

# Administrative Law, Patents, and Distorted Rules

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## ABSTRACT

*Since 1935, courts have embraced a uniformly lenient approach toward congressional delegations of authority to agencies across different regulatory areas with one notable exception. The U.S. Court of Appeals for the Federal Circuit has crafted its own limitations on the authority of a presidentially controlled agency, the U.S. Patent and Trademark Office ("PTO"). Amid ongoing efforts to reform the patent system, this Article provides the first analysis of the development of this major administrative law anomaly. It shows that, surprisingly, the Federal Circuit's approach derives little support from the Constitution, the PTO's organic statute, Supreme Court precedent, or, for that matter, any other appellate court decision. Indeed, the Federal Circuit has never proffered a coherent rationale for its approach. This Article further demonstrates that the Federal Circuit's approach has generated an incoherent and normatively dysfunctional distinction between valid procedural rules and invalid substantive rules that (1) creates perverse incentives for the PTO to keep the public out of its decisionmaking process, (2) stifles the PTO's ability to upgrade its notoriously slow and ineffective review process, and (3) sets a precedent that allows the judicial branch to distort congressional delegations of authority.*

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## INTRODUCTION

Over the last century, Congress has used increasingly broad language to delegate authority to other institutions—predominantly, administrative agencies.<sup>1</sup> Debates have raged as to whether such broad delegations are defensible.<sup>2</sup> Nonetheless, since 1935, courts have al-

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<sup>1</sup> See Lisa Schultz Bressman, *Schechter Poultry at the Millennium: A Delegation Doctrine for the Administrative State*, 109 YALE L.J. 1399, 1405 (2000) (discussing how, since 1935, the Supreme Court has upheld congressional delegations of authority that involved “vague statutory standards”); Richard J. Pierce & Sidney A. Shapiro, *Political and Judicial Review of Agency Action*, 59 TEX. L. REV. 1175, 1179 (1981) (“Almost five decades of heavy reliance on administrative government have resulted in . . . Congress [finding] that it can solve many of our social problems only by relying on delegations of authority that are broad and vague, rather than clear and specific.”).

<sup>2</sup> Margaret H. Lemos, *The Consequences of Congress’s Choice of Delegate: Judicial and Agency Interpretations of Title VII*, 63 VAND. L. REV. 363, 364 (2010). Some commentators criticize such delegations as abdicating congressional responsibility for policy choices. See, e.g., DAVID SCHOENBROD, *POWER WITHOUT RESPONSIBILITY: HOW CONGRESS ABUSES THE PEOPLE THROUGH DELEGATION* 3–21 (1993) (“When the lawmakers we elect have others make the law, the people lose.”); Peter H. Aranson, Ernest Gellhorn & Glen O. Robinson, *A Theory of Legislative Delegation*, 68 CORNELL L. REV. 1, 7, 63–67 (1982) (arguing for a “renewed nondelegation doctrine” and proposing to “deprive the legislature of its ability to shift responsibility and to create lotteries in private benefits through regulation”); Ernest Gellhorn, *Returning to First Principles*, 36 AM. U. L. REV. 345, 347–52 (1987) (“The constitutional problem that underlies the current dissatisfaction is that Congress has not fulfilled its constitutional responsibilities.”); Marci A. Hamilton, *Representation and Nondelegation: Back to Basics*, 20 CARDOZO L. REV. 807, 819–20 (1999) (asserting that “the nondelegation doctrine serves crucial constitutional ends when applied against delegations to the President and against delegation to administrative agencies”); Gary Lawson, *Delegation and Original Meaning*, 88 VA. L. REV. 327, 333 (2002) (arguing

most uniformly upheld such delegations.<sup>3</sup> Regardless of one's views as to the propriety of these broad grants of authority, a whole host of benefits stems from what can only be described as the federal courts' uniformly lenient approach toward these delegations—they restrain courts from substituting their own preferences for those of the legislative and executive branches of government, promote predictability in the law, and give expert agencies flexibility to craft measures that benefit their constituents. One federal appellate court, however, has disregarded this wisdom.

Rather than uphold a congressional delegation of authority, the U.S. Court of Appeals for the Federal Circuit, which has exclusive nationwide jurisdiction over appeals from all district court cases arising under the patent laws,<sup>4</sup> has arrogated to itself the power of a pre-

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that the Constitution contains “a discernable, textually grounded nondelegation principle that is far removed from modern doctrine”); David Schoenbrod, *Delegation and Democracy: A Reply to My Critics*, 20 CARDOZO L. REV. 731, 732 (1999) (responding to criticism by participants in a constitutional law symposium who disagreed with his proposition that democracy suffers when Congress delegates legislative powers to the executive branch). Others defend the delegations as being inevitable in light of Congress's lack of resources, time, foresight, and flexibility to address each minute detail of regulatory policy. See, e.g., David Epstein & Sharyn O'Halloran, *The Nondelegation Doctrine and the Separation of Powers: A Political Science Approach*, 20 CARDOZO L. REV. 947, 950–51 (1999) (viewing delegation as a self-regulated balance of “competing inefficiencies”); Jerry L. Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J.L. ECON. & ORG. 81, 99 (1985) (“[D]elegation to experts [is] a form of consensus building that, far from taking decisions out of politics, seeks to give political choice a form in which potential collective agreement can be discovered and its benefits realized.”); David B. Spence & Frank Cross, *A Public Choice Case for the Administrative State*, 89 GEO. L.J. 97, 101–02 (2000) (presenting a public choice argument for delegation); David B. Spence, *A Public Choice Progressivism, Continued*, 87 CORNELL L. REV. 397, 398 (2002) (same).

<sup>3</sup> See *Santise v. Schweiker*, 676 F.2d 925, 933 (3d Cir. 1982) (“It is well established, moreover, that Congress may ‘delegate[ ] broad powers to executives to determine [through implementing regulations] the details of any legislative scheme.’” (alterations in original) (quoting *United States v. Rock Royal Coop., Inc.*, 307 U.S. 533, 574 (1939))); *Ethyl Corp. v. EPA*, 541 F.2d 1, 68 (D.C. Cir. 1976) (en banc) (Leventhal, J., concurring) (“Congress has been willing to delegate its legislative powers broadly—and courts have upheld such delegation . . . .”); Thomas W. Merrill, *Rethinking Article I, Section 1: From Nondelegation to Exclusive Delegation*, 104 COLUM. L. REV. 2097, 2103 (2004) (“Only in 1935 . . . did the Court actually strike down federal legislation as an unconstitutional delegation of legislative power. . . . Notwithstanding the modern Court's occasional flirtation with stricter enforcement of separation-of-powers requirements, this pattern continues today.”); Sidney A. Shapiro, *A Delegation Theory of the APA*, 10 ADMIN. L.J. AM. U. 89, 98 (1996) (“The ultimate adoption of the APA . . . signaled that broad delegations of power and combined functions would be tolerated as long as they were checked by more extensive procedures.”). See generally *Mistretta v. United States*, 488 U.S. 361, 415 (1989) (Scalia, J., dissenting) (“[W]hile the doctrine of unconstitutional delegation is unquestionably a fundamental element of our constitutional system, it is not an element readily enforceable by the courts.”).

<sup>4</sup> See Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 19(b), 125 Stat. 284, 332 (2011) (to be codified at 28 U.S.C. § 1295(a)).

sidentially controlled institution, the U.S. Patent and Trademark Office ("PTO"),<sup>5</sup> and thereby expanded the scope of its judicial review. The Federal Circuit construes the PTO's authority narrowly and even imposes its own judicially crafted limitations on the PTO's rulemaking powers.<sup>6</sup> As a result, unlike the Environmental Protection Agency, the Federal Communications Commission, and other agencies that regulate in complex, technical areas, the PTO lacks the authority to issue substantive rules, and traditional notions of agency deference have little relevance when courts review its decisions.<sup>7</sup> This peculiar approach to administrative law prompted S. Jay Plager, a Federal Circuit judge, to observe in the early 1990s:

I thought the PTO was an administrative agency. But we don't review it as if it is. There is no other administrative agency in the United States that I know of in which the standard of review over the agency's decisions gives the appellate court as much power over the agency as we have over the Patent Office.<sup>8</sup>

Indeed, for many years the Federal Circuit even denied that the Administrative Procedure Act ("APA")<sup>9</sup> had any relevance to its review of the PTO's decisions.<sup>10</sup>

The U.S. Supreme Court has not been blind to the Federal Circuit's interference in PTO affairs. In *Dickinson v. Zurko*,<sup>11</sup> the Court

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<sup>5</sup> The PTO is charged with examining patent applications and issuing patents for new inventions. See 35 U.S.C. § 2(a) (Supp. IV 2011).

<sup>6</sup> Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 270–71 (2007).

<sup>7</sup> *Id.* For an informative description of the development of the PTO's rulemaking authority, see Brian E. Mack, Note, *PTO Rulemaking in the Twenty-First Century: Defining the Line Between Strategic Planning and Abuse of Authority*, 75 FORDHAM L. REV. 2105, 2109–34 (2007).

<sup>8</sup> Ronald Zibelli & Steven D. Glazer, *An Interview with Circuit Judge S. Jay Plager*, 5 J. PROPRIETARY RTS., Dec. 1993, at 2, 5 (interviewing S. Jay Plager, Circuit Judge, U.S. Court of Appeals for the Federal Circuit).

<sup>9</sup> Administrative Procedure Act (APA), 5 U.S.C. §§ 500–596, 701–706 (2006).

<sup>10</sup> See generally *Dickinson v. Zurko*, 527 U.S. 150, 165 (1999) (rejecting the Federal Circuit's application of pre-APA standards to its review of PTO factfinding). Historically, the patent arm of the PTO was also the only adjudicative body to which the Federal Circuit did not grant *Chevron* deference. See Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415, 1432–33 (1995) (discussing how Federal Circuit panel majorities have applied *Chevron* deference to other adjudicative bodies, and noting that the court had even granted *Chevron* deference to the Trademark Trial and Appeals Board—an adjudicative body within the PTO—in a nonpatent-related context). See *infra* Part I.B (discussing *Chevron* deference). The court has since applied *Chevron* deference to the PTO in several patent cases.

<sup>11</sup> *Dickinson v. Zurko*, 527 U.S. 150 (1999).

intervened on behalf of the PTO.<sup>12</sup> The Court illuminated the PTO's right to be reviewed under standard administrative law principles, including those set out in the APA,<sup>13</sup> and stressed the importance of applying administrative law uniformly, without a carve-out for patent law.<sup>14</sup> Although *Zurko* spurred a movement to bring patent law into conformity with administrative law,<sup>15</sup> the case did little to alter the Federal Circuit's lack of deference toward established administrative law principles.<sup>16</sup> After *Zurko*, the Federal Circuit continued to deny the PTO substantive rulemaking authority<sup>17</sup> even though this limitation conflicted with the express language of the Patent Act.<sup>18</sup>

Recent developments in the patent system have increased the impetus for fixing this administrative law anomaly. A crippling backlog of unreviewed applications currently forces would-be patentees to wait on average almost three years to receive a patent.<sup>19</sup> And the long

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<sup>12</sup> See *id.* at 152. The petitioner, Q. Todd Dickinson, was the PTO Director when *Zurko* was decided. *Id.* at 150.

<sup>13</sup> See 5 U.S.C. § 706.

<sup>14</sup> See *Zurko*, 527 U.S. at 155.

<sup>15</sup> See Benjamin & Rai, *supra* note 6, at 270 (explaining that otherwise divergent groups broadly agree that the patent system should be reformed by fortifying administrative procedures in accordance with *Zurko*); Clarisa Long, *The PTO and the Market for Influence in Patent Law*, 157 U. PA. L. REV. 1965, 1973 (2009) (discussing the importance of *Zurko* for the PTO as part of the PTO's efforts to increase its influence by having administrative law principles govern patent law); Adam Mossoff, *The Use and Abuse of IP at the Birth of the Administrative State*, 157 U. PA. L. REV. 2001, 2002 (2009) (discussing how *Zurko* helped break down the "self-imposed segregation" between administrative law and intellectual property law); Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2056–57 (2009) (suggesting ways in which the trend toward bringing substantive patent law into conformity with administrative law could be mirrored in the area of procedure). But see Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WM. & MARY L. REV. 127, 129 (2000) (challenging the merits of *Zurko* and arguing that administrative law doctrines should not apply within patent law).

<sup>16</sup> See Benjamin & Rai, *supra* note 6, at 299 ("Both before and after *Zurko*, the Federal Circuit has repeatedly stated that it grants no deference whatsoever to PTO legal interpretations."); Kerr, *supra* note 15, at 128, 168 (arguing that *Zurko* had "more symbolic than practical importance").

<sup>17</sup> See *Tafas v. Doll (Tafas II)*, 559 F.3d 1345, 1354 (Fed. Cir.), *appeal dismissed as moot sub nom. Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996).

<sup>18</sup> See 35 U.S.C. § 2(b)(2) (2006) (giving the PTO somewhat broad powers, such as the power to facilitate and expedite the processing of patents, and requiring that the PTO, in promulgating rules, comply with a provision of the APA focused on substantive rulemaking).

<sup>19</sup> U.S. PATENT & TRADEMARK OFFICE, UNITED STATES PATENT AND TRADEMARK OFFICE: 2010–2015 STRATEGIC PLAN 10 (2010), available at [http://www.uspto.gov/about/stratplan/USPTO\\_2010-2015\\_Strategic\\_Plan.pdf](http://www.uspto.gov/about/stratplan/USPTO_2010-2015_Strategic_Plan.pdf) (showing that in fiscal year 2009, the average time from the filing of an application to patent issuance or abandonment was 34.6 months, and the delay was projected to increase to 34.8 months in fiscal year 2010); see ARTI RAI ET AL., U.S. DEP'T OF COMMERCE, PATENT REFORM: UNLEASHING INNOVATION, PROMOTING ECONOMIC GROWTH &

wait for a patent does not mean that applications receive careful attention by patent examiners. In fact, an abundance of low-quality patents have been issued by the PTO.<sup>20</sup> In an attempt to ameliorate the backlog of patent applications and to improve its effectiveness, the PTO has initiated a number of creative programs that test the limits of its rulemaking authority.<sup>21</sup> The Federal Circuit has demonstrated reluctance to invalidate the rules underlying these programs.<sup>22</sup> Yet the court has declined to abandon its narrow view of PTO authority, leaving the law in an unpredictable state and rendering numerous valuable programs vulnerable to attack.

The disordered state of the law was exposed in 2009 when a Federal Circuit panel in *Tafas v. Doll* (“*Tafas II*”)<sup>23</sup> reviewed the legality of four PTO rules designed to address the backlog problem and enhance the effectiveness of the patent system.<sup>24</sup> The majority opinion held that the PTO only had the authority to promulgate procedural, but not substantive, rules.<sup>25</sup> However, the three judges on the panel expressed three clashing views as to (1) what it means for a rule to be a valid procedural rule as opposed to an invalid substantive one, and (2) whether the rules at issue were procedural or substantive.<sup>26</sup> The

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PRODUCING HIGH-PAYING JOBS 4–5 (2010), available at [http://www.commerce.gov/sites/default/files/documents/migrated/Patent\\_Reform-paper.pdf](http://www.commerce.gov/sites/default/files/documents/migrated/Patent_Reform-paper.pdf).

<sup>20</sup> See DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 22–29 (2009).

<sup>21</sup> For example, in November 2009, the PTO established the Patent Application Backlog Reduction Stimulus Plan, 74 Fed. Reg. 62,285 (Nov. 27, 2009). Under this program, a small entity that expressly abandons a copending, unexamined application could have another application advanced out of turn. See *id.* at 62,285–87. The duration of this pilot program was extended on February 1, 2010, until June 30, 2010. Notice of Extension of the Patent Application Backlog Reduction Stimulus Plan, 75 Fed. Reg. 5041, 5041 (Feb. 1, 2010). More recently, on June 3, 2010, the PTO announced a proposal to establish three distinct patent-processing tracks. Press Release, U.S. Patent & Trademark Office, USPTO Proposes to Establish Three Patent Processing Tracks (June 3, 2010), available at [http://www.uspto.gov/news/pr/2010/10\\_24.jsp](http://www.uspto.gov/news/pr/2010/10_24.jsp). The proposed tracks consist of an accelerated examination (Track I), traditional examination (Track II), and an applicant-controlled examination that could be delayed for up to thirty months prior to examination (Track III). *Id.*

<sup>22</sup> See, e.g., *Tafas II*, 559 F.3d at 1359–64 (upholding three of four rules designed to address the backlog and improve the quality of issued patents); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335–43 (Fed. Cir. 2008) (giving *Chevron* deference to the PTO’s broad interpretation of which patents are subject to inter partes reexamination, a procedure that improves the quality of patents by empowering third parties to have a greater role in the reexamination of issued patents).

<sup>23</sup> *Tafas v. Doll* (*Tafas II*), 559 F.3d 1345 (Fed. Cir.), appeal dismissed as moot *sub nom.* *Tafas v. Kappos* (*Tafas IV*), 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

<sup>24</sup> See *id.* at 1349–51.

<sup>25</sup> *Id.* at 1352–54.

