, Interest Groups in the Rulemaking Process: An Empirical Investigation (Dec. 2008) (unpublished manuscript, on file with author).

which the claimed invention is an improvement over the prior art. ¹⁰¹ To an administrative lawyer not steeped in the intricacies of patent law, such a requirement—even as applied to all patents and not simply to large ones—might appear unexceptional. Many applications for benefits conferred by the government require the applicant to provide evidence in favor of its application. Indeed, in the case of the Food and Drug Administration, pharmaceutical firms spend hundreds of millions of dollars compiling the human clinical data necessary to make their case. ¹⁰²

To be sure, in the case of the patent system, portions of the patent statute suggest that the burden of proving lack of patentability is on the examiner. For example, the novelty provision of the patent statute provides that a person "shall be entitled to a patent *unless*... the invention [is anticipated by the prior art]." In addition, courts, including the Federal Circuit, have held that the PTO has the initial burden of proving lack of patentability. However, even assuming that the PTO bears this burden with respect to all requirements of the patent statute (and not just novelty), the ESD requirement cannot fairly be read to shift the *legal* burden of proving patentability onto the applicant. Rather, as the Federal Circuit opinion in *Tafas v. Doll* points out, the ESD merely requires information production in certain cases.

In any event, in the case of the ESD, much of the opposition by interest groups appears to stem not from philosophical resistance to the idea of providing information but from problematic Federal Circuit case law that arguably punishes applicants who attempt to provide useful information and explanation about their patent applications. Applicants note, with some justification, that under current Federal Circuit law any explanation they volunteer during the examination process may expose them to subsequent charges that they made a "material misrepresentation or omission" before the PTO. Even worse, under current Federal Circuit case law, the sanction is a virtual death penalty. If the defendant in an infringement action succeeds in prov-

¹⁰¹ See supra notes 82-85 and accompanying text.

See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (estimating that the development of a new drug, including marketing approval, costs hundreds of millions of dollars).

¹⁰³ 35 U.S.C. § 102 (2006) (emphasis added).

ing such deception or "inequitable conduct" with respect to a single patent claim, the entire patent can be rendered unenforceable. ¹⁰⁴

Specifically, under the Federal Circuit's somewhat inconsistent and shifting precedent for inequitable conduct, there exist at least five different tests of materiality, ¹⁰⁵ and information can be deemed material under any of these tests. ¹⁰⁶ In contrast, the PTO's own definition of what constitutes a material misrepresentation or omission is much more circumspect. The PTO limits a finding of materiality to the situation where the noncumulative information either establishes a "prima facie case of unpatentability of a claim" or where the information is inconsistent with an argument that the applicant has made regarding patentability. ¹⁰⁷ But the Federal Circuit has repeatedly held that the PTO definition is merely a starting point for this thinking about materiality—it is at best one of the many standards that applicants must satisfy. ¹⁰⁸

Concerns about inequitable conduct also appear to have chilled the use of some promising mechanisms that the PTO has established to "tier" patent applications so that applicants who are willing to provide more information get more in exchange. For example, under the agency's current procedure for accelerated examination, the applicant is promised a decision within one year if the application complies with certain disclosure requirements. On its face, one might imagine that accelerated examination could be attractive to applicants that deem their patents particularly important. However, in part because of concerns of inequitable conduct, these disclosure requirements are considered sufficiently onerous that relatively few appli-

¹⁰⁴ See, e.g., Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362-63 (Fed. Cir. 2003) (stating that if inequitable conduct is found, the patent is rendered unenforceable).

 $^{^{105}}$ See, e.g., Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006) (describing the five standards).

¹⁰⁶ Id. at 1316 (noting that the PTO's newest standard did not replace the older standards).

¹⁰⁷ 37 C.F.R. § 1.56(b) (2008).

Digital Control Inc., 437 F.3d at 1316.

¹⁰⁹ See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 Fed. Reg. 36,323 (June 26, 2006) (describing the accelerated examination process); see also U.S. Patent & Trademark Office, Petition To Make Special Under Accelerated Examination Program, http://www.uspto.gov/web/forms/sb0028_fill.pdf (last visited Apr. 15, 2009) (listing the conditions for receiving accelerated-examination treatment).

cants choose this option. Between 2006, when the program was initiated, and October 10, 2008, only 2460 applications were filed. 110

III. THE DESIRABILITY OF INCREMENTAL REFORM

The obvious next question addresses the steps that should be taken going forward. It is tempting for academics to propose fundamental changes to existing law that would create an ideal system. Although such proposals for an ideal system are by definition first-best, they are daunting for policymakers to implement. At a minimum, the transition costs associated with fundamental change create a situation where proponents of such change bear a considerable burden. ¹¹¹

Relative to more fundamental reform, incremental changes fare well if they are more realistic and grant us much of what we want. In what follows, I focus on some incremental options that would give the PTO an appropriate level of control over caseload management.

