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**PATENT POWERS**

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## I. INTRODUCTION

A new era in patent law has dawned. After years of demand for patent reform and six years of intense negotiations over potential reforms,<sup>1</sup> the enactment of the historic Leahy-Smith America Invents Act (the “America Invents Act”)<sup>2</sup> in September of 2011 set into motion what at least one commentator has called “the most significant overhaul to our patent system, since the founding fathers first conceived of codifying a grand bargain between society and invention.”<sup>3</sup> Already, leaders in the patent community have divided in their opinions about the Act. David Kappos, the Director of the U.S. Patent and Trademark Office (the “USPTO” or “Patent Office”), has lavished his praises upon the law he says will help “accelerate our economic recovery, and ensure[] that our nation’s innovators and job creators aren’t held back.”<sup>4</sup> Others, such as former Chief Judge Paul Michel of the U.S. Court of Appeals for the Federal Circuit (the “Federal Circuit”), have loudly criticized the Act for being poorly written and rife with ambiguity.<sup>5</sup> Another knowledgeable source has characterized the resulting package of changes as a “sausage,” a random mixture of reforms rather than a cohesive, unified product.<sup>6</sup> As far as sausages go, the America Invents Act is a supersized one. Although the Act did not expand the USPTO’s authority as far as certain earlier versions of the legislation had proposed to do, it will likely change forever the institutional structure of the patent system, particularly the roles of the Patent Office and Federal Circuit and the relationship between administrative law and patent law.

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1. See Patent Lawsuit Reform Act of 2010, H.R. 6352, 111th Cong. (2010); Patent Reform Act of 2009, S. 610, 111th Cong. (2009); Patent Reform Act of 2009, S. 515, 111th Cong. (2009); Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009); Patent Reform Act of 2008, S. 3600, 110th Cong. (2008); Patent Reform Act of 2007, S. 1145, 110th Cong. (2007); Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2006); U.S. Patent & Trademark Fee Modernization Act of 2005, H.R. 2791, 109th Cong. (2005); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

2. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

3. David Kappos, *Re-Inventing the U.S. Patent System*, DIRECTOR’S FORUM: DAVID KAPPOS’ PUBLIC BLOG (Sept. 16, 2011, 5:45 PM), [http://www.uspto.gov/blog/director/entry/re\\_inventing\\_the\\_us\\_patent](http://www.uspto.gov/blog/director/entry/re_inventing_the_us_patent).

4. See *id.*

5. Jan Wolfe, *What Effects Will the America Invents Act Have on U.S. Patent Law?*, LAW.COM (Sept. 13, 2011), <http://www.law.com/jsp/cc/PubArticleCC.jsp?id=1202514170593> (quoting Judge Michel as stating that “[t]he bill makes fundamental changes, and many sections are poorly written and ambiguous”).

6. Interview with anonymous government official, in Dall., Tex. (2011).

Implementing the brunt of the reforms falls on the shoulders of the Patent Office. The Agency now has responsibility for a handful of new and amended proceedings in which patent rights may be terminated or strengthened,<sup>7</sup> setting its own fees,<sup>8</sup> conducting various policy studies,<sup>9</sup> and replacing its Board of Patent Appeals and Interferences with a brawnier Patent Trial and Appeal Board.<sup>10</sup> Coupled with these new responsibilities, the America Invents Act grants the USPTO a dizzying array of new powers, including powers to set forth standards and procedures for the institution of its proceedings, to set forth standards and procedures for discovery of relevant evidence, to specify when parties may amend or supplement their patents, to prescribe sanctions for abuses in discovery, and to define certain ambiguous terms.<sup>11</sup> The Act further stipulates that the Patent Office may promulgate rules prioritizing the examination of applications of importance to the national economy or national competitiveness,<sup>12</sup> such as environmentally beneficial technologies.<sup>13</sup> The user-friendly chart in the Appendix depicts the smorgasbord of new USPTO rulemaking powers.