<sup>26</sup> See generally *id.*

inharmonious opinions in *Tafas II* highlight the murkiness inherent in determining whether a particular PTO regulation is substantive or procedural, and leave judges, the PTO, and patent law practitioners with shaky guidance in determining whether a PTO regulation is valid.<sup>27</sup>

Since *Tafas II*, the PTO has continued to initiate programs that seek to improve the patent system at the risk of overstepping the bounds of its procedural rulemaking authority. For example, in December 2009, the PTO developed a short-term program that purported to expedite the review of environmentally beneficial technologies, including technologies that could combat climate change and promote the Nation's energy independence, and suggested that it may expand this program to other forms of socially valuable technologies.<sup>28</sup> Even though this program created constructive opportunities for improving the patent system, enhanced critical social goals, and fell clearly under the PTO's rulemaking power to promulgate rules that facilitate and expedite the processing of patent applications, the program could have been rendered invalid on the basis that the PTO exceeded its procedural rulemaking authority.<sup>29</sup>

In September 2011, Congress passed a historic patent reform bill that granted the PTO a whole array of new rulemaking powers,<sup>30</sup> including powers that appear to require the PTO to set substantive patent law standards and patent policy.<sup>31</sup> These new powers supplement, without replacing, the PTO's other rulemaking powers. Although it is not entirely clear how the Federal Circuit will interpret the patent reform legislation, a key question arises whether the court should continue to limit the PTO's preexisting powers to procedural rulemaking.

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27 The Federal Circuit later agreed to rehear the case en banc. *Tafas v. Doll (Tafas III)*, 328 F. App'x 658, 658 (Fed. Cir. 2009) (en banc) (per curiam). Before it could do so, however, the PTO rendered the case moot by rescinding the rules that formed the basis of the litigation. See Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 74 Fed. Reg. 52,686, 52,687 (Oct. 14, 2009) (to be codified at 37 C.F.R. pt. 1). Upon a joint motion by the parties, the Federal Circuit held the appeal moot and ordered the dismissal of the appeal. *Tafas IV*, 586 F.3d at 1371. It refused to grant the parties' joint motion for vacatur of the district court's judgment, however, because the mootness arose from the PTO's own actions, not from an external cause over which the parties had no control. *Id.*

28 See Pilot Program for Green Technologies Including Greenhouse Gas Reduction, 74 Fed. Reg. 64,666, 64,666–68 (Dec. 8, 2009).

29 See *infra* Part II.C.1.

30 See Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 28 and 35 U.S.C.).

31 See Sarah Tran, *Patent Powers*, 25 HARV. J.L. & TECH. (forthcoming 2012).

In light of the pressing need for the PTO to have more tools to tackle the backlog problem and upgrade the quality of the patents it issues, the incoherence of the substantive/procedural doctrine, and the overarching importance of bringing patent law under the umbrella of administrative law,<sup>32</sup> this Article demonstrates that it is time to reconsider the merits of the Federal Circuit's peculiar approach to administrative law.

Prior scholarly debate has focused on whether the PTO should have essentially unlimited substantive rulemaking authority, which would enable the PTO to promulgate rules on core issues of patentability like obviousness or novelty,<sup>33</sup> or whether the status quo should be preserved.<sup>34</sup> This Article identifies a more moderate approach for defining the scope of the PTO's authority. It advances the benign principle that an administrative agency's authority be defined by its statutory authority. Although the Patent Act does not give the PTO an open-ended invitation to issue regulations on any subject it pleases,<sup>35</sup> the statute has long given the PTO specific rulemaking pow-

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<sup>32</sup> A point of clarification is required. This Article repeatedly discusses the importance of uniformity in administrative law. It does not suggest, however, that all agencies should be entitled to the same authority. Congress routinely delegates authority to administrative agencies on a case-by-case basis, and an agency's authority is always constrained by agency-specific statutory language. Rather, this Article highlights the benefits of a uniform judicial approach toward upholding congressional delegations of authority.

<sup>33</sup> See Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1800 (2011) (arguing that granting the PTO substantive rulemaking authority would require "significant changes to the PTO's capabilities, organization, and funding"); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1134–35 (2003) ("In order for the PTO to be a reasonably good policymaker, . . . Congress would have to change the PTO into an altogether different agency . . .").

<sup>34</sup> Compare BURK & LEMLEY, *supra* note 20, at 106–07 (suggesting that it would be unwise to expand the PTO's authority because it is susceptible to agency capture), with Burstein, *supra* note 33, at 1759–61 (proposing that Congress restructure the patent system to allow the PTO to engage in full substantive rulemaking so that the PTO could tailor patentability requirements to diverse circumstances). For an engaging argument that the PTO has already played a pivotal role in developing substantive patent law standards despite its inability to promulgate substantive rules under the Federal Circuit's precedent, see Melissa F. Wasserman, *The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379, 387–400 (2011).

<sup>35</sup> Unlike a number of other institutional actors, the PTO does not have the authority to issue any regulations that are "necessary or appropriate" to administer its organic act. Compare 35 U.S.C. §§ 2(b), 132(b) (2006 & Supp. IV 2011) (providing the PTO with specific rulemaking powers), with 15 U.S.C. § 45 (2006) (detailing the rulemaking power of the Federal Trade Commission, which includes making rules and regulations for the purpose of carrying out the provisions of the section), and 21 U.S.C. § 371(a) (2006) ("The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary [of Health and Human Services]."), and 47 U.S.C. §§ 154, 303(r) (2006 & Supp. 2011) ("Except as otherwise provided in this chapter, the [Federal Communications] Com-



ers that readily encompass substantive rulemaking.<sup>36</sup> Depriving the PTO of substantive rulemaking power, therefore, distorts congressional delegations of power.

This Article makes several new contributions to the literature. It begins in Part I by reviewing the historical origins of the substantive restriction on the PTO's rulemaking authority and reveals that the Federal Circuit has never articulated a sound rationale for the doctrine. Rather, much like a children's game of telephone in which a statement is accidentally distorted each time a different child repeats it, the Federal Circuit's approach emerged out of a few loose lines of dicta that have been embellished over time almost beyond recognition. Here, bad dicta has produced bad law as judges grappling with this administrative law aberration have struggled to apply it in a coherent manner.

Part II shows that legal, practical, and policy grounds, which have largely been overlooked by the literature, support interpreting the Patent Act as giving the PTO substantive rulemaking authority with respect to the powers that predate the Leahy-Smith America Invents Act ("AIA").<sup>37</sup> The plain text of the Patent Act provides the PTO with a handful of specific rulemaking powers that readily encompass substantive rulemaking and that must be promulgated in accordance with APA procedures designed primarily for substantive rulemaking.<sup>38</sup> By refusing to recognize the PTO's authority to engage in substantive rulemaking, the Federal Circuit has violated the fundamental canon of statutory construction that terms in a statute should not be construed in a manner that renders any provision of that statute meaningless or superfluous.<sup>39</sup> Additionally, from a public policy standpoint, the Federal Circuit's approach has created the unsettling precedent that al-

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mission from time to time, as public convenience, interest, or necessity requires, shall . . . [m]ake such rules and regulations and prescribe such restrictions and conditions, not inconsistent with law, as may be necessary to carry out the provisions of this chapter.").

<sup>36</sup> See 35 U.S.C. § 2(b)(2); *see also infra* text accompanying note 161. Additionally, section 132(b) of the Act requires the PTO to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." 35 U.S.C. § 132(b). Part II.A describes how these powers readily encompass substantive rulemaking. Further examination of how to limit the PTO's authority exceeds the scope of this Article, but I intend to address that issue at a later time.

<sup>37</sup> Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 28 and 35 U.S.C.).

<sup>38</sup> Pursuant to 35 U.S.C. § 2(b)(2), the PTO "may establish regulations, not inconsistent with law, which . . . shall be made in accordance with section 553 of title 5." 35 U.S.C. § 2(b)(2).

<sup>39</sup> See *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . ." (internal quotation marks omitted)).

lows a federal court to tailor administrative law principles, including the requirements of the APA, to suit its own preferences and thereby disrupt the sensitive balance of powers between the judicial, legislative, and executive branches of government. Finally, the substantive limitation has created deleterious practical implications for the patent system. It has impeded innovation and the express goal of Article I of the U.S. Constitution to promote “the Progress of Science and useful Arts”<sup>40</sup> by limiting the PTO’s ability to remedy the shortcomings in its review process. It further has created a perverse incentive for the PTO to frame rules as procedural so as to avoid the ambit of the notice-and-comment requirements of the APA,<sup>41</sup> thereby eliminating opportunities for public participation in bettering the patent system.

Part III responds to potential objections to the proposal presented in Part II. This proposal superficially conflicts with the abundant literature detailing the imbalance between the PTO’s limited resources and heavy workload, and resulting concerns about interest group capture.<sup>42</sup> At a time when virtually all agencies deal with tight budgets, however, rulemaking can represent a more efficient means for a resource-strapped agency to manage its workload than case-by-case adjudications. Other courts have routinely deferred to agencies’ decisions about how to manage their limited resources in similar situations.<sup>43</sup>

This proposal can further be distinguished from instances where it may be beneficial to let a bad law remain on the books out of con-

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<sup>40</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>41</sup> 5 U.S.C. § 553 (2006).

<sup>42</sup> Many critics of the PTO, including academics, judges, PTO officials, and this author, have pointed out the agency’s shortcomings. See, e.g., Brief Amici Curiae of 37 Law, Business, and Economics Professors in Support of Petitioner at 3–6, *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238 (2011) (No. 10-290), 2011 WL 380832 [hereinafter Brief of 37 Professors]; RAI ET AL., *supra* note 19, at 4–6 (discussing the problems of delay and poor quality control in the PTO’s review process); Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FLA. ST. U. L. REV. 119, 132–33 (2005) (asserting that “at the heart of both the speed and the quality problems in the Patent Office is the overcrowded nature of the patent grant system: there are simply too many cars on the patent grant highway”); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 316–22 (identifying the social costs of the PTO’s improvident issuance of many low-quality patents); Sarah Tran, *Expediting Innovation*, 36 HARV. ENVTL. L. REV. (forthcoming Mar. 2012) (arguing that the PTO greenwashed itself by initiating a so-called “green” program that did not provide meaningful opportunities for applications pertaining to green technologies to be expedited).

<sup>43</sup> See *SEC v. Chenery Corp.*, 332 U.S. 194, 207–09 (1947). See generally *Nat’l Nutritional Foods Ass’n v. Weinberger*, 512 F.2d 688, 698 (2d Cir. 1975) (“[R]ule-making has been increasingly substituted for adjudication as a regulatory technique, with the support and encouragement of courts.”).

cerns about long-term expectations or to maintain the power balance between the Federal Circuit and the PTO. One might argue that, because of the Federal Circuit's unique relationship with the PTO given the court's specialized jurisdiction, the court is inherently qualified to impose exceptional limitations on the PTO. The Supreme Court has flatly rejected this argument, however, on the persuasive ground that creating an anomaly in administrative law may "prove disruptive by too readily permitting other agencies to depart from uniform APA requirements."<sup>44</sup> And even though a substantive restriction on the PTO's authority has been in place for several decades, this is not an area of the law marked with clarity. To the other extreme, the constraints on the PTO's authority have resulted in internally inconsistent judicial decisions that provide questionable guidance to the PTO, patent practitioners, and judges.<sup>45</sup> These policy considerations weigh heavily against permitting the Federal Circuit to distort the PTO's delegated authority.

This historical analysis of the substantive restriction on the PTO's authority,<sup>46</sup> the doctrine's lack of statutory support,<sup>47</sup> and its negative implications<sup>48</sup> will hopefully draw attention to the need for the courts to abandon the unwarranted doctrine. By reforming the PTO's rulemaking authority, the patent system could better fulfill its core mission of fostering innovation while fixing a substantive defect in both patent law and the uniformity of administrative law.

## I. DEVELOPMENT OF A THIN-SHELLED DOCTRINE

Although it is too early to tell how the Federal Circuit will interpret the PTO's new powers in light of recent patent reform,<sup>49</sup> the court's view that the PTO's preexisting powers do not give the PTO substantive rulemaking authority is deeply entrenched.<sup>50</sup> Yet, a quick glance into the oft-quoted case for the principle, *Animal Legal De-*

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<sup>44</sup> *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999).

<sup>45</sup> See *infra* Part I.C.

<sup>46</sup> See *infra* Part I.

<sup>47</sup> See *infra* Part II.A.

<sup>48</sup> See *infra* Part II.C.

<sup>49</sup> See generally Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 28 and 35 U.S.C.).

<sup>50</sup> See *Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1336 (Fed. Cir. 2010) (holding that "the PTO lacks substantive rulemaking authority"); *Tafas v. Doll* (*Tafas II*), 559 F.3d 1345, 1352 (Fed. Cir.) (same), *appeal dismissed as moot sub nom. Tafas v. Kappos* (*Tafas IV*), 586 F.3d 1369 (Fed. Cir. 2009) (en banc); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008) (same); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) (same).

*fense Fund v. Quigg*,<sup>51</sup> reveals that it has a brittle foundation. This Article shows for the first time that, just as the imprecise repetition of a statement via a children's game of telephone may alter the statement's meaning, so too has the Federal Circuit distorted the meaning of *Animal Legal* to the point that the recent propositions being attributed to it scarcely resemble the actual statements in the case.

#### A. *Animal Legal Defense Fund v. Quigg*

*Animal Legal* was an unlikely candidate to strip the PTO of all substantive rulemaking authority for several reasons. First, the PTO indisputably "won" *Animal Legal*.<sup>52</sup> Additionally, the language from the case that has been regurgitated in decisions by the Federal Circuit was mere dicta and did not distinguish procedural rulemaking from substantive rulemaking.<sup>53</sup> Nowhere in the *Animal Legal* opinion did the Federal Circuit hold that the PTO lacked all substantive rulemaking authority, and for five years after the opinion, the Federal Circuit assumed that the PTO had considerable legal discretion.<sup>54</sup>

The controversy leading to the *Animal Legal* decision arose when the PTO issued a notice stating that nonhuman living organisms, such as animals, were patentable.<sup>55</sup> Various animal rights organizations and individuals filed suit, arguing that the Commissioner of the PTO had violated the APA by issuing this rule without complying with the APA's notice-and-comment procedures.<sup>56</sup> The Federal Circuit held that the PTO Commissioner was not required to comply with section 553 of the APA before issuing the rule because it was an interpretative rule, which the APA exempts from its notice-and-comment requirements,<sup>57</sup> rather than a substantive rule that represents "a change in existing law or policy."<sup>58</sup> The court explained that the PTO had merely interpreted two prior decisions from the Board of Patent Appeals and Interferences in which the Board had relied on the Supreme

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<sup>51</sup> *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991).

<sup>52</sup> *Id.* at 938–39.

<sup>53</sup> See *infra* note 63 and accompanying text.

<sup>54</sup> See *infra* note 74 and accompanying text.

<sup>55</sup> *Animal Legal*, 932 F.2d at 922. The court was interpreting a patent eligibility statute that existed before the enactment of the AIA. See 35 U.S.C. § 101 (1988). The AIA amended that particular section to preclude patents from issuing for inventions "directed to or encompassing a human organism." Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011) (to be codified at 35 U.S.C. § 101).

<sup>56</sup> *Animal Legal*, 932 F.2d at 923–24.

<sup>57</sup> See 5 U.S.C. § 553(b)(A) (2006).

<sup>58</sup> *Animal Legal*, 932 F.2d at 927–31 (internal quotation marks omitted).

Court's decision in *Diamond v. Chakrabarty*,<sup>59</sup> and thus, the notice did not set forth new law.<sup>60</sup>

The court next addressed the plaintiffs' additional argument that the rule was substantive rather than interpretative because it was issued pursuant to a grant of general rulemaking authority to promulgate regulations governing the conduct of PTO proceedings.<sup>61</sup> The court rejected this argument on the ground that "nothing in the Notice suggests that the Commissioner invoked his section 6 authority in issuing the Notice."<sup>62</sup> The court then stated, in dicta, the language that would later haunt the PTO:

[T]he authority granted in section 6 [of the Patent Act] is directed to the "conduct of proceedings" before the Office. A substantive declaration with regard to the Commissioner's interpretation of the patent statutes . . . does not fall within the usual interpretation of such statutory language. That is not to say that the Commissioner does not have authority to issue such a Notice but, if not issued under the statutory grant, the Notice cannot possibly have the force and effect of law.<sup>63</sup>

The precise meaning of this passage has provoked disagreement among scholars.<sup>64</sup> However, it is highly unlikely that the court intended for this language to completely and permanently strip the PTO of all substantive rulemaking authority.

First, it is important to recognize that the court did not appear to fully understand the administrative law principles it was trying to apply. Interpretative rules, like legislative rules and policy statements, are a type of substantive rule, not a distinct category of rule as the court assumed.<sup>65</sup> By holding that the PTO's notice was a properly promulgated interpretative rule, the court was essentially saying that

<sup>59</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>60</sup> *Animal Legal*, 932 F.2d at 928.

<sup>61</sup> *Id.* at 928–30.

<sup>62</sup> *Id.* at 930.

<sup>63</sup> *Id.* (citation omitted).

<sup>64</sup> Compare Nard, *supra* note 10, at 1453 n.148 (noting that the Federal Circuit "did not deny that the Commissioner possessed the authority to promulgate legislative rules" and stating that the PTO "Commissioner has the power to promulgate rules on matters of substantive patent and trademark law"), with Rayan Tai, *Substantive Versus Interpretative Rulemaking in the United States Patent and Trademark Office: The Federal Circuit Animal League Defense Fund Decision*, 32 IDEA 235, 237, 247 (1991–1992) (stating that the Federal Circuit concluded in *Animal Legal* that the PTO's authority "does not extend to the interpretation of substantive criteria under which a patent may be granted").