Given the difficulties of securing congressional action—particularly when Congress may be unwilling or unable to separate relatively simple administrative reform from highly contentious issues like damage awards in litigation—the judiciary is probably the more promising venue for conferring such control. With respect to the critical question of authority over fees, however, only Congress can confer the requisite power upon the PTO. The PTO should thus work to build the coalitions necessary to press Congress on relatively discrete legislation on fees.

PTO, PATENT DATA UPDATE, supra note 25, at 26 fig.

Thus, for example, although Abramowicz and Duffy's proposal for multiple bodies that would compete to perform the patent-search-and-evaluation function is intriguing, a move of that sort may best be attempted after more incremental steps have failed. Even a move to a government-owned corporation, long advocated as a mechanism for avoiding some of the bureaucratic difficulties associated with government employment and procurement regulations, may be a step better attempted after more incremental steps have failed. In addition to imposing substantial transition costs, these options may also undermine the important role that a national patent office should play in helping the executive formulate innovation policy in the overall public interest. See generally Stuart Minor Benjamin & Arti K. Rai, Fixing Innovation Policy: A Structural Perspective, 77 GEO. WASH. L. REV. 1 (2008).

A. What the Judiciary Can Do

1. Substance Versus Procedure

The highly controversial rules at issue in *Tafas v. Doll* make the case a less-than-ideal platform for a Federal Circuit decision offering a liberal interpretation of the PTO's authority to manage its caseload. Nonetheless, the liberal interpretation offered by the majority opinion in the case is desirable. The category of "substance" should not encompass any circumstance where the rule in question could be seen as altering applicant rights. Such a definition unduly constrains agencies, particularly an agency like the PTO that cannot afford to have any significant effort it makes to address its enormous workflow problems subject to a claim that its actions are ultra vires.

The Federal Circuit opinion in *Tafas* correctly follows the approach of the D.C. Circuit, which has shifted its focus from asking whether a given rule change has a "substantial impact" on parties' rights to inquiring "more broadly" into whether the rule change embodies a "substantive value judgment." The D.C. Circuit views its "gradual move away from looking solely into the substantiality of the impact [as] reflect[ing] a candid recognition that even unambiguously procedural measures affect parties to some degree." Moreover, under D.C. Circuit case law, rules that impose time limits on applications are not substantive, even if they could be seen as embodying a value judgment that applications exceeding the time limit are in some way less worthy than those filed within the time limit.

To be sure, these D.C. Circuit cases parse the substance versus procedure dichotomy in the context of whether an agency needs to follow notice-and-comment rulemaking under section 553. As both Judge Bryson's concurrence and Judge Rader's dissent in *Tafas* point out, interpretations rendered in the section 553 context should not necessarily dictate the scope of the PTO's statutory rulemaking power. Even so, for purposes of interpreting the relatively terse statutory language of the PTO's organic statute, the D.C. Circuit cases provide valuable guideposts. They also reflect the experience of a court that is constantly exposed to the challenges faced by agencies with significant workloads. Regardless, any difference in context does not suggest that the PTO's power should be any *narrower* than the D.C. Circuit case law

 $^{^{112}}$ Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1047 (D.C. Cir. 1987).

¹¹³ Id.

¹¹⁴ Nat'l Whistleblower Ctr. v. NRC, 208 F.3d 256, 263 (D.C. Cir. 2000).

on section 553 would suggest. As Judge Bryson's concurrence in *Tafas* properly notes, "Congress has not used the broadest available language in the statute that authorizes the PTO to engage in rulemaking, but neither has it used the narrowest." 115