<sup>65</sup> Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1323 (1992).

the PTO had substantive rulemaking authority, not that it lacked such authority. And although the meaning of the PTO's power to govern the conduct of its proceedings is somewhat ambiguous, if the court had applied the established administrative law principle of interpreting congressional delegations broadly,<sup>66</sup> the PTO's power to govern the conduct of its proceedings could have readily been interpreted as giving the PTO broad rulemaking authority. Indeed, the Federal Circuit remarked three years later that this very rulemaking power was a broad power.<sup>67</sup>

Second, the court had not been called on to consider the validity of a PTO rule or even the extent of the PTO's authority. It was merely asked whether the PTO had followed the appropriate procedures for issuing the notice. Had the court determined that the PTO did not comply with the APA, the PTO would have been free to promulgate the exact same rule again if it did so in accordance with the APA's procedures. The court's vague statement about the PTO's authority was pure dicta, and poorly written dicta at that. The court stated that a "substantive declaration with regard to the Commissioner's interpretation of the patent statutes . . . does not fall within the . . . interpretation of such statutory language."<sup>68</sup> The court did not say that a substantive declaration *never* falls within such statutory language; merely that the PTO's interpretation does not fall within the "*usual* interpretation of such statutory language."<sup>69</sup> The court may have been suggesting nothing more than the fundamental principle that a substantive rule is not valid if it is not issued under the authority of a statutory grant, which was the case here. Alternatively, the court could have been observing generally how the PTO's statutory authority to govern the conduct of its proceedings was narrower than the authority of some other agencies and that the ordinary language of the Patent Act thus raised questions about the PTO's ability pursuant to this power to issue rules on questions of patentability—specifically, whether a nonhuman organism is patentable. Given that this discussion was pure dicta, it is understandable that the court did not clarify

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<sup>66</sup> See Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 511–16.

<sup>67</sup> See *In re Alappat*, 33 F.3d 1526, 1534–35 (Fed. Cir. 1994) (discussing how the court's holding that the PTO Commissioner has the authority to designate the members of a panel to consider a request for rehearing was consistent with the Commissioner's broad rulemaking authority), *abrogated on other grounds by In re Bilski*, 545 F.3d 943, 958 (Fed. Cir. 2008) (en banc), *aff'd on other grounds sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>68</sup> Cf. *Animal Legal*, 932 F.2d at 930.

<sup>69</sup> *Id.* (emphasis added).

its language. The court was not trying to determine whether the PTO had exceeded its authority, nor was it trying to impose new limits on the PTO's authority; the court was merely considering whether the PTO had complied with the APA procedures for notice-and-comment rulemaking. To the extent that the Federal Circuit did contemplate crafting sweeping limitations on the PTO's substantive rulemaking authority, the court failed to delineate the limits of such a doctrine or provide any rationale for it.<sup>70</sup>

Third, at the time that *Animal Legal* was decided, the PTO had very few rulemaking powers.<sup>71</sup> In 1999, Congress dramatically expanded the PTO's rulemaking powers in ways suggesting that the PTO had substantive rulemaking authority.<sup>72</sup> This reform should have rendered judicial decisions issued prior to that date of limited precedential value with respect to the scope of the PTO's authority.

#### B. Merck & Co. v. Kessler

Few could have anticipated that *Animal Legal* would be destined to transform the PTO's authority.<sup>73</sup> The Federal Circuit cited *Animal Legal* just six times in the first five years after the decision was issued, and none of those references, which related to various principles of law, suggested that the PTO's authority to conduct substantive rulemaking was limited.<sup>74</sup> Even more remarkably, in one of these

<sup>70</sup> Moreover, as highlighted by both the majority and dissenting opinions in *Tafas II*, it is questionable whether the court's efforts to distinguish substantive from interpretative rules for APA notice-and-comment purposes clarifies the distinction between substantive and procedural rules. See *Tafas v. Doll (Tafas II)*, 559 F.3d 1345, 1355 (Fed. Cir.) ("While this court has previously evaluated [PTO] rules in terms of whether they 'affect individual rights and obligations,' it has done so in the process of distinguishing between 'interpretive' and 'substantive' rules . . . [and this] is not dispositive on the issue of whether the Final Rules are procedural."), *appeal dismissed as moot sub nom. Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc); *id.* at 1368–69 (Rader, J., concurring in part and dissenting in part) (contending that the distinction made between "substantive" and "interpretative" rules in *Animal Legal* "has no relevance to the question of exceeding a grant of rulemaking authority").

<sup>71</sup> See *infra* Part II.A.2.

<sup>72</sup> See American Inventors Protection Act (AIPA) of 1999, Pub. L. No. 106-113, secs. 4711–4712, §§ 1–2, 113 Stat. 1501A-552, 1501A-572 to -575; *infra* Part II.A.2.

<sup>73</sup> In the wake of *Animal Legal*, leading scholars who were examining the Federal Circuit's lack of deference to the PTO failed to note much significance in the case. See, e.g., Nard, *supra* note 10, at 1453 n.148 (discussing in a footnote how the panel in *Animal Legal* "did not deny that the [PTO] Commissioner possessed the authority to promulgate legislative rules").

<sup>74</sup> See *LeFevre v. Sec'y, Dep't of Veterans Affairs*, 66 F.3d 1191, 1197 (Fed. Cir. 1995); *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1033 (Fed. Cir. 1995); *In re Alappat*, 33 F.3d 1526, 1535 (Fed. Cir. 1994); *Cedars-Sinai Med. Ctr. v. Watkins*, 11 F.3d 1573, 1578 n.7 (Fed. Cir. 1993); *Franchi v. Manbeck*, 972 F.2d 1283, 1288 (Fed. Cir. 1992); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 479 (Fed. Cir. 1991).

cases, the court interpreted the PTO's authority to promulgate regulations pursuant to Provision 35 U.S.C. § 6,<sup>75</sup> the same provision discussed in *Animal Legal* and the predecessor to the PTO's current rulemaking powers provision, as evidence that Congress had granted the PTO Commissioner broad authority.<sup>76</sup> It was not until 1996 that *Animal Legal* rose to much consequence when a unanimous panel, consisting of Judges Nies, Archer, and Michel, created an administrative law aberration in *Merck & Co. v. Kessler*.<sup>77</sup>

At issue in *Merck* was whether *Chevron* deference should be given to a PTO legal interpretation. In *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,<sup>78</sup> the Supreme Court established the standard for judicial review of legal interpretations made by an agency.<sup>79</sup> It held that courts must defer to reasonable agency interpretations not only when Congress expressly delegates interpretative authority to an agency, but also when Congress is silent or leaves ambiguity in a statute that an agency is charged with administering.<sup>80</sup> The Supreme Court subsequently reined in the breadth of *Chevron* deference, but it left open the possibility that *Chevron* could apply to agency actions that do not involve formal rulemaking or adjudication.<sup>81</sup> For *Chevron* deference to apply in such a situation, there must be a congressional delegation of "authority to the agency generally to make rules carrying the force of law, and . . . the agency interpretation claiming deference [must be] promulgated in the exercise of that authority."<sup>82</sup>

In *Merck*, the PTO sought *Chevron* deference for its interpretation of the Hatch-Waxman<sup>83</sup> and Uruguay Rounds Agreement Acts.<sup>84</sup> The PTO had issued a Final Determination interpreting these complex

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<sup>75</sup> 35 U.S.C. § 6 (1988) (repealed 1999).

<sup>76</sup> See *In re Alappat*, 33 F.3d at 1534–35 (discussing how the court's holding that the PTO Commissioner has the authority to designate the members of a panel to consider a request for rehearing was consistent with the Commissioner's broad rulemaking authority).

<sup>77</sup> *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

<sup>78</sup> *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

<sup>79</sup> See *id.* at 842–45.

<sup>80</sup> See *id.* at 843.

<sup>81</sup> See *United States v. Mead Corp.*, 533 U.S. 218, 225–27 (2001) (refusing to give *Chevron* deference to a ruling by the U.S. Customs Service that classified the respondent publisher's day planners as bound diaries under the Harmonized Tariff Schedule); see also *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000) (holding that agency opinion letters are not entitled to *Chevron* deference).

<sup>82</sup> See *Mead*, 533 U.S. at 226–27.

<sup>83</sup> 35 U.S.C. § 156 (1994) (last amended 2011).

<sup>84</sup> *Id.* § 154 (amended 2011); see also *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546–49 (Fed. Cir. 1996).



statutes as limiting the length of potential patent term extensions for patents granted prior to June 8, 1995.<sup>85</sup> Judge Nies, writing for the unanimous panel, rejected the PTO's claim for deference for its Final Determination with a single damning statement: "As we have previously held, the broadest of the PTO's rulemaking powers—35 U.S.C. § 6(a)—authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [PTO]'; it does NOT [sic] grant the Commissioner the authority to issue substantive rules."<sup>86</sup>

The court then held that "[b]ecause Congress has not vested the Commissioner with any general substantive rulemaking power, [the PTO's Final Determination] cannot possibly have the 'force and effect of law.'"<sup>87</sup> The court further explained that "[s]uch deference as we owe to the PTO's interpretive 'Final Determination' . . . thus arises, not from the rule of *Chevron*, but solely from, *inter alia*, the thoroughness of its consideration and the validity of its reasoning, *i.e.*, its basic power to persuade if lacking power to control."<sup>88</sup>

As the foregoing analysis of *Animal Legal* demonstrates,<sup>89</sup> the *Merck* panel mischaracterized its precedent. *Animal Legal* did not hold that the PTO lacked all substantive rulemaking authority. It merely suggested, in dicta, that there might be limits on the PTO's rulemaking authority—a fairly benign principle. The *Merck* panel further inaccurately cited three cases as supporting the sweeping proposition that the PTO lacked all substantive rulemaking authority: *Glaxo Operations UK Ltd. v. Quigg*,<sup>90</sup> *Hoechst Aktiengesellschaft v. Quigg*,<sup>91</sup> and *Ethicon, Inc. v. Quigg*.<sup>92</sup> Not one of these cases substantiates such a proposition.<sup>93</sup> In *Glaxo*, the Federal Circuit declined to defer to the

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<sup>85</sup> *Merck*, 80 F.3d at 1548.

<sup>86</sup> *Id.* at 1549–50 (alteration in original) (quoting *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991)).

<sup>87</sup> *Id.* at 1550 (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979)).

<sup>88</sup> See *id.* (citing *EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 257 (1991); *Gen. Elec. Co. v. Gilbert*, 429 U.S. 125, 140–46 (1976); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

<sup>89</sup> See *supra* Part I.A.

<sup>90</sup> *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 398 (Fed. Cir. 1990).

<sup>91</sup> *Hoechst Aktiengesellschaft v. Quigg*, 917 F.2d 522, 526 (Fed. Cir. 1990).

<sup>92</sup> *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1425–26 (Fed. Cir. 1988).

<sup>93</sup> Under the two-step framework provided by the Supreme Court in *Chevron*, before a court can grant deference to an agency interpretation, the court must take the first step of considering whether the intent of Congress is clear. *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). If Congress's intent is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. However, "if the statute is silent or ambiguous with respect to the specific issue," the court must proceed to step two and determine "whether the agency's answer is based

PTO's interpretation of the term "product" as used in section 156(f)(2) of the Hatch-Waxman Act<sup>94</sup> because *Chevron* deference "is limited to when the statutory language has 'left a gap' or is ambiguous."<sup>95</sup> The court concluded that "section 156(f)(2)'s operative terms, individually and as combined in the full definition, have a common and unambiguous meaning, which leaves no gap to be filled in by the administering agency."<sup>96</sup> Similarly, in *Hoechst* and *Ethicon*, the Federal Circuit declined to accord the PTO *Chevron* deference because it determined that the PTO's interpretations of specific provisions of the Patent Act were directly inconsistent with congressional intent, not because the PTO lacked substantive rulemaking authority.<sup>97</sup> These cases, therefore, simply did not support the *Merck* panel's blanket assertion that the PTO lacked all substantive rulemaking authority.

What had started out as unremarkable dicta in *Animal Legal* became in *Merck* the impetus for depriving the PTO of all substantive rulemaking authority in its patent law affairs.<sup>98</sup> The PTO overnight became a "strange animal in administrative law terms"<sup>99</sup>—the only adjudicative body the Federal Circuit has denigrated in such a manner.<sup>100</sup>

### C. *Tafas v. Doll* (*Tafas II*)

Applying the *Merck* precedent has proved to be exceptionally difficult for the Federal Circuit in recent years. In an attempt to respond to concerns about its mounting backlog of unreviewed patent applications and the unpredictable quality of issued patents, the PTO has initiated a number of creative programs that test the ostensible boundaries of its rulemaking authority.<sup>101</sup> The Federal Circuit has failed to review the legality of these programs in a coherent manner.

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on a permissible construction of the statute." *Id.* at 843. All three of the cases cited by the *Merck* panel were resolved at step one. *See Hoechst*, 917 F.2d at 526; *Glaxo*, 894 F.2d at 398; *Ethicon*, 849 F.2d at 1425–26.

<sup>94</sup> See 35 U.S.C. § 156(f)(7) (1988) (amended 2011).

<sup>95</sup> See *Glaxo*, 894 F.2d at 398.

<sup>96</sup> *Id.*

<sup>97</sup> See *Hoechst*, 917 F.2d at 526–28; *Ethicon*, 849 F.2d at 1425–27.

<sup>98</sup> See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996).

<sup>99</sup> E-mail from Nathan Cortez, Assistant Professor of Law, S. Methodist Univ., Dedman Sch. of Law, to Sarah Tran, Assistant Professor of Law, S. Methodist Univ., Dedman School of Law (Jan. 25, 2011, 10:06 AM) (on file with author).

<sup>100</sup> See generally Nard, *supra* note 10.

<sup>101</sup> See, e.g., Patent Application Backlog Reduction Stimulus Plan, 74 Fed. Reg. 62,285, 62,286–87 (Nov. 27, 2009) (enabling small entities that expressly abandon a copending, unexamined application to have another application advanced out of turn); Press Release, U.S. Patent & Trademark Office, *supra* note 21 (proposing a patent filing system in which applicants could pay

In *Tafas II*, for example, the Federal Circuit issued a muddled decision attempting to address the legality of a PTO effort to improve the patent system.<sup>102</sup> The PTO had promulgated four new rules: two rules pertaining “to continuation applications and requests for continued examination . . . [that] were issued to address the ‘large and growing backlog of unexamined patent applications,’” and two other rules designed to “address the [PTO’s] difficulty in examining applications that contain a large number of claims.”<sup>103</sup> Among other things, the rules retroactively (1) limited the ability of a patent applicant to file continuation or continuation-in-part applications, (2) required patent applicants to submit an examination support document<sup>104</sup> if more than five independent or twenty-five total claims were included in certain sets of copending applications, and (3) increased the burdens on applicants to disclose information about their inventions.<sup>105</sup>

Unsurprisingly, the Federal Circuit panel held that the PTO only has the authority to promulgate procedural, not substantive, rules.<sup>106</sup> But unlike the unanimous opinion in *Merck*, the judges in *Tafas II* wrote three conflicting opinions.<sup>107</sup> The judges embraced clashing views on two of the most basic questions of the dispute: (1) what is a substantive rule, and (2) are the rules at issue procedural or substantive.<sup>108</sup> Table 1 parses the three opinions.

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a fee for expedited examination, thereby encouraging applicants whose inventions are of “questionable value” not to pursue their applications).

<sup>102</sup> See *Tafas v. Doll (Tafas II)*, 559 F.3d 1345, 1349–50 (Fed. Cir.), *appeal dismissed as moot sub nom. Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

<sup>103</sup> *Id.* at 1350 (citations omitted) (reviewing 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 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1)).

<sup>104</sup> As part of the examination support document, applicants must disclose all prior art that is deemed most closely related to the subject matter encompassed by the claims. See *id.* Applicants must further explain what the prior art teaches and how their invention differs from it. *Id.*

<sup>105</sup> *Id.* at 1350, 1363.

<sup>106</sup> *Id.* at 1354.

<sup>107</sup> Judge Prost authored the majority opinion, Judge Bryson wrote a concurring opinion, and Judge Rader concurred in part and dissented in part. See *generally id.* at 1348–74.

<sup>108</sup> *Id.* at 1345–69.

**Table 1. Three Opinions in *Tafas II***

	Judge Prost	Judge Rader	Judge Bryson
<b>What is a substantive rule?</b>	A rule that forecloses effective opportunity to make one's case on the merits. <sup>109</sup>	A rule that has substantive effects that are sufficiently grave. <sup>110</sup>	Irrelevant <sup>111</sup>
<b>Were the PTO's new rules substantive or procedural?</b>	Procedural <sup>112</sup>	Substantive <sup>113</sup>	Irrelevant <sup>114</sup>
<b>Did the PTO exceed its statutory authority?</b>	No, with one exception <sup>115</sup>	Yes <sup>116</sup>	No, with one exception (same as majority) <sup>117</sup>

Judge Prost's majority opinion adopted the D.C. Circuit's approach in *JEM Broadcasting Co. v. FCC*<sup>118</sup>—a case that distinguished between substantive and procedural rules for the purpose of verifying compliance with APA rulemaking requirements<sup>119</sup>—finding that rules are procedural when they do not “foreclose effective opportunity to make one's case on the merits.”<sup>120</sup> Then—Associate Judge Rader also purported to follow *JEM* but viewed the majority as “sadly overlook[ing]” more instructive language in *JEM*: “The issue, therefore, is *one of degree* . . . . [O]ur task is to identify which substantive effects are *sufficiently grave*.”<sup>121</sup> Judge Bryson refused to support either view.<sup>122</sup> He instead asserted that the procedural/substantive distinction was irrelevant.<sup>123</sup>

<sup>109</sup> *Id.* at 1356.

<sup>110</sup> *Id.* at 1369 (Rader, J., concurring in part and dissenting in part).

<sup>111</sup> *Id.* at 1365 (Bryson, J., concurring).

<sup>112</sup> *Id.* at 1356 (majority opinion).

<sup>113</sup> *Id.* at 1371 (Rader, J., concurring in part and dissenting in part).

<sup>114</sup> *Id.* at 1366 (Bryson, J., concurring).

<sup>115</sup> The majority opinion sustained three of the PTO's rules but held that Rule 78, which limited the number of continuation applications that could be filed even if all of the continuation applications were filed while the first application was pending, was invalid as contrary to the plain language of section 120 of the Patent Act. *Id.* at 1360 (majority opinion).

<sup>116</sup> *Id.* at 1374 (Rader, J., concurring in part and dissenting in part).

<sup>117</sup> *Id.* at 1366–67 (Bryson, J., concurring).

<sup>118</sup> *JEM Broad. Co. v. FCC*, 22 F.3d 320 (D.C. Cir. 1994).

<sup>119</sup> *Id.* at 326–28.

<sup>120</sup> *Tafas II*, 559 F.3d at 1356 (majority opinion) (quoting *JEM*, 22 F.3d at 328).

<sup>121</sup> *Id.* at 1369 (Rader, J., concurring in part and dissenting in part) (internal quotation marks omitted).

<sup>122</sup> See *id.* at 1366 (Bryson, J., concurring).

<sup>123</sup> See *id.* (“I do not think it necessary, or particularly helpful, to consider whether those regulations would be deemed ‘substantive,’ ‘interpretive,’ or ‘procedural.’”).

The judges next failed to reach any agreement on the issue of whether the rules were procedural or substantive. Judge Prost's majority opinion classified all of the PTO's Final Rules as procedural because they only controlled the timing of and materials that had to be submitted with a patent application but did not "foreclose effective opportunity" for patent applicants to present applications for examination.<sup>124</sup> Judge Rader took the diametrically opposite view, agreeing with the district court and the appellees that all the rules were substantive.<sup>125</sup> In his view, the rules "affect[ed] individual rights and obligations, and mark[ed] a startling change in existing law and patent policy."<sup>126</sup> Judge Bryson again refused to support either view.<sup>127</sup> Instead, he agreed with the PTO's argument that the rules were well within the PTO's statutory authority regardless of how they were classified.<sup>128</sup>

The inharmonious opinions in *Tafas II* highlight the chaos inherent in determining whether a particular PTO regulation is substantive or procedural, and provide poor guidance for judges, the PTO, and patent law practitioners. This Article does not purport to address whether the rules in *Tafas II* were procedural or substantive. Rather, it simply points out that a number of potentially valuable rules—rules that could address the PTO's notorious backlog of applications and promote the effectiveness of the patent system—would not fall within a murky zone of invalidity if the Federal Circuit did not limit the PTO's authority to procedural rulemaking.

Judge Bryson recognized the murkiness inherent in the procedural/substantive doctrine and wrote a stealthily radical concurrence challenging it.<sup>129</sup> Instead of simply citing *Animal Legal* and its progeny, as the Federal Circuit had grown accustomed to doing,<sup>130</sup> he analyzed how the breadth of the PTO's statutory authority compared to congressional grants of authority to other agencies.<sup>131</sup> In so doing, he was the first judge who actually considered the breadth of Congress's

<sup>124</sup> *Id.* at 1356 (majority opinion) (citing *JEM*, 22 F.3d at 326, 328).

<sup>125</sup> *Id.* at 1371 (Rader, J., concurring in part and dissenting in part).

<sup>126</sup> *Id.* Judge Rader concurred with the majority's "conclusion that the PTO is not entitled to *Chevron* deference with respect to its own rulemaking authority." *Id.* at 1368. However, because he viewed the Final Rules as substantive, not procedural, he concluded that the PTO had exceeded its statutory rulemaking authority in promulgating the rules. *Id.*

<sup>127</sup> See *id.* at 1366 (Bryson, J., concurring).

<sup>128</sup> See *id.*

<sup>129</sup> See *id.* at 1365–68.

<sup>130</sup> See, e.g., *id.* at 1352 (majority opinion); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335–36 (Fed. Cir. 2008); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

<sup>131</sup> See *Tafas II*, 559 F.3d at 1365 (Bryson, J., concurring).

delegation of statutory rulemaking authority to the PTO, a critical step that had been neglected in *Animal Legal* and *Merck*. The PTO's delegated authority, in his view, "charted a middle course."<sup>132</sup> It was neither as broad as a delegation to issue any regulations that are necessary or appropriate to administer the patent laws,<sup>133</sup> nor did it relegate the PTO to the narrow authority of 5 U.S.C. § 301, "which allows all agencies to prescribe regulations 'for the government of . . . [the] department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.'"<sup>134</sup>

The logical implication of Judge Bryson's position that the procedural/substantive distinction was irrelevant is that the PTO's authority is not confined to procedural rulemaking. This provocative proposition was further implied by Judge Bryson's statement that it was only "generally fair to characterize [the Patent Act] as authorizing the promulgation of 'procedural' regulations."<sup>135</sup> Judge Bryson retreated from the conventional Federal Circuit view that the PTO lacked all substantive rulemaking authority.<sup>136</sup> He failed, however, to provide any rationale for veering from the Federal Circuit's line of cases that declared that the PTO lacked substantive rulemaking authority.<sup>137</sup> Discussion of *Animal Legal* and *Merck* was conspicuously missing from his concurrence.<sup>138</sup>

Unlike Judge Bryson's generally shrewd concurrence, the majority opinion contained a handful of logical fallacies. First, the majority opinion relied on *Animal Legal* for the proposition that the PTO lacks substantive rulemaking authority, yet refused to give *Animal Legal* much weight when defining what constitutes a substantive rule.<sup>139</sup> The court's rationale for declining to invoke *Animal Legal* in the latter circumstance was that *Animal Legal* pertained to the boundary between interpretative and substantive rules, not to the boundary be-

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<sup>132</sup> See *id.*

<sup>133</sup> See, e.g., 5 U.S.C. § 8347(a) (2006) (giving the Office of Personnel Management authority to prescribe "such regulations as are necessary and proper to carry out [the Civil Service Retirement Act]"); 38 U.S.C. § 501(a) (2006) (authorizing the Secretary of Veterans Affairs to prescribe "all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department").

<sup>134</sup> *Tafas II*, 559 F.3d at 1365 (quoting 5 U.S.C. § 301).

<sup>135</sup> See *id.* at 1366 (emphasis added).

<sup>136</sup> See *supra* note 86 and accompanying text.

<sup>137</sup> See *Tafas II*, 559 F.3d at 1365-68.

<sup>138</sup> *Id.*

<sup>139</sup> *Id.* at 1352, 1355 (majority opinion).

tween procedural and substantive rules.<sup>140</sup> This reasoning was a non sequitur. If *Animal Legal* cannot be used to define a substantive rule when the issue arises in the context of defining the boundary between procedural and substantive rules, its (supposed) principle that the PTO lacks substantive rulemaking authority should be of similarly limited relevance under such circumstances because defining what it means to be “substantive” is necessary to define the limits of “substantive” rulemaking.

The majority also failed to justify constraining the PTO to procedural rulemaking. The majority opinion stated that 35 U.S.C. § 2(b) did “not vest the [PTO] with any general substantive rulemaking power” because *Animal Legal*, *Merck*, and *Cooper Technologies Co. v. Dudas*<sup>141</sup> said so.<sup>142</sup> However, *Cooper Technologies* simply recycled the flawed limitation from the earlier cases.<sup>143</sup> Hence, there is little reason to rely on these three cases for such a principle. The *Tafas II* majority next asserted that Congress had acquiesced in the court’s narrow interpretation of the PTO’s rulemaking authority.<sup>144</sup> In making this argument, the majority failed to recognize widespread changes Congress had made to the patent system, as well as to the PTO’s rulemaking authority, in 1999.<sup>145</sup>

Finally, the majority conducted a problematic two-step analysis. The majority first evaluated whether the rules at issue were procedural or substantive, then, having concluded they were procedural, evaluated whether they fell within the PTO’s statutory authority.<sup>146</sup> This reasoning was again a non sequitur. Because agencies should be able to implement any power within their statutory authority,<sup>147</sup> step one served no purpose except to add redundancy to the court’s analysis and enable the Federal Circuit to impede the PTO’s ability to act pursuant to its statutory authority. These flaws highlight the incongruity

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<sup>140</sup> *Id.* at 1355.

<sup>141</sup> *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330 (Fed. Cir. 2008).

<sup>142</sup> *Tafas II*, 559 F.3d at 1352 (quoting *Tafas v. Dudas (Tafas I)*, 541 F. Supp. 2d 805, 811 (E.D. Va. 2008), *aff’d in part, vacated in part sub nom. Tafas II*, 559 F.3d 1345, *appeal dismissed as moot sub nom. Tafas v. Kappas (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc)) (internal quotation marks omitted).

<sup>143</sup> See *Cooper*, 536 F.3d at 1335.

<sup>144</sup> See *Tafas II*, 559 F.3d at 1352.

<sup>145</sup> Because these reforms are discussed at length in Part II.A, a full analysis of the weaknesses of the court’s acquiescence argument is located there.

<sup>146</sup> *Tafas II*, 559 F.3d at 1352–65.

<sup>147</sup> See *Morton v. Ruiz*, 415 U.S. 199, 231 (1974) (“The power of an administrative agency to administer a congressionally created and funded program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.”).

of using a procedural/substantive limitation to delineate the boundaries of the PTO's authority.

The jumbled *Tafas II* opinions attracted the attention of the full court—the Federal Circuit agreed to rehear the case en banc.<sup>148</sup> But before the en banc court could issue a potentially adverse decision, the PTO took the drastic measure of rescinding the rules that formed the basis for the litigation.<sup>149</sup> Upon a joint motion by the parties, the Federal Circuit held the appeal moot and ordered its dismissal.<sup>150</sup> The court refused to grant the parties' joint motion for vacatur of the district court's judgment, however, because the mootness arose from the PTO's own actions, not from an external cause over which the parties had no control.<sup>151</sup>

As a natural consequence of *Tafas II*, the tension between the Federal Circuit and the PTO over the proper scope of PTO rulemaking power has intensified, rendering the legality of many valuable PTO programs vulnerable to attack. The disjointedness of the *Tafas II* decision demonstrates how bad law (here, the substantive restriction on the PTO's rulemaking authority that arose through a series of misstatements of earlier cases) can produce more bad law.

## II. DEFICIENCIES IN THE RULEMAKING DOCTRINE

The Federal Circuit's failure to provide a coherent rationale for denying the PTO substantive rulemaking authority leaves an open question: should this limitation on the PTO's authority exist? The answer is a firm "no." Neither the Constitution nor the Patent Act support construing the PTO's authority as limited to procedural rulemaking. Instead, the Patent Act has granted the PTO specific powers that readily encompass substantive rulemaking and require that the PTO comply with APA procedures.<sup>152</sup> Imposing a more stringent standard on the PTO than on other agencies runs directly contrary to Supreme Court precedent and creates an administrative law anomaly that disturbs the sensitive balance of powers between the federal branches of government. It further impairs important public

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<sup>148</sup> *Tafas v. Doll (Tafas III)*, 328 F. App'x 658, 658 (Fed. Cir. 2009) (en banc) (per curiam) (granting petition for rehearing en banc).

<sup>149</sup> See *Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369, 1371 (Fed. Cir. 2009) (en banc).

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> See 35 U.S.C. § 2(b)(2) (Supp. IV 2011) (providing the PTO with six specific rulemaking powers, including the requirement that it comply with 5 U.S.C. § 553, the notice-and-comment provision of the APA); *id.* § 132(b) (providing the PTO with the power to "prescribe regulations to provide for the continued examination of applications for patent").



policy concerns, such as promoting the innovation of key technologies and providing members of the public with opportunities to participate in administrative decisionmaking.

### A. *Lack of Statutory Support*

The judicially fabricated procedural/substantive doctrine derives little support from the plain text of the Constitution or the Patent Act. Moreover, in 1999, Congress broadened the PTO's rulemaking authority under the Patent Act<sup>153</sup> in a manner that can only be interpreted as an explicit rejection of the Federal Circuit's approach of limiting the PTO to procedural rulemaking.

#### 1. *Background*

To identify the proper limits of the PTO's authority, it is helpful first to understand the source of its powers. The national patent system traces its roots to the U.S. Constitution, which grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."<sup>154</sup> The Constitution creates a bargain: the grant of a patent to an inventor in exchange for the benefit to society of promoting "the Progress of [the] useful Arts."<sup>155</sup> Optimizing this bargain requires the delicate balancing of policy considerations. What types of inventions further the Progress of the "useful Arts"? What is considered "useful" in this context? This constitutional provision bestowed extremely broad authority upon Congress and certainly did not limit Congress's power to procedural matters.

Congress in turn delegated the task of reviewing patent applications and granting patents to the PTO.<sup>156</sup> The PTO has general powers, subject to the policy direction of the Secretary of Commerce, to regulate the granting and issuing of patents.<sup>157</sup> Once again, this delegation is broad and conveys no limitations on the PTO's discretion in reviewing patent applications and granting patents except that it is subject to the Secretary of Commerce's policy direction.<sup>158</sup>

<sup>153</sup> See Long, *supra* note 15, at 1974.

<sup>154</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>155</sup> See *id.*

<sup>156</sup> See 35 U.S.C. § 1(a).

<sup>157</sup> *Id.* § 2(a).

<sup>158</sup> *Id.*

Proponents of limited PTO authority could assert that, because the PTO's general powers are subject to the policy direction of the Secretary of Commerce, Congress intended that only the Secretary of Commerce, not the PTO, make policy decisions. Similar language has routinely been employed in other statutes, however, where it is clear that both parties mentioned have policymaking authority.<sup>159</sup> Thus, rather than removing all policymaking authority from the PTO, the language of the Patent Act merely confirms the hierarchy that exists between the Secretary of Commerce and the PTO<sup>160</sup> and suggests that the PTO has the ability to set policy initiatives except where there is a conflict with a policy decision of the Secretary of Commerce.

In addition to its general powers, the PTO possesses "specific" rulemaking powers. Seven of these specific rulemaking powers pre-date the AIA. Pursuant to 35 U.S.C. § 2(b)(2), the PTO

- (2) may establish regulations, not inconsistent with law, which—
  - (A) shall govern the conduct of proceedings in the Office;
  - (B) shall be made in accordance with section 553 of title 5;
  - (C) shall facilitate and expedite the processing of patent applications . . . ;
  - (D) may govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office . . . ;
  - (E) shall recognize the public interest in continuing to safeguard broad access to the United States patent system through the reduced fee structure for small entities . . . ; and
  - (F) provide for the development of a performance-based process that includes quantitative and qualitative measures and standards for evaluating cost-ef-

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<sup>159</sup> See, e.g., 19 U.S.C. § 3010(a)(1) (2006) ("Subject to the policy direction of the Office of the United States Trade Representative, . . . the Department of the Treasury, the Department of Commerce, and the Commission shall . . . (A) be primarily responsible for formulating United States Government positions on technical and procedural issues; and (B) represent the United States Government."); Exec. Order No. 12,512, 3 C.F.R. 340, 341 (1986) ("The President's Council on Management Improvement, subject to the policy direction of the Domestic Policy Council, shall conduct such additional studies as are necessary to improve Federal real property management by appropriate agencies and groups.").

<sup>160</sup> The PTO is under the jurisdiction and supervision of the Secretary of Commerce. 15 U.S.C. § 1511(4) (2006).

fectiveness and is consistent with the principles of impartiality and competitiveness[.]<sup>161</sup>

The seventh preexisting rulemaking power is embodied in 35 U.S.C. § 132(b), which requires the PTO to “prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.”<sup>162</sup>

## 2. Analysis

Over the years, commentators have adopted the view that the Federal Circuit expressed in *Merck*—that the broadest of the PTO’s rulemaking authority is embodied in 35 U.S.C. § 2(b)(2)(A) and that it “is fairly narrow, focusing on the PTO’s internal procedures” without examining whether the court’s viewpoint is the correct one.<sup>163</sup> Such a view rests on several erroneous assumptions. First, the PTO’s rulemaking authority was never as narrow as the *Merck* court portrayed it to be.<sup>164</sup> But much more significantly, the Patent Act changed considerably three years after the *Merck* decision was issued. Although establishing regulations that govern the conduct of proceedings in the PTO was the broadest of the PTO’s rulemaking authority at the time of the *Merck* decision, this was no longer true in 1999. The specific powers that Congress granted the PTO in 1999 readily encompass substantive rulemaking authority.<sup>165</sup> Therefore, at a minimum, the substantive/procedural distinction should not be applied when a PTO rule falls under at least one of the PTO’s 1999 rulemaking powers.<sup>166</sup>

Even at the time that *Merck* was decided, there was little reason for the courts to circumscribe the PTO’s authority to procedural rulemaking. Although the PTO’s authority was not as broad as the

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<sup>161</sup> 35 U.S.C. § 2(b)(2).