2. Inequitable Conduct

The judiciary should also fix the anomaly of Federal Circuit case law that sets up courts as the sole arbiters of what constitutes fraud on the PTO and what the sanctions for such fraud should be.¹¹⁶ In the context of other agencies, the Supreme Court has suggested that the agency itself should have the primary responsibility to police against fraud in its administrative processes.¹¹⁷ Given this Supreme Court case law, a strong argument can be made for the PTO taking the lead in reform of inequitable conduct. Moreover, because rulemaking in this arena is properly regarded as procedural, and there is little if anything in the patent statute that speaks directly to the question, it should be subject to *Chevron* deference.¹¹⁸ Indeed, even absent new rulemaking, litigants could argue that the Federal Circuit must defer to the single, relatively narrow standard of materiality articulated by the PTO in Rule 56.¹¹⁹

The progress that could be achieved through inequitable-conduct reform is difficult to overstate. With such reform, interactions with applicants could be regulated in a much more rational manner. In addition to accelerated examination, inequitable-conduct reform could also create opportunities (where appropriate) for more intensive, on-the-record engagement between the examiner and the applicant. For example, in appropriate cases, on-the-record pre-first-office-action interviews that obviate the need for multiple subsequent rounds of negotiation between examiner and applicant might be possible.

 $^{^{115}}$ Tafas v. Doll, 559 F.3d 1345, 1365 (Fed. Cir. 2009) (Bryson, J., concurring).

See supra Section II.F.

^{(2001) (}noting this point in the context of the FDA). Interestingly, in that case the Court noted that allowing "fraud-on-the-FDA claims" to be made in litigation would "cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens" *Id.* at 351. Similarly, a common complaint on the part of the PTO is that certain applicants provide a plethora of prior art references with little explanation of their relevance.

¹¹⁸ 467 U.S. 837 (1984).

¹¹⁹ PTO, MPEP, supra note 45, app. R §1.56.

More generally, inequitable-conduct reform would make the option of selecting faster¹²⁰ or more rigorous ¹²¹ examination significantly more attractive. The appeal of a faster examination is obvious. More rigorous examination may also be attractive to those applicants who want to enforce their patents because, under default principles of administrative law, courts should give greater deference to rigorous examinations than they do to ordinary examination. ¹²²

B. What Congress Must Do

As noted above, in order for a request for intervention by Congress to achieve traction quickly, it may be prudent to keep such a request narrow and divorced from the various litigation-stage controversies that have stymied patent reform in prior Congresses. The key step Congress must take involves giving the PTO significantly greater authority over fee setting. At a minimum, this fee-setting authority should include the authority to recoup expenses incurred on behalf of the applicant.

As a supplement to the authority to recoup expenses, Congress could also consider granting the PTO some authority to use fees to regulate applicant behavior. To protect against the possibility of the PTO using this authority recklessly (and against nondelegation concerns), Congress could set out guidelines and criteria for the PTO. Congress could also provide that this grant of authority be reviewed periodically to determine whether it should be renewed.

Perhaps the most prudent course would be for Congress to direct the PTO to do a study of mechanisms for employing user fees to regulate behavior. As a prelude to action on a controversial question, such an approach is hardly unprecedented. For example, in patent-reform legislation proposed in the 110th Congress, Congress included a provision directing the PTO to submit, within two years of the legisla-

See supra notes 109-110 and accompanying text (discussing accelerated examination).

See, e.g., Jay P. Kesan, Carrots and Sticks To Create a Better Patent System, 17 BERKE-LEY TECH. L.J. 763, 770-75 (2002); Mark Lemley et al., What To Do About Bad Patents, REGULATION, Winter 2005–2006, at 10, 12 (proposing that applicants that selected into rigorous examination could get a stronger patent).

¹²² See Benjamin & Rai, supra note 5, at 273 ("In circumstances where rigorous administrative proceedings are in place, the result would be significantly greater deference than the Federal Circuit currently gives.").

Even the creation of a better postgrant administrative alternative to costly litigation, important as it is as a matter of the proper functioning of the patent system, *see* Benjamin & Rai, *supra* note 5, at 320-28, might be kept separate.

tion's enactment, a report "on the operation of prior user rights in selected countries in the industrialized world." ¹²⁴

CONCLUSION

Incremental reform that gives the PTO greater control over its procedures and its budgetary outlook would move us a long way toward a more efficient system of patent examination. In our search for a first-best system, such incremental possibilities should not be overlooked. Indeed, in the area of substantive patent law, incremental movement toward a more administrative role for the PTO has been the major story of the last ten years of patent reform.

¹²⁴ See H.R. REP. NO. 110-319, at 6 (2007) (directing the PTO to submit a report that examines how prior-user rights affect, inter alia, innovation rates and the ability of start-up enterprises to attract venture capital).