<sup>162</sup> *Id.* § 132(b).

<sup>163</sup> See Benjamin & Rai, *supra* note 6, at 298 n.149; see also *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 2009) (“[T]he broadest of the PTO’s rulemaking powers . . . authorizes the Commissioner to promulgate regulations directed only to ‘the conduct of proceedings in the [PTO]’; it does NOT [sic] grant the Commissioner the authority to issue substantive rules.” (second alteration in original) (citation omitted)).

<sup>164</sup> See *supra* Part I.B.

<sup>165</sup> See, e.g., 35 U.S.C. § 2(b)(2) (granting the PTO power to promulgate rules that facilitate and expedite the processing of patent applications, among other powers).

<sup>166</sup> The PTO raised this argument in the briefing for *Tafas II*, where it argued that its rules could be independently authorized under either 35 U.S.C. §§ 2(b)(2)(C), 2(b)(2)(D), or 132(b), in addition to under § 2(b)(2)(A). See Reply Brief for the Appellants at 5–6, *Tafas v. Doll* (*Tafas II*), 559 F.3d 1345 (Fed. Cir. 2009) (No. 08-1352), 2008 WL 4972959.

authority certain other agencies enjoy,<sup>167</sup> the PTO had two distinct powers that could have been interpreted as encompassing substantive rulemaking: (1) the power to promulgate rules governing the conduct of its proceedings<sup>168</sup> and (2) the power to promulgate rules governing the conduct and recognition of patent practitioners.<sup>169</sup>

Rules that govern the conduct of an agency's proceedings control how the agency performs hearings, inquiries, investigations, and adjudications.<sup>170</sup> Many of these rules, such as rules that specify the number of pages permitted in an application, where to submit an application, and what personal information an applicant must give to the PTO, would likely be classified as "procedural" rules under either the majority's or Judge Rader's approach in *Tafas II*, as they do not foreclose effective opportunity to present one's case on the merits or create substantial effects that are grave. But many rules that would likely be classified as substantive under any of the tests proposed in *Tafas II*, such as a rule requiring patent practitioners to submit supplemental information along with their patent applications and permitting PTO examiners to reject claims when the supplemental information did not prove that the claims were patentable,<sup>171</sup> could govern the conduct of the PTO's proceedings as well. The fact that the Federal Circuit first determines whether a rule is substantive or procedural and then separately considers whether the rule is consistent with the PTO's statutory authority to govern the conduct of its

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<sup>167</sup> See, e.g., 15 U.S.C. § 1604(a) (2006) ("The [Bureau of Consumer Financial Protection] shall prescribe regulations to carry out the purposes of this subchapter. . . . [T]hese regulations may contain such classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for all or any class of transactions, as in the judgment of the [Bureau] are necessary or proper to effectuate the purposes of this subchapter."); 21 U.S.C. § 463(b) (2006) ("The Secretary [of Health and Human Services] shall promulgate such other rules and regulations as are necessary to carry out the provisions of this chapter.").

<sup>168</sup> See 35 U.S.C. § 6 (1994) (repealed 2000).

<sup>169</sup> See *id.* § 31 (repealed 2000) ("The Commissioner . . . may prescribe regulations governing the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Patent Office, and may require them, before being recognized as representatives of applicants or other persons, to show that they are of good moral character and reputation and are possessed of the necessary qualifications to render to applicants or other persons valuable service, advice, and assistance in the presentation or prosecution of their applications or other business before the Office.").

<sup>170</sup> *Black's Law Dictionary* defines an "administrative proceeding" as "[a] hearing, inquiry, investigation, or trial before an administrative agency, usu[ally] adjudicatory in nature but sometimes quasi-legislative." BLACK'S LAW DICTIONARY 51 (9th ed. 2009).

<sup>171</sup> The majority opinion in *Tafas II* was careful to distinguish the rules at issue in that case from such a rule. See *Tafas II*, 559 F.3d at 1357 ("It is important to note that an examiner is not permitted [under the proposed rules] to substantively reject claims on grounds that the [examination support document] did not prove that the claims are patentable.").

proceedings demonstrates that the court has divorced its view of the PTO's authority from the statute's text.<sup>172</sup>

In addition to the PTO's power to govern the conduct of its own proceedings, its power to govern patent practitioners could also encompass substantive rules. Indeed the PTO's "Rule 56" exemplifies this possibility.<sup>173</sup> Since it was promulgated in 1992, Rule 56 has imposed a duty of candor and good faith on parties prosecuting a patent application.<sup>174</sup> A party who fails to disclose information to the PTO that is material to the issue of patentability faces severe consequences. Breach of the duty of candor and good faith during the prosecution of a patent application constitutes "inequitable conduct" and renders all the claims of the patent unenforceable for the life of the patent.<sup>175</sup>

Although the Patent Act still authorizes the PTO to promulgate regulations for the conduct of its proceedings, since 1999 the PTO has had much broader rulemaking authority than it did at the time that *Merck* was decided. Congress amended the Patent Act in 1999 when it passed the American Inventors Protection Act ("AIPA"),<sup>176</sup> giving the PTO five new powers in 35 U.S.C. § 2(b)(2), as well as a new power in 35 U.S.C. § 132(b), to establish regulations.<sup>177</sup> These powers do not authorize the PTO to promulgate regulations on any subject,

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<sup>172</sup> See *id.* at 1354–64. Interestingly, the Federal Circuit held in a nonpatent context in *Rumsfeld v. General Dynamics Corp.*, 365 F.3d 1380 (Fed. Cir. 2004), that the term "proceeding" must be interpreted broadly. *Id.* at 1386. The central dispute in that case was whether a civil settlement of a claim qualified as a "proceeding" as used in 10 U.S.C. § 2324(k), a provision that defines when "costs incurred by a contractor in connection with a criminal, civil, or administrative proceeding commenced by the United States or a State" are reimbursable under defense contracts. 10 U.S.C. § 2324(k) (2000); *General Dynamics Corp.*, 365 F.3d at 1389. The court noted that Congress could have drafted narrower language indicating that the legal costs of proceedings "are unallowable on a claim-by-claim basis . . . [but] [i]nstead, Congress chose to employ the broader term 'proceeding.'" *General Dynamics Corp.*, 365 F.3d at 1386 (quoting 10 U.S.C. § 2324(k)). In the Patent Act, Congress also chose to use the broad term "proceeding." Nonetheless, the Federal Circuit has construed the PTO's statutory grant in an unconventionally narrow manner.

<sup>173</sup> See Duty to Disclose Information Material to Patentability, 37 C.F.R. § 1.56 (2011).

<sup>174</sup> See Duty of Disclosure, 57 Fed. Reg. 2021, 2034 (Jan. 17, 1992) (codified as amended at 37 C.F.R. § 1.56); see also Changes to Implement the Patent Business Goals, 65 Fed. Reg. 54,604, 54,666–67 (Sept. 8, 2000) (codified at 37 C.F.R. § 1.56) (amending Rule 56).

<sup>175</sup> See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc) (upholding the inequitable conduct doctrine but refusing to adopt the PTO's standard of materiality found in Rule 56); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (en banc).

<sup>176</sup> American Inventors Protection Act (AIPA) of 1999, Pub. L. No. 106-113, 113 Stat. 1501A-552 (codified as amended in scattered sections of 35 U.S.C.).

<sup>177</sup> The AIPA was a part of the Intellectual Property and Communications Omnibus Reform Act of 1999, Pub. L. No. 106-113, 113 Stat. 1501 (codified as amended in scattered sections of 35 U.S.C.), which "expanded the top ranks of the PTO" and gave the agency greater control

such as patentability standards, but they do provide bases for substantive rulemaking.

Several aspects of the 1999 amendments to the PTO's rulemaking powers show that Congress intended for the PTO to have substantive rulemaking authority. Most significantly, several of the new powers in § 2(b)(2) are described by language that defies procedural limitations. Section 2(b)(2)(E), for example, requires the PTO to "*recognize the public interest in continuing to safeguard broad access to the United States patent system through the reduced fee structure for small entities.*"<sup>178</sup> This language demands the exercise of independent judgment by the PTO and the weighing of competing policy concerns. The PTO's authority to "facilitate and expedite the processing of patent applications," pursuant to § 2(b)(2)(C),<sup>179</sup> further suggests that Congress intended the PTO to have substantive rulemaking authority. "Facilitate" and "expedite" are inherently broad terms. Other than the clause "particularly those which can be filed, stored, processed, searched, and retrieved electronically,"<sup>180</sup> which now reflects the norm for all patent application filings, Congress has provided no guidance on how the PTO should facilitate the processing of patent applications nor what criteria the PTO should consider when deciding which types of patent applications to expedite.

A variety of substantive rules could fall squarely within the PTO's statutory authority. Take for instance a hypothetical PTO rule requiring that, before an inventor files an application for an invention, the inventor must first receive a statement from an attorney that the invention is patentable beyond a reasonable doubt. Such a rule would facilitate and expedite the PTO's processing of patent applications by weeding out many worthless applications from the PTO's backlog. Yet, as shown below in Table 2, it would likely foreclose some inventors from prosecuting their applications and therefore would qualify as a substantive rule under any rule that the Federal Circuit might apply.

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over its operations. Long, *supra* note 15, at 1974; see AIPA secs. 4711–4712, §§ 1–2, 113 Stat. at 1501A-572 to -575.

<sup>178</sup> 35 U.S.C. § 2(b)(2)(E) (emphasis added).

<sup>179</sup> *Id.* § 2(b)(2)(C).

<sup>180</sup> *Id.*

**Table 2. Hypothetical PTO Rule**

<b>Rule:</b> Before an inventor files an application for an invention, she must first receive a statement from an attorney that the invention is patentable beyond a reasonable doubt		
<b>Definition of Substantive Rule</b>	<b>Source of Definition</b>	<b>Is Hypothetical Rule Substantive or Procedural?</b>
A rule that forecloses effective opportunity to make one's case on the merits	Judge Prost's majority opinion in <i>Tafas II</i> <sup>181</sup>	Likely substantive because some inventors would be foreclosed from prosecuting their applications if they could not obtain an opinion from an attorney that their invention is patentable <sup>182</sup>
A rule having substantive effects that are sufficiently grave	Judge Rader's dissent in <i>Tafas II</i> <sup>183</sup>	Likely substantive for the same reason as above
A rule that changes existing law or policy	<i>Animal Legal</i> <sup>184</sup>	Likely substantive because the PTO has never had such a policy or law in the past

By granting the PTO new powers in 1999 that readily encompassed substantive rulemaking, as demonstrated by the analysis of the hypothetical rule in Table 2, Congress indicated its intent that the PTO have substantive rulemaking authority.

Additionally, Congress required in § 2(b)(2)(B) that the PTO promulgate rules in accordance with section 553 of the APA,<sup>185</sup> a provision that articulates the notice-and-comment procedures that must be followed for *substantive rulemaking*.<sup>186</sup> By its own terms, this provision has little relevance to procedural rulemaking.<sup>187</sup> Adopting the view that Congress simply erred in enacting this provision ignores the fundamental canon of statutory construction that terms in a statute

<sup>181</sup> *Tafas v. Doll (Tafas II)*, 559 F.3d 1345, 1356 (Fed. Cir.), *appeal dismissed as moot sub nom. Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

<sup>182</sup> To prevent attorneys from providing statements liberally, sanctions would probably need to be imposed for unscrupulous behavior.

<sup>183</sup> *Tafas II*, 559 F.3d at 1369 (Rader, J., concurring in part and dissenting in part).

<sup>184</sup> *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927–31 (Fed. Cir. 1991).

<sup>185</sup> 35 U.S.C. § 2(b)(2)(B).

<sup>186</sup> 5 U.S.C. § 553 (2006).

<sup>187</sup> Section 553(b) of the APA explicitly does not apply to “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.” *Id.* § 553(b); *see also id.* § 553(d)(2) (exempting “interpretive rules and statements of policy” from publication more than thirty days before its effective date). The only aspect of section 553 that may have relevance to procedural rules is section 553(e), which requires agencies to “give an interested person the right to petition for the issuance, amendment, or repeal of a rule.” *Id.* § 553(e). But the Patent Act directs the PTO to *make* rules in accordance with § 553. Section 553(e) of the APA does not relate to the *making* of rules, although the other requirements for substantive rules in section 553 do.

should not be construed in a manner that renders any provision of that statute meaningless or superfluous.<sup>188</sup> Thus, “courts must presume that a legislature says in a statute what it means and means in a statute what it says there. . . . When the words of a statute are unambiguous, then, this first canon is also the last: ‘judicial inquiry is complete.’”<sup>189</sup> Although there is some debate as to whether § 2(b)(2)(B) applies to all of the PTO’s regulations,<sup>190</sup> the section unambiguously requires the PTO to promulgate some regulations in accordance with section 553 of the APA. Therefore, this provision provides strong evidence that Congress intended for the PTO to engage in substantive rulemaking.

Finally, there is also evidence that Congress had reason to know as early as 1997 that members of the patent community viewed the proposed amendments to the PTO’s rulemaking powers, which were ultimately embodied in much the same form in the 1999 Act, as a disavowal of *Merck* and the substantive limitation on the PTO’s authority.<sup>191</sup> Nonetheless, Congress did not add any language in the new powers distinguishing between substantive and procedural rulemaking or limiting the PTO’s ability to engage in substantive rulemaking.<sup>192</sup>

In summary, because the Patent Act has expressly required the PTO to promulgate rules in compliance with APA requirements designed primarily for substantive rules since 1999, and because the rules provide specific, albeit limited, bases for substantive rulemaking, Congress demonstrated its clear intent that the PTO engage in substantive rulemaking within the confines of the Patent Act.

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188 See *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (“A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . .” (internal quotation marks omitted)).

189 *Conn. Nat’l Bank v. Germain*, 503 U.S. 249, 253–54 (1992) (citations omitted).

190 The Eastern District of Virginia proclaimed in *Tafas* that every PTO regulation must be made in accordance with this provision. *Tafas v. Dudas* (*Tafas I*), 541 F. Supp. 2d 805, 812 (E.D. Va. 2008), *aff’d in part, vacated in part sub nom. Tafas v. Doll* (*Tafas II*), 559 F.3d 1345 (Fed. Cir.), *appeal dismissed as moot sub nom. Tafas v. Kappos* (*Tafas IV*), 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

191 See, e.g., *The Omnibus Patent Act of 1997: Hearing on S. 507 and H.R. 400 Before the S. Comm. on the Judiciary*, 105th Cong. 97–99 (1997) (statement of Thomas E. Constance, General Counsel, Bracco, s.p.a. & Bracco Diagnostics, Inc.) (recognizing that the *Merck* decision “adversely affected the Commissioner’s rule making authority” by limiting his ability to engage in substantive rulemaking, asserting that *Merck*’s reasoning was “contrary to a whole body of Supreme Court precedents requiring deference to an agency’s reasonable interpretation of a statute that the agency administers or enforces,” and supporting “S. 507 because it would clarify the Commissioner’s rule making authority”).

192 See 35 U.S.C. § 2 (Supp. IV 2011).



### 3. Counterarguments

Although no court has articulated a coherent rationale for the substantive limitation on the PTO's authority, some courts have attempted to defend this doctrine by writing off § 2(b)(2)(B) and by suggesting that Congress acquiesced in the Federal Circuit's narrow interpretation of PTO authority. Neither of these arguments is persuasive.

The courts have struggled to get around § 2(b)(2)(B) when construing the PTO's rulemaking authority narrowly. In *Tafas II*, for example, the Federal Circuit adopted the district court's view that "Congress did not hide the 'elephant' of substantive rulemaking authority in the 'mousehole' of § 2(b)(2)(B)."<sup>193</sup> But the Federal Circuit has neglected to provide any reasoned analysis for likening the explicit statutory requirement of § 2(b)(2) to a "mousehole."<sup>194</sup>

The rationale behind the mousehole analogy reveals that it has no relevance to the PTO's rulemaking authority. The Supreme Court first espoused the mousehole analogy in *Whitman v. American Trucking Ass'ns*,<sup>195</sup> where it explained that "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes."<sup>196</sup> But Congress did not bury § 2(b)(2)(B) in an ancillary or vague provision of the Patent Act; it appears prominently and clearly in section 2 of the Act.<sup>197</sup> Moreover, Congress amended the PTO's rulemaking powers through the AIPA, which elevated the PTO's status generally and dramatically expanded the PTO's rulemaking powers.<sup>198</sup> Finally, Congress enacted this provision in November 1999, just five months after the Supreme Court chastised the Federal Circuit in *Zurko* for isolating PTO regulations from administrative law principles and for failing to comply with the APA.<sup>199</sup> Although proposals to amend § 2(b) had contained substantially similar

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<sup>193</sup> *Tafas II*, 559 F.3d at 1352 n.3; see *Tafas I*, 541 F. Supp. at 812.

<sup>194</sup> *Tafas II*, 559 F.3d at 1352 n.3.

<sup>195</sup> *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001).

<sup>196</sup> *Id.* at 468.

<sup>197</sup> 35 U.S.C. § 2(b)(2)(B).

<sup>198</sup> See Long, *supra* note 15, at 174 (discussing how the AIPA gave "the PTO more power and self-governance" by elevating the position of the PTO Director, providing the PTO with greater control over its operations, and "expand[ing] the top ranks of the PTO to include two commissioners appointed by the Director").

<sup>199</sup> See *infra* Part II.B.

language in 1997 to what was enacted in 1999,<sup>200</sup> there was one critical difference. Earlier versions of § 2(b)(2)(B) required that the PTO promulgate rules “after notice and opportunity for full participation by interested public and private parties.”<sup>201</sup> It was not until August 1999, less than two months after *Zurko*,<sup>202</sup> that § 2(b) was amended to refer to section 553 of the APA.<sup>203</sup> This legislative history bolsters two arguments: (1) that Congress intended to give the PTO substantive rulemaking authority because notice and opportunities for public participation are associated with substantive rules, not procedural rules, and (2) Congress wanted the Federal Circuit to follow APA and other administrative law principles with respect to the PTO. Thus, the timing and scope of this patent reform suggest that Congress intended to affirm *Zurko* and bring the PTO’s rulemaking authority into conformance with the APA and general administrative law.

In addition to the mousehole analogy, courts have raised two acquiescence arguments to support limiting the PTO to procedural rulemaking. First, the District Court for the Eastern District of Virginia asserted that “Congress has debated and considered whether it should grant the [PTO] substantive rulemaking authority but has declined to do so.”<sup>204</sup> This is an inaccurate and misleading statement. Congress has entertained and ultimately declined the possibility of giving the PTO authority “to promulgate such rules, regulations and orders that the Director determines appropriate to carry out the provisions of Title 35 or any other applicable law.”<sup>205</sup> Such language would unquestionably have expanded the PTO’s rulemaking author-

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<sup>200</sup> See, e.g., 21st Century Patent System Improvement Act, H.R. 400, 105th Cong. § 112 (1997).

<sup>201</sup> *Id.*

<sup>202</sup> *Dickinson v. Zurko*, 527 U.S. 150 (1999).

<sup>203</sup> See American Inventors Protection Act (AIPA) of 1999, H.R. 1907, 106th Cong. § 612 (as passed by the House, Aug. 4, 1999).

<sup>204</sup> *Tafas v. Dudas (Tafas I)*, 541 F. Supp. 2d 805, 812 (E.D. Va. 2008) (“The Director may by regulation limit the circumstances under which an application for patent, other than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date for a prior-filed application.” (internal quotation marks omitted)), *aff’d in part, vacated in part sub nom.* *Tafas v. Doll (Tafas II)*, 559 F.3d 1345 (Fed. Cir.), *appeal dismissed as moot sub nom.* *Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc); *id.* (granting the PTO “authority to promulgate rules that ‘carry out’ the Patent Act” (quoting S. 3818, 109th Cong. § 6(e) (2006))); *id.* (“The powers granted under paragraph (2) of subsection (b) include the authority to promulgate regulations to ensure the quality and timeliness of applications and their examination, including specifying circumstances under which an application for patent may claim the benefit under sections 120, 121, and 365(c) of the filing date of a prior filed application for patent.” (internal quotation marks omitted)).

<sup>205</sup> Long, *supra* note 15, at 179 (internal quotation marks omitted) (quoting John J. Sullivan, General Counsel of the U.S. Department of Commerce, thanking Congress for including

ity. But debating whether to increase an agency's statutory authority does not imply that Congress never intended to grant the PTO substantive rulemaking authority. Such debates merely demonstrate that there are limits on the PTO's statutory authority, as Judge Bryson observed with respect to the PTO in his *Tafas II* concurrence.<sup>206</sup>

The second acquiescence argument was articulated by the Federal Circuit. The *Tafas II* majority pointed out that Congress replaced 35 U.S.C. § 6(a), which had been in effect at the time of the *Merck* decision, with § 2(b)(2), which was in effect at the time of the *Tafas II* decision.<sup>207</sup> Like § 6(a), § 2(b)(2) granted the PTO the authority to regulate "the conduct of proceedings in the Office."<sup>208</sup> The recodification of this language suggested to the *Tafas II* majority that Congress had acquiesced in the court's narrow interpretation of the PTO's rulemaking authority.<sup>209</sup>

Although it is true that "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change,"<sup>210</sup> the Supreme Court has cautioned that "reliance on congressional inaction . . . 'deserve[s] little weight in the interpretive process.'"<sup>211</sup> This warning is of particular relevance here because Congress did not reenact the provision without change. Rather, Congress added the requirement that the PTO comply with APA procedures for substantive rulemaking without exempting any of the PTO's rulemaking powers (new or old) from this requirement. Congress also created a new proceeding called inter partes reexamination, a trial-like proceeding in which third parties could participate in the reexamination of a patent, but did not create any rulemaking powers specifically designed for this proceeding.<sup>212</sup> The availability of inter partes reexamination and the need for the PTO to promulgate regulations implementing it suggested that the PTO's power to govern the conduct of its proceedings was broader than the Federal Circuit had traditionally assumed. Furthermore, for the same reasons that the timing and scope of the AIPA

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language in the proposed Patent Reform Act that would give the PTO broad rulemaking authority); see also Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 14 (2007).

<sup>206</sup> *Tafas II*, 559 F.3d at 1365 (Bryson, J., concurring).

<sup>207</sup> *Id.* at 1352 (majority opinion).

<sup>208</sup> *Id.* (quoting 35 U.S.C. § 2(b)(2)(A) (Supp. IV 2011)).

<sup>209</sup> *Id.*

<sup>210</sup> *Id.* at 1352–53 (internal quotation marks omitted).

<sup>211</sup> *Alexander v. Sandoval*, 532 U.S. 275, 292 (2001) (alteration in original) (quoting *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994)).

<sup>212</sup> American Inventors Protection Act (AIPA) of 1999, Pub. L. No. 106-113, secs. 4711–4712, §§ 1–2, 113 Stat. 1501A-552, 1501A-572 to -575.

diminished the Federal Circuit's mousehole analogy, they also undercut the acquiescence argument by revealing that Congress intended to broaden the PTO's rulemaking authority in 1999 and did not agree with the Federal Circuit's narrow interpretation. Thus, Congress's use of the words "conduct of proceedings" in 35 U.S.C. § 2(b)(2)(A) does not indicate that Congress adopted the *Merck* interpretation that the PTO lacks substantive rulemaking authority.

Even if Congress could somehow be viewed as acquiescing in the Federal Circuit's narrow interpretation of PTO authority in *Merck*, this would only justify limiting the PTO's authority with regard to its powers that existed at the time that *Merck* was decided. Congress clearly intended that the rulemaking powers added in 1999 encompass substantive rulemaking by using broad language to define these powers and by requiring that the PTO comply with APA procedures for substantive rulemaking.<sup>213</sup> Therefore, at a minimum, courts should not limit the PTO to procedural rulemaking with regard to its post-*Merck* rulemaking powers. But given the strong evidence that Congress did not acquiesce in the Federal Circuit's narrow interpretation of PTO authority, the courts should not apply the restriction at all. In creating its own limitation on the PTO's rulemaking authority, the Federal Circuit has ignored express statutory language, and, as the next Section shows, its approach toward the PTO diverges from its treatment of other agencies in violation of Supreme Court precedent.

#### *B. Conflict with Supreme Court Precedent*

Not only does the substantive limitation on the PTO's rulemaking authority lack statutory support, it flouts Supreme Court precedent. The Court has made clear that administrative law should be applied uniformly, without carve-outs for patent law.<sup>214</sup> The Federal Circuit's eccentric rulemaking doctrine disturbs the uniform application of administrative law, as well as the sensitive balance of powers between the federal branches of government.

Three years after *Merck*, the Supreme Court elucidated the interrelationship between patent law and administrative law in its hallmark decision, *Dickinson v. Zurko*. The Court held in *Zurko* that the APA provides the governing standards for reviewing PTO factfinding.<sup>215</sup> In so holding, the Court reversed the Federal Circuit's view that the "clearly erroneous" standard, a less-deferential standard under which

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<sup>213</sup> See *supra* Part II.A.2.

<sup>214</sup> See *Dickinson v. Zurko*, 527 U.S. 150, 152 (1999).

<sup>215</sup> *Id.* at 165.

the Federal Circuit had been reviewing PTO decisions, applied.<sup>216</sup> Prior to this case, the Federal Circuit denied that the APA had any relevance to its review of PTO factfinding for patent denials.<sup>217</sup> Although the case had limited legal effect because it dealt with the narrow issue of the appropriate standard for reviewing PTO factfinding,<sup>218</sup> it was widely viewed as a symbolic effort by the Supreme Court to redirect the Federal Circuit's general approach toward the PTO:

[T]he symbolic importance of *Zurko* looms large. . . . [*Zurko* was] the first major PTO win in the legal battle to increase its influence vis-à-vis the Federal Circuit. Indeed, . . . the Supreme Court . . . address[ed] (and chid[ed]) the Federal Circuit as if the court and its supporters, rather than Mary Zurko, were parties to the case.<sup>219</sup>

The Supreme Court's rationale for reprimanding the Federal Circuit in *Zurko* has just as much relevance to the substantive limitation on the PTO's authority as to the review of PTO factfinding. The Court was particularly perturbed by the Federal Circuit's brazenness in creating an administrative law anomaly. It chided the lower court for crafting a stricter standard for reviewing PTO decisions than for decisions by other agencies.<sup>220</sup> The Court explained that "[t]he APA was meant to bring uniformity to a field full of variation and diversity," and that unwarranted deviations from administrative law frustrated these purposes.<sup>221</sup>

The Supreme Court then emphasized that the Federal Circuit did not need to apply a stricter standard of review to the PTO.<sup>222</sup> The Court noted that, because of the Federal Circuit's specialized expertise in patent law, the court could review PTO "[fact]finding through the lens of patent-related experience."<sup>223</sup> In the Court's view, the Federal Circuit's expertise produced multiple benefits. It enabled the Federal Circuit to better understand the basis for the PTO's findings of fact and could "play a more important role in assuring proper re-

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<sup>216</sup> See *id.* at 164–65.

<sup>217</sup> See generally *id.* at 152–54 (rejecting the Federal Circuit's application of pre-APA standards to its review of PTO factfinding).

<sup>218</sup> Kerr, *supra* note 15, at 128–29.

<sup>219</sup> Long, *supra* note 15, at 1978–79.

<sup>220</sup> *Zurko*, 527 U.S. at 165.

<sup>221</sup> *Id.* at 155.

<sup>222</sup> See *id.* at 163.

<sup>223</sup> *Id.*

view than would a theoretically somewhat stricter standard.”<sup>224</sup> The Supreme Court thus gave credit to the Federal Circuit’s patent-related expertise, while pointing out that this special expertise did not justify allowing the Federal Circuit to constrict the PTO’s authority.

*Zurko* should have been a wakeup call for the Federal Circuit to reconsider the merits of *Merck* and its progeny. Just as the Federal Circuit had failed to defend its tougher review standards for PTO factfindings in *Zurko*, the court has also failed to proffer a coherent excuse for singling out the PTO as lacking substantive rulemaking authority, a judicially contrived limitation that the court has not imposed on any other federal administrative agency and that other courts have frowned upon.<sup>225</sup> Although the PTO’s authority has been narrower than that of a number of other agencies,<sup>226</sup> it is not the job of the Federal Circuit to further restrict the limited substantive rulemaking powers that Congress did grant the PTO. The Federal Circuit’s approach of imposing its own restrictions upon the PTO’s authority thus conflicts with the uniform judicial practice of upholding delegations of congressional authority.<sup>227</sup> Nowhere in *Animal Legal* or *Merck* did the Federal Circuit justify the creation of this administrative law anomaly. Instead, *Merck* distorted the language of *Animal Legal* and subsequent cases recited *Merck*’s flawed doctrine without questioning its legitimacy. Additionally, *Zurko* highlighted the fact that the Federal Circuit does not need to limit the PTO to procedural rulemaking because it can use its expertise to better understand the basis for the

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<sup>224</sup> *Id.*

<sup>225</sup> See, e.g., *Nat’l Petrol. Refiners Ass’n v. FTC*, 482 F.2d 672, 681 (D.C. Cir. 1973) (rejecting the argument that the Federal Trade Commission lacked substantive rulemaking authority and explaining that “there is little question that the availability of substantive rule-making gives any agency an invaluable resource-saving flexibility in carrying out its task of regulating parties subject to its statutory mandate. More than merely expediting the agency’s job, use of substantive rule-making is increasingly felt to yield significant benefits to those the agency regulates.”).

<sup>226</sup> Compare 35 U.S.C. §§ 2(b), 132(b) (2006 & Supp. IV 2011) (conferring upon the PTO specific rulemaking powers), with 15 U.S.C. § 45 (2006) (detailing the rulemaking power of the Federal Trade Commission, which includes making rules and regulations for the purpose of carrying out the provisions of the Section), and 21 U.S.C. § 371 (2006) (“The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.”), and 47 U.S.C. § 303(r) (Supp. IV 2011) (“Except as otherwise provided in this chapter, the [Federal Communications] Commission from time to time, as public convenience, interest, or necessity requires, shall . . . [m]ake such rules and regulations and prescribe such restrictions and conditions, not inconsistent with law, as may be necessary to carry out the provisions of this chapter . . .”).

<sup>227</sup> See *supra* note 3.

PTO's rules and thereby better assure "proper review than would a theoretically somewhat stricter standard."<sup>228</sup>

Unfortunately, the Federal Circuit did not heed the broad lessons of *Zurko*. The unsupported statements in *Merck* that formed the basis of the decision continue to represent the Federal Circuit's stance on the scope of PTO authority.<sup>229</sup> As such, the Federal Circuit has created an unsettling precedent that a court can usurp the authority delegated to a presidentially controlled institution to the detriment of both the legislative and executive branches of government.

### C. *Practical Repercussions*

Beyond its inconsistency with the Patent Act and Supreme Court precedent, the Federal Circuit's refusal to recognize the PTO's substantive rulemaking authority has created an assortment of serious repercussions over the years. The restriction has impeded the PTO's ability to trim its backlog and improve its efficiency. It further has (counterintuitively) created incentives for the PTO to eliminate opportunities for public participation in bettering the patent system.

#### 1. *Obstacles to Regulatory Reform*

The judicially contrived constraints on the PTO's authority impede its ability to promote innovation—the cornerstone of the patent system.<sup>230</sup> Under existing Federal Circuit precedent, the PTO can only implement new rules in the face of a very real risk that its work will be challenged and invalidated in a lawsuit. Given the PTO's limited budget and staggering workload, the doctrine hinders the PTO's ability to implement the kinds of aggressive programs that are needed to rectify the PTO's problems.<sup>231</sup>

##### a. *An Agency with Serious Troubles*

In the lead-up to the passage of the AIA, the PTO was an agency under fire. Countless commentators identified deficiencies in the pat-

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<sup>228</sup> *Zurko*, 527 U.S. at 163.

<sup>229</sup> See *Tafas v. Doll (Tafas II)*, 559 F.3d 1345, 1352 (Fed. Cir.), *appeal dismissed as moot sub nom. Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

<sup>230</sup> See U.S. CONST. art. I, § 8, cl. 8.

<sup>231</sup> Budget cuts in 2011, for instance, prompted the PTO to halt the implementation of a proposed fee-based prioritized examination program, which the PTO had planned to go into effect on May 4, 2011. Courtenay Brinkerhoff, *USPTO Budget Cuts Halt Track I & Other USPTO Initiatives*, PHARMAPATENTS (Apr. 25, 2011), <http://www.pharmapatentsblog.com/patent-office-practice/uspto-budget-cuts-halt-track-i-other-uspto-initiatives>.

ent system,<sup>232</sup> and, over the last decade, Congress considered a number of patent reform proposals.<sup>233</sup> The Department of Commerce acknowledged the major deficiencies in the patent system and emphasized that “the current patent system fails to provide consistent timeliness and quality. To the contrary, the current U.S. system is highly prone to delay and uncertainty as well as inconsistent quality.”<sup>234</sup> Other noted problems with the patent system have included uncertainty about patent scope and validity, overlapping rights, and excessive litigation, damage awards, and royalty payments.<sup>235</sup>

One of the PTO’s primary problems is its notoriously long review process.<sup>236</sup> To obtain a patent, an inventor must file an application with the PTO in a timely fashion.<sup>237</sup> However, applicants do not usually receive a timely response from the PTO regarding the patentability of their applications. Whereas Alexander Graham Bell received a patent for the telephone less than one month after submitting an application to the PTO in 1876,<sup>238</sup> applicants now wait almost three years on average to receive their patents.<sup>239</sup>

The delays in the review process impose considerable costs on patentees and society at large. A patent owner has the right to exclude others from engaging in various activities for a limited time.<sup>240</sup> By giving startups and other businesses this right to exclude, the patent system provides entrepreneurs with a distinct competitive advantage: they can use patents to attract venture capital investment, develop additional products and services, and create new jobs.<sup>241</sup> But because the monopoly exists for only a limited time after an applica-

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<sup>232</sup> See, e.g., Brief of 37 Professors, *supra* note 42, at 3–6; Osenga, *supra* note 42, at 130–33; Thomas, *supra* note 42, at 314.

<sup>233</sup> RAI ET AL., *supra* note 19, at 2.

<sup>234</sup> *Id.* at 4.

<sup>235</sup> BURK & LEMLEY, *supra* note 20, at 22–29.

<sup>236</sup> I have previously described the problematic nature of the backlog at the PTO and argued that the PTO should take more proactive measures to remedy the problem. See Tran, *supra* note 42. As discussed in Part II.C.1.b, however, the substantive restriction on the PTO’s rulemaking authority reduces its ability to take such measures.

<sup>237</sup> 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1, at OV-1 to -2 (2011).

<sup>238</sup> BURK & LEMLEY, *supra* note 20, at 22.

<sup>239</sup> See U.S. PATENT & TRADEMARK OFFICE, *supra* note 19, at 10.

<sup>240</sup> The Patent Act entitles patent owners to exclude others from making, using, selling, or offering to sell the claimed invention in this country, and entitles the patent owners to exclude others from importing the invention from another country without the authority of the patent owner. See 35 U.S.C. § 271(a), (e)(4)(B) (2006 & Supp. IV 2011).

<sup>241</sup> See RAI ET AL., *supra* note 19, at 2–4; see also Henry R. Nothhaft & David Kline, *The Biggest Job Creator You Never Heard Of: The Patent Office*, HBR BLOG NETWORK (May 6, 2010, 12:37 PM), [http://blogs.hbr.org/cs/2010/05/the\\_biggest\\_job\\_creator\\_you\\_ne.html](http://blogs.hbr.org/cs/2010/05/the_biggest_job_creator_you_ne.html).



tion is filed,<sup>242</sup> long pendency times reduce the opportunities for applicants to exploit the competitive advantages of acquiring a patent.<sup>243</sup> At the same time, parties may postpone commercializing a technology until a patent is granted, as it is difficult to predict *ex ante* the precise scope of any patent rights that will be granted.<sup>244</sup> Although the length of the review process may not affect some patent applicants,<sup>245</sup> these applicants constitute the exception, not the rule. When individual inventors and the public perceive diminished benefits from innovation, the backlog disrupts the constitutional patent bargain justifying the existence of the patent system: the grant of a patent to an inventor in exchange for the benefit to society of the promotion of “the Progress of Science and useful Arts.”<sup>246</sup> Reports “conclude that the U.S. backlog . . . could ultimately cost the U.S. economy billions of dollars annually in ‘foregone innovation.’”<sup>247</sup>

Another thorn in the side of the PTO is the abundance of low-quality patents that it has issued. Several leading commentators have pointed out that “[p]atent owners—and the Federal Circuit itself—are beset on all sides by those complaining about the proliferation of bad patents and the abuse of those patents in court.”<sup>248</sup> It is perhaps easiest to understand what a low-quality patent is by considering what it is not. Professor Wagner has defined a high-quality patent as one with the capacity “to meet (or exceed) the statutory standards of patentability—most importantly, to be novel, nonobvious, and clearly and

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<sup>242</sup> See 35 U.S.C. § 154(a)(2) (2006). The term of a patent usually ends

20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

*Id.* Statutory and regulatory provisions, however, provide several bases for patent term extensions. See 35 U.S.C. § 154(b), *amended by Leahy-Smith America Invents Act (AIA)*, Pub. L. No. 112-29, §§ 3(j), 9(a), 125 Stat. 284, 290, 316 (2011); *id.* § 156, *amended by AIA* § 37(a), 125 Stat. at 341; 37 C.F.R. § 1.701 (2011).

<sup>243</sup> See LONDON ECON., PATENT BACKLOGS AND MUTUAL RECOGNITION: AN ECONOMIC STUDY BY LONDON ECONOMICS, at viii (2010), *available at* <http://www.ipo.gov.uk/p-backlog-report.pdf> (commissioned by the U.K. Intellectual Property Office).

<sup>244</sup> See *id.* at xi.

<sup>245</sup> See *id.* at xii (“In estimating the impact [of delays in the review process] on innovation, it is important to understand that not all applications will be affected by increased pendency. Many applications relate to inventions which have lead times longer than the pendency period.”).

<sup>246</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>247</sup> RAI ET AL., *supra* note 19, at 1.

<sup>248</sup> BURK & LEMLEY, *supra* note 20, at 1.

sufficiently described.”<sup>249</sup> He has further explained that low-quality patents are those “granted for an invention that does not meet these standards.”<sup>250</sup> Low-quality patents wreak havoc on the patent system by increasing uncertainty about patentability, validity, the scope of granted patents, and patent enforceability.<sup>251</sup>

The PTO has had scarce resources to prevent low-quality patents from slipping through its review process.<sup>252</sup> To evaluate a single patent application, an examiner must review documentation submitted by the applicant, which is frequently complex and voluminous, use computerized databases and other available sources to search for invalidating prior art, and correspond with the applicant’s lawyers.<sup>253</sup> Although the processing of a patent generally occurs over a period of several years, examiners typically are given merely sixteen to seventeen hours to work on each patent application.<sup>254</sup> There is no easy fix to the problem: “To accurately evaluate the merits of every patent application would cost billions of dollars. . . . And so examiners make judgment calls, deciding not to inquire into certain areas of validity . . . at all and engaging in a form of triage as to others.”<sup>255</sup>

*b. A Substantive Obstacle*

The PTO has expressed its desire to tackle the backlog and improve the quality of issued patents, but its ability to do so is constrained by the substantive/procedural rulemaking doctrine. Aggressive actions to improve the patent system run a precarious risk of exceeding the PTO’s procedural rulemaking authority and enticing litigation. This was evidenced by the PTO’s willingness to rescind its four *Tafas II* rules before the en banc court could issue an adverse decision, even though a panel had already concluded that the rules were valid.<sup>256</sup> Less aggressive, but still beneficial, programs fall within a murky zone of legality even if they comply with explicit statutory grants of authority.

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<sup>249</sup> R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2138 (2009).

<sup>250</sup> *Id.*

<sup>251</sup> *Id.* at 2140.

<sup>252</sup> *See id.* at 2151.

<sup>253</sup> *See* Nature of Examination, 37 C.F.R. § 1.104 (2011) (setting out the general duties of a patent examiner).

<sup>254</sup> Brief of 37 Professors, *supra* note 42, at 3–4; Osenga, *supra* note 42, at 130; Thomas, *supra* note 42 at 314.

<sup>255</sup> Brief of 37 Professors, *supra* note 42, at 4.

<sup>256</sup> *See* *Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369, 1371 (Fed. Cir. 2009) (en banc) (recognizing that the PTO rescinded its rules to render the case moot).

To explore the uncertain legality of less aggressive efforts to address the backlog, it is useful to consider the PTO's Green Technology Pilot Program, which provided opportunities for the expedited review of socially valuable green technologies.<sup>257</sup> In initiating the program, the PTO highlighted economic and social justifications for providing a more timely review process for these technologies. David Kappos, Under Secretary of Commerce for Intellectual Property and Director of the PTO, explained that green technologies are "of fundamental importance to sustainable development as well as to the growth of our economy."<sup>258</sup> He further stated that "[e]very day an important green tech innovation is hindered from coming to market is another day we harm our planet and another day lost in creating green businesses and green jobs."<sup>259</sup> Although Congress did not specifically authorize this program, its implementation fell clearly within the PTO's statutory authority to enact rules that facilitate and expedite the processing of patent applications.<sup>260</sup> Now that Congress has passed the AIA, the PTO has even more explicit authority to prioritize socially valuable technologies like green technologies.<sup>261</sup>

Despite the social benefits of the Green Technology Pilot Program and its clear statutory support, its legality under the substantive/procedural doctrine is opaque. On the one hand, under the *Tafas II* majority rule, the PTO or other proponents of the program could argue that the PTO did not exceed its rulemaking authority in establishing the program because it does not foreclose applicants from having their applications reviewed;<sup>262</sup> it merely changes the processing time for certain applications. On the other hand, the courts could construe the program as delaying the review process for other inventions, ren-

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<sup>257</sup> See Pilot Program for Green Technologies Including Greenhouse Gas Reduction, 74 Fed. Reg. 64,666 (Dec. 8, 2009).

<sup>258</sup> Remarks at Press Conference, David Kappos, Dir., U.S. Patent & Trademark Office, Pilot to Accelerate Green Technology Applications (Dec. 7, 2009), available at <http://www.uspto.gov/news/speeches/2009/2009nov07.jsp>.

<sup>259</sup> See Press Release, U.S. Patent & Trademark Office, The U.S. Commerce Department's Patent and Trademark Office (USPTO) Will Pilot a Program to Accelerate the Examination of Certain Green Technology Patent Applications (Dec. 7, 2009), available at [http://www.uspto.gov/news/pr/2009/09\\_33.jsp](http://www.uspto.gov/news/pr/2009/09_33.jsp).

<sup>260</sup> See 35 U.S.C. § 2(b)(2)(C) (Supp. IV 2011).

<sup>261</sup> See Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 25, 125 Stat. 284, 338 (2011) (to be codified at 35 U.S.C. § 2(b)(2)(G)) (providing the PTO with authority to prioritize the "examination of applications for products, processes, or technologies that are important to the national economy or national competitiveness without recovering the aggregate extra cost of providing such prioritization").

<sup>262</sup> *Tafas v. Doll* (*Tafas II*), 559 F.3d 1345, 1356 (Fed. Cir.), appeal dismissed as moot *sub nom.* *Tafas v. Kappos* (*Tafas IV*), 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

dering some of them obsolete and worthless by the time they are reviewed. Such a result could potentially foreclose effective opportunities for these applicants to make a case for their patents on the merits, thus requiring that the courts interpret the rule as substantive.<sup>263</sup> It is also important to recognize that the majority rule in *Tafas II* was only supported by one judge—Judge Prost. Under Judge Rader's alternative rule, the Green Technology Pilot Program could similarly be viewed as exceeding the PTO's authority as it has substantial effects on the review process that are sufficiently grave.<sup>264</sup> Changing the processing time arguably alters the commercial viability and investment opportunities for some inventions in a sufficiently grave manner.

As the Green Technology Pilot Program example demonstrates, the practical effect of the substantive limitation on the PTO's authority is to render valuable programs susceptible to attack.<sup>265</sup> If programs that are clearly within the PTO's statutory authority can conflict with the substantive restrictions on the PTO's authority, it is difficult to envision what meaningful limits exist on the procedural/substantive doctrine. It is even more difficult to justify why the doctrine has so little relationship to the Patent Act. What is obvious is that the PTO has limited incentives to expend its precious resources on programs that the courts may invalidate.

## 2. *Reduced Opportunities for Public Participation*

Beyond harm to the public through reduced innovation, depriving the PTO of substantive rulemaking authority creates perverse incentives for the PTO to disengage the public from its decisionmaking process. The Federal Circuit's narrow construction of PTO authority motivates the PTO to frame its rules as procedural. But procedural rules fall outside the ambit of the notice-and-comment requirements of the APA,<sup>266</sup> and the public therefore has limited opportunities to participate in improving the Nation's patent system. The Federal Cir-

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<sup>263</sup> *Id.*

<sup>264</sup> *Id.* at 1369 (Rader, J., concurring in part and dissenting in part).

<sup>265</sup> Similar points can be raised with regard to the Patent Application Backlog Reduction Stimulus Plan, under which a small entity that expressly abandoned a copending, unexamined application had the opportunity to have another application advanced out of turn, and the Three-Track Program, which proposed to delay or expedite the review of patent applications based on a fee system. See Extension of the Patent Application Backlog Reduction Stimulus Plan, 75 Fed. Reg. 5041, 5041 (Feb. 1, 2010); Patent Application Backlog Reduction Stimulus Plan, 74 Fed. Reg. 62,285, 62,286 (Nov. 27, 2009); Press Release, U.S. Patent & Trademark Office, *supra* note 21.

<sup>266</sup> See generally 5 U.S.C. § 553(b) (2006).

cuit's doctrine thus sacrifices public input on matters that are meant to benefit the public, as well as transparency in the PTO's decision-making.

The APA includes various mechanisms that force agencies to inform the public about proposed substantive rules and consider the public's comments on those rules. Agencies generally must inform the public of proposed rulemaking by publishing a notice in the *Federal Register*.<sup>267</sup> The notice must include information about the proposed rulemaking to provide members of the public an opportunity to formulate comments on the legality and substance of the proposal.<sup>268</sup> After providing the public with notice, the agency then "shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity for oral presentation."<sup>269</sup> The rules typically need to incorporate a short general statement of the basis and purpose for the rules.<sup>270</sup> None of these notice-and-comment requirements applies to procedural rules.<sup>271</sup>

Requiring agencies to consider public concerns about proposed rules generates important social benefits. Making the decisionmaking process accessible to the public increases agency transparency.<sup>272</sup> Governmental transparency has been described as "[a] fundamental attribute of democracy, a norm of human rights, a tool to promote political and economic prosperity and to curb corruption, . . . a means to enable effective relations between nation states," and "clearly among the pantheon of great political virtues."<sup>273</sup> The public (and courts) can be assured that an agency has in fact considered potential weaknesses in its proposals and is not acting arbitrarily if the agency is forced to acknowledge comments by members of the public. Additionally, public participation enables the agency to learn about the public's priorities and alternative solutions.<sup>274</sup> The regulatory mea-

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<sup>267</sup> *Id.*

<sup>268</sup> *See id.*

<sup>269</sup> *Id.* § 553(c).

<sup>270</sup> *Id.*

<sup>271</sup> *Id.* § 533(b).

<sup>272</sup> *See* Sarah McQuillen Tran, *Rebuilding Our Power Without Procedural Safeguards: A Federal Response to the 2005 Hurricanes that Outlasted the "Emergency,"* 32 HARV. ENVTL. L. REV. 217, 250–51 (2008) (arguing that the Federal Energy Regulatory Commission's efforts to evade public participation when it expanded the opportunities for natural gas companies to construct new projects with minimal review were harmful to the public).

<sup>273</sup> Mark Fenster, *The Opacity of Transparency*, 91 IOWA L. REV. 885, 888 (2006) (footnotes omitted) (identifying the benefits of transparency while pointing out its limits).

<sup>274</sup> *See id.* at 895–910.

tures that an agency develops with the public's input therefore reflect more informed decisionmaking. Finally, the more information the public has, the better it can understand the challenges facing the industry subject to the proposed rules and can take appropriate measures to address the challenges.<sup>275</sup>

The constitutional rationale for the patent system heightens the importance of providing the public with meaningful opportunities to participate in the PTO's decisionmaking process.<sup>276</sup> The core purpose of the patent system is to balance a benefit to society (increased innovation) with a burden on society (grants of limited monopolies to patent owners). Because the public bears the burden of the monopolies, fairness compels the conclusion that the public should be able to provide direct input into how the agency charged with administering the patent system makes these tradeoffs that affect the public.<sup>277</sup>

Despite the pronounced benefits of public participation in regulatory decisionmaking, agencies are not always eager to take the initiative to engage public discourse.<sup>278</sup> Statutes requiring that agencies solicit public input have resulted in the delay, "reconsideration, redesign, and even withdrawal" of federal agency decisions.<sup>279</sup> One potential motivation for an agency to engage in notice-and-comment rulemaking is to attain *Chevron* deference.<sup>280</sup> However, the PTO has learned that performing notice-and-comment rulemaking can land it in undesirable situations. In *Tafas II*, Judge Rader viewed the PTO's voluntary efforts to provide a notice-and-comment period for the

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275 Professor Hope Babcock has observed that "[a]n informed public can do a better job of protecting itself than an uninformed one, and can provide more useful and specific comments on agency initiatives and plans to protect the public, leading to 'more rational' and better-supported agency decisions." Hope Babcock, *National Security and Environmental Laws: A Clear and Present Danger?*, 25 VA. ENVTL. L.J. 105, 136–37 (2007) (footnotes omitted).

276 I owe this concept to Professor Nathan Cortez.

277 See Tran, *supra* note 42, at Part III.B.2.

278 See Fenster, *supra* note 273, at 889–90 (discussing how "government seems eternally resistant to disclosure").

279 See Lynton K. Caldwell, *Beyond NEPA: Future Significance of the National Environmental Policy Act*, 22 HARV. ENVTL. L. REV. 203, 207 (1998) (discussing some of the benefits of the National Environmental Policy Act, which, like the APA, forces agencies to let members of the public express concerns about agency decisionmaking).

280 See *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001) ("[A]dministrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority. Delegation of such authority may be shown in a variety of ways, as by an agency's power to engage in adjudication or notice-and-comment rulemaking, or by some other indication of a comparable congressional intent.").

rules at issue as evidence that the rules were in fact invalid substantive rules, rather than procedural ones.<sup>281</sup> This interpretation puts the PTO in a catch-22. Either the PTO can engage the public in its rulemaking efforts and run the risk that its rules will be classified as substantive (and therefore impermissible under Federal Circuit precedent), or the PTO can label them “procedural” and accordingly decline to partake in any public participation obligations under the APA. Given the serious need for reform at the PTO, it is generally better to let these programs evade the APA than not permit them at all.

Not surprisingly, the PTO does not strictly fulfill the notice-and-comment obligations of the APA. For instance, PTO officials have acknowledged that they solicited and received comments on the Green Technology Pilot Program, but they have not released the comments to the public.<sup>282</sup> Comments on the program could reveal flaws in the PTO’s designation of which technologies are eligible for expedited treatment or reasons why the program has been undersubscribed. Unless the PTO reveals what comments it has received, however, there is no way of knowing whether the PTO considered the comments or whether they went straight into a garbage can.

By forcing agencies to incorporate public participation into their decisionmaking processes, the APA renders agency decisions more transparent and better informed. The substantive limitation on the PTO’s authority encourages the PTO to keep the public out of its decisionmaking process and sacrifices these important social benefits. At a time when action is needed to resolve the PTO’s shortcomings, giving the public opportunities to voice suggestions and express concerns about proposals with broad impacts on the patent community and the goals of the patent system holds critical importance.

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<sup>281</sup> *Tafas v. Doll (Tafas II)*, 559 F.3d 1345, 1370 (Fed. Cir.) (Rader, J., concurring in part and dissenting in part), *appeal dismissed as moot sub nom. Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

<sup>282</sup> Telephone Interview with Anonymous PTO Representative, U.S. Patent & Trademark Office (Aug. 12, 2010) (interviewed by Randall Beane, Research Assistant to the Author); *see also Changes to Practice for Petitions to Make Special in Patent Applications Pertaining to Green Technologies*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;dt=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=PTO-P-2009-0038> (last visited Feb. 10, 2012) (showing no public submissions available); *Elimination of Classification Requirement in the Green Technology Pilot Program*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;dt=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=PTO-P-2010-0042> (last visited Feb. 10, 2012) (same); *Green Technology Pilot Program*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;dt=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=PTO-P-2010-0050> (last visited Feb. 10, 2012) (same).

### III. OBJECTIONS

Although the substantive limitation on the PTO's authority creates negative legal, practical, and policy implications, some commentators may disagree with the present proposal to abandon the doctrine entirely. In essence, the present proposal provokes two normative objections: (1) given the Federal Circuit's ingrained stance on the scope of PTO rulemaking authority,<sup>283</sup> it is better that the law remain settled than be settled right, and (2) the courts are justified in keeping a watchful eye on the PTO as it is not doing its job properly. The second concern derives from the widespread views that the PTO lacks the resources to effectively manage its authority and is overly susceptible to interest group capture.<sup>284</sup> These objections and concerns subside, however, in light of the importance of uniformity in administrative law, the unpredictability of recent decisions that have attempted to distinguish between procedural and substantive rules, and the principle of separation of powers.

#### A. *Better to Remain Settled than to be Settled Right*

Those opposed to abandoning the substantive limitation on the PTO's authority could raise the argument that, given the Federal Circuit's well-established interpretation of the PTO's rulemaking authority, it would be harmful to disrupt settled expectations by changing the law. In other words, "it is more important that the applicable rule of law be settled than that it be settled right."<sup>285</sup> Supporters of such a view could point out that courts routinely draw the line between substantive and procedural rules in the context of determining whether a particular rule must comply with the notice-and-comment requirements of the APA.<sup>286</sup> These commentators could further contend that the limitations on the PTO's authority are justified as a means of preserving the status quo in terms of the allocation of power between the PTO and the courts.<sup>287</sup> Though this argument has some merit, the Supreme Court has already espoused persuasive grounds for dismissing

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<sup>283</sup> See *supra* Part I.

<sup>284</sup> See BURK & LEMLEY, *supra* note 20, at 106-07.

<sup>285</sup> *Burnet v. Coronado Oil & Gas Co.*, 285 U.S. 393, 406 (1932) (Brandeis, J., dissenting), *overruled on other grounds* by *Helvering v. Mountain Producers Corp.*, 303 U.S. 376, 387 (1938), and *Helvering v. Bankline Oil Co.*, 303 U.S. 362, 369-70 (1938).

<sup>286</sup> See, e.g., *JEM Broad. Co. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994) (concluding that notice and comment were not required because a rule was procedural, not substantive).

<sup>287</sup> See, e.g., Kerr, *supra* note 15, at 131.



these concerns.<sup>288</sup> Moreover, this is not an area of the law marked with clarity given the inherent murkiness of the Federal Circuit's procedural/substantive doctrine,<sup>289</sup> so it is unlikely that established expectations can be measurably injured.

Most significantly, the Supreme Court has already provided compelling reasons for rejecting this stare decisis argument given the critical importance of uniformity in administrative law. In *Zurko*, amici supporting the Federal Circuit's unique approach to reviewing factfinding argued that it was "better that the matter remain 'settled than that it be settled right.'" <sup>290</sup> While recognizing the Federal Circuit's specialized experience in patent matters, the Supreme Court nonetheless spurned this argument for its potential to "prove disruptive by too readily permitting other agencies to depart from uniform APA requirements."<sup>291</sup> Likewise, here the Federal Circuit's track record of denying the PTO substantive rulemaking authority could provide fodder to other courts to make exceptions to administrative law (including the notice-and-comment procedures of the APA), encouraging them to fulfill their own paternalistic desires to impose limits on agency rulemaking authority that do not derive from organic statutes and that are inconsistent with the APA. Allowing such a blister in the uniformity of administrative law to persist is therefore just as unacceptable with respect to the substantive rulemaking doctrine as it was with respect to the standard of review for PTO factfinding in *Zurko*.

Additionally, although the principle that the PTO possesses limited rulemaking authority may be well entrenched, application of the doctrine has been erratic. The serious ails affecting the patent system now require a wholly different application of the doctrine than (1) the Federal Circuit could have anticipated several decades ago when it created the limitation, or (2) the D.C. Circuit could have foreseen when it issued *JEM. Merck*, *Animal Legal*, and *JEM* did not involve a situation in which a court evaluated the legality of an administrative agency's rule. *Animal Legal* and *JEM* addressed the question of whether an agency had complied with the APA's notice-and-comment

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<sup>288</sup> *Dickinson v. Zurko*, 527 U.S. 150, 154 (1999) (acknowledging "the importance of maintaining a uniform approach to judicial review of administrative action").

<sup>289</sup> See Rai, *supra* note 15, at 2072–73 (noting that recent Federal Circuit jurisprudence has made the proper management of the PTO's caseload unclear).

<sup>290</sup> *Zurko*, 527 U.S. at 162 (quoting Brief of the Patent, Trademark & Copyright Section of the Bar Association of the District of Columbia as Amicus Curiae in Support of Respondents at 23, *Lehman v. Zurko*, 525 U.S. 961 (1998) (No. 98-377), 1999 WL 21291).

<sup>291</sup> *Id.*

period.<sup>292</sup> *Merck* focused on whether *Chevron* deference should be given to a PTO interpretation of the Hatch-Waxman Act and the Uruguay Round Agreements Act.<sup>293</sup> Deciding that an agency should not receive a particular level of deference (as the court did in *Merck*) or that it should comply with the notice-and-comment requirements of the APA (as the court did in *Animal Legal* and *JEM*) is far less consequential than declaring rules invalid (as the doctrine is now being applied). The fact that three judges in *Tafas II* adopted three diverging methods of reviewing the legality of PTO authority<sup>294</sup> shows that there is no obvious way to adapt the doctrine to current needs.

In summary, though there may be some situations in which it is better to let a bad law lie, this is not such a situation. The Federal Circuit's peculiarly restrictive view of PTO authority violates the Supreme Court's direct guidance in *Zurko* by allowing long-term expectations to trump the uniformity of administrative law. Concerns about tampering with established expectations further deteriorate in light of the unpredictability of Federal Circuit decisions that have been issued in recent years.

### B. *An Inadequate Agency*

Critics may further contend that the PTO's deficiencies as a regulator justify the courts in denying it substantive rulemaking authority. Commentators may believe that eliminating the substantive restriction on the PTO's authority would entitle the PTO to pass far-reaching rules for the first time, such as rules defining what constitutes "obviousness" and "written description" and determining whether the word "process" in section 101 of the Patent Act includes business methods. Similarly, because *Chevron* deference is more readily applied to administrative agencies that have the power to make rules carrying the force of law,<sup>295</sup> granting the PTO substantive rulemaking authority could result in more opportunities for the PTO to receive *Chevron* deference. A number of academics would likely oppose such changes due to the imbalance between the PTO's resources and workload.<sup>296</sup> To state it more crudely, because the PTO lacks the resources to do its job properly, the courts should have room to step in to fix its errors or

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<sup>292</sup> *JEM Broad. Co. v. FCC*, 22 F.3d 320, 322 (D.C. Cir. 1994); *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 923-24 (Fed. Cir. 1991).

<sup>293</sup> *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

<sup>294</sup> See *supra* Part I.C.

<sup>295</sup> See *supra* note 281.

<sup>296</sup> See Brief of 37 Professors, *supra* note 42, at 3-6, 13.

prevent them from happening. A related concern is that the PTO is particularly susceptible to being captured by its “customers,” the patentees.<sup>297</sup>

This Article does not deny that the PTO is an imperfect regulator. Instead, it shows that an agency’s imperfections do not justify a court in confiscating the agency’s authority to promulgate substantive rules. The Article further demonstrates that, even if the PTO were empowered to promulgate substantive rules, its authority likely would not encroach on the courts’ ability to define patentability standards.

First, the PTO is not the only agency that possesses disproportionately limited resources for its workload. This phenomenon plagues virtually every federal administrative agency in the United States, including agencies to which courts routinely uphold congressional delegations of substantive rulemaking authority. The Federal Energy Regulatory Commission (“FERC”) and the U.S. Army Corps of Engineers, for example, have had to institute fairly extreme measures to regulate entities within their allotted budgets. Instead of reviewing proposed projects on a case-by-case basis, these agencies have issued nationwide blanket certificates and permits, respectively, to enable projects with substantial environmental, economic, and safety risks to go forward.<sup>298</sup> For these agencies (as well as many others), rulemaking represents a more efficient means to manage their workloads than case-by-case adjudications. Just as the PTO is susceptible to capture by patent applicants, these agencies are susceptible to industry capture given the discrepancy between their sizable workloads and tight budgets.<sup>299</sup> This Article does not highlight these examples to

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<sup>297</sup> If the PTO had the authority to promulgate substantive rules, Professor Orin Kerr has suggested that patentees might spend their resources trying to influence the PTO rather than research new discoveries. Kerr, *supra* note 15, at 183 (arguing that “deference [to the PTO] would harm the patent system by encouraging patent applicants to divert resources away from research into new discoveries and towards efforts to influence PTO discretion”). This Article provides a brief response to Professor Kerr. Further examination of why agency capture would not be a concern if the PTO had substantive rulemaking authority is beyond the scope of this Article, but I intend to explore this issue in greater depth at a future time.

<sup>298</sup> See Revisions to the Blanket Certificate Regulations and Clarification Regarding Rates, 71 Fed. Reg. 63,680 (Oct. 31, 2006) (codified at 18 C.F.R. pt. 157 (2011)) (describing FERC’s blanket certificate program); *Nationwide Permit Program*, U.S. ARMY CORPS ENGINEERS: S.F. DISTRICT, <http://www.spn.usace.army.mil/regulatory/nwp.html> (last updated Feb. 24, 2011) (seeking comments on a proposal to renew and revise its nationwide permitting of work in wetlands and other waters and on a proposal to issue nationwide permits for work related to renewable energy generation projects); see also Tran, *supra* note 272, at 219 n.10 (explaining that projects undertaken under FERC’s blanket certificate program involve minimal or no regulatory review).

<sup>299</sup> See, e.g., Tran, *supra* note 272, at 225–29 (arguing that FERC used Hurricane Katrina to

suggest that regulatory actions of nationwide applicability are desirable or even acceptable as a policy matter, but merely to point out that in some respects the PTO has fewer budgetary constraints than other agencies that have substantive rulemaking authority. And the PTO's financial resources recently grew with the passage of the AIA.<sup>300</sup> Hence the PTO's budget should not be a cause for the courts to construe the PTO's authority more narrowly than they would other agencies. The correct analysis turns on whether a particular agency interpretation was justified.

Overreliance on congressional budgetary allocations is also disconcerting given that agency budgets change all the time. In 2011, the Environmental Protection Agency ("EPA") saw its budget drop by a whopping \$1.6 billion, a sixteen percent cut from its 2010 budget.<sup>301</sup> Does that mean that courts should now treat EPA's interpretations with less deference? By contrast, the Bureau of Ocean Energy Management, Regulation and Enforcement ("BOEMRE") saw its budget rise by \$58 million in 2011.<sup>302</sup> Should BOEMRE's interpretations now be accorded greater weight than in the prior year? Should a rule be presumed that for every \$10 million change in an agency's budget, the level of deference that the agency receives changes accordingly? The answer to all of these questions is "of course not." Tying congressional allocations of funds to the level of deference an agency receives would subvert administrative law principles and plain statutory language to a form of congressional mindreading.

Finally, eliminating the substantive restriction on the PTO's authority would not empower the PTO to promulgate regulations on any subject it pleases. The specific rulemaking powers embodied in the Patent Act have constrained the PTO's discretion.<sup>303</sup> As Judge Bryson pointed out in *Tafas II*, Congress "charted a middle course" in allocating the PTO rulemaking authority by making that authority neither as broad nor as narrow as possible.<sup>304</sup> A number of PTO rules that have been upheld by the Federal Circuit fall squarely within the PTO's stat-

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justify expanding authorization for larger and varied types of natural gas pipeline projects under the relaxed regulatory requirements of FERC's blanket certificate program).

<sup>300</sup> See Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, sec. 6, §§ 301, 311–319, 321–329, 125 Stat. 284, 299–313 (2011); *id.* § 18, 125 Stat. at 329–31 (to be codified at 35 U.S.C. § 321).

<sup>301</sup> Bill Murray, *US Budget: EPA Loses, Offshore Agency Gains*, OIL DAILY, Apr. 14, 2011, available at 2011 WLNR 8329649.

<sup>302</sup> *Id.*

<sup>303</sup> See 35 U.S.C. §§ 2(b), 132(b) (2006 & Supp. IV 2011).

<sup>304</sup> *Tafas v. Doll (Tafas II)*, 559 F.3d 1345, 1365 (Fed. Cir.) (Bryson, J., concurring), *appeal dismissed as moot sub nom. Tafas v. Kappos (Tafas IV)*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

utory authority without the substantive/procedural distinction, including rules (1) addressing the admission and discipline of attorneys practicing before the PTO, (2) permitting conferences between an administrative patent judge and the parties to an interference proceeding, and (3) establishing that the movant has the burden of proof and duty of translating earlier filed documents into English to demonstrate that the international application included the same disclosure as in the national stage application.<sup>305</sup> Nonetheless, the PTO's statutory authority has been more limited than that of the Federal Trade Commission,<sup>306</sup> the Food and Drug Administration,<sup>307</sup> the Federal Communications Commission,<sup>308</sup> the Federal Reserve Board,<sup>309</sup> the Secretary of Agriculture,<sup>310</sup> and many other institutional actors that have legislative authority to issue any regulations that are "necessary or appropriate" for administering a particular statute. Congress has contemplated giving the PTO such authority,<sup>311</sup> but has never done so.<sup>312</sup>

Although the PTO is an imperfect regulator, the PTO's inadequacies do not create an open-ended invitation for the courts to meddle in the PTO's affairs. Doing so unjustifiably alienates patent law from

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<sup>305</sup> See *id.* at 1365–66.

<sup>306</sup> See 15 U.S.C. § 45(a)(2) (2006) ("The Commission is hereby empowered and directed to prevent persons . . . from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce."); *Nat'l Petrol. Refiners Ass'n v. FTC*, 482 F.2d 672, 676–78 (D.C. Cir. 1973) (explaining that the Supreme Court has given "broad construction" to the FTC's powers).

<sup>307</sup> See 21 U.S.C. § 371(a) (2006) (vesting in the Secretary of Health and Human Services "[t]he authority to promulgate regulations for the efficient enforcement of this [Act]"); *Nat'l Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 698 (2d Cir. 1975) (holding that Congress did not intend to "deny the [Food and Drug Administration] the power to make binding rules specifying those products that would require a prescription").

<sup>308</sup> See 47 U.S.C. §§ 154, 303(r) (2006 & Supp. IV 2011) (detailing qualifications, as well as powers and duties of members of the Commission); *Nat'l Petrol. Refiners Ass'n*, 482 F.2d at 678–79 (discussing Supreme Court cases that have extended FCC authority beyond specification of technical guidelines).

<sup>309</sup> See 15 U.S.C. § 1604 ("The [Bureau of Consumer Financial Protection] shall prescribe regulations to carry out the purposes of this subchapter. . . . [T]hese regulations may contain such classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for all or any class of transactions, as in the judgment of the [Bureau] are necessary or proper to effectuate the purposes of this subchapter.").

<sup>310</sup> See 21 U.S.C. § 463(b) ("The Secretary shall promulgate such other rules and regulations as are necessary to carry out the provisions of this chapter."); *Nat'l Petrol. Refiners Ass'n*, 482 F.2d at 680 (discussing the powers of the Secretary of Agriculture to promulgate rules and regulations).

<sup>311</sup> See Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); Long, *supra* note 15, at 1979.

<sup>312</sup> Long, *supra* note 15, at 1979.

mainstream administrative law and second guesses intentional delegations of power to an administrative body.

#### CONCLUSION

The Federal Circuit's anomalous approach to administrative law conflicts with the goals of the U.S. Constitution, the language of the Patent Act and the APA, Supreme Court precedent, and decisions by the Federal Circuit's sister appellate courts. In recent years, serious repercussions have arisen as a result of the court's cramped view of PTO authority. The substantive limitation on the PTO's rulemaking authority has hindered the PTO's ability to initiate programs that address the ails of the patent system, including woefully long delays in a review process that does not accurately assess whether inventions are patent worthy. The doctrine has further given the PTO a perverse incentive to disengage the public from its decisionmaking process, thereby reducing its transparency and the likelihood that its decisions will be informed.

In light of changing regulatory needs, ongoing reform efforts, and the peculiar evolution of the Federal Circuit's approach, this Article suggests that it is time to abandon the distinction between invalid substantive rules and valid procedural rules with respect to the powers that the PTO has held since 1999. By permitting the PTO to engage in any form of rulemaking authority that is authorized under these powers, the Federal Circuit would better promote the effectiveness of the patent system, restore the proper balance of power between the three branches of government, and bring patent law under the umbrella of administrative law.