The expansions to the USPTO's authority will indubitably intensify a raging debate over the proper relationship between patent law and administrative law. Over the years, the Federal Circuit has assumed primary responsibility for interpreting the Patent Act and crafted limitations on the USPTO's authority that have limited the Agency to a rubberstamping, ministerial role rather than a policy-setting or substantive rulemaking role.<sup>14</sup> This narrow interpretation of an admin-

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7. See America Invents Act sec. 6 ("Post-grant review proceedings"); *id.* sec. 12 ("Supplemental examination"); *id.* sec. 18 ("Transitional program for covered business method patents").

8. See *id.* sec. 10 ("Fee setting authority").

9. See *id.* sec. 26 ("Study on implementation"); *id.* sec. 27 ("Study on genetic testing"); *id.* sec. 29 ("Establishment of methods for studying the diversity of applicants"); *id.* sec. 31 ("USPTO study on international patent protections for small businesses").

10. See *id.* sec. 7 ("Patent Trial and Appeal Board").

11. See Chart of New Patent Office Powers, *infra* Appendix; discussion *infra* Part III.A.2.

12. America Invents Act sec. 25 (providing that "notwithstanding section 41 or any other provision of law," the USPTO "may, subject to any conditions prescribed by the Director and at the request of the patent applicant, provide for prioritization of 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").

13. This provision codifies the USPTO's practice of expediting the review of certain high priority applications, such as those relating to counterterrorism, the safety of research relating to recombinant DNA, HIV/AIDS, cancer, certain biotechnology inventions by small entities, energy and the environment. See discussion *infra* Part IV.B.2.

14. See, e.g., *Koninklijke Philips Elecs. N.V. v. Cardiac Sci.*, 590 F.3d 1326, 1336 (Fed. Cir. 2010) (citing *Animal Legal* for the holding that the Patent Office "lacks substantive rulemaking authority"); *Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009) (same), *reh'g en banc granted*, 328 F. App'x 658 (Fed. Cir. 2009), *appeal dismissed*, *Tafas v. Kappos*, 586 F.3d 1369, 1371 (Fed. Cir. 2009); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336

istrative agency's authority has set the USPTO apart from the Environmental Protection Agency ("EPA"), the Federal Communications Commission ("FCC"), and other agencies that exercise broad discretion when regulating in complex, technical areas,<sup>15</sup> and has flared the interests of numerous commentators. The Supreme Court,<sup>16</sup> at least two Federal Circuit judges,<sup>17</sup> and a handful of scholars<sup>18</sup> have challenged the merits of the peculiar division of power between the Federal Circuit and USPTO. Several noted scholars have attempted to rationalize the power divide.<sup>19</sup> Other prominent scholars have analyzed its effects on the development of patent law.<sup>20</sup> In my prior

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(Fed. Cir. 2008) (same); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) (same).

15. 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, 271 (2007).

16. See *Dickinson v. Zurko*, 527 U.S. 150, 162–64 (1999) (reprimanding the Federal Circuit for crafting a special review standard for USPTO decisions and thereby isolating its review of patent appeals from administrative law). The Supreme Court is expected to address the relationship between the Federal Circuit and the USPTO again in 2012 when it hears *Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 3064 (2011).

17. See *Hyatt*, 625 F.3d at 1342 (Dyk, J., dissenting) (asserting that the en banc court's holding that 35 U.S.C. § 145, which entitles patent applicants to file civil actions in district courts to determine whether they should be entitled to receive a patent, does not limit the applicant's right to introduce new evidence before a district court "denigrates the important expertise of the USPTO, is contrary to established principles of administrative law, finds no support in the language of the statute, and is contrary to decisions of at least five other circuits"); *Tafas*, 559 F.3d at 1366 (Bryson, J., concurring) (agreeing with the USPTO that the agency's authority should not be confined by a distinction between invalid substantive rules and valid procedural rules).

18. See Michael Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1747–48 (2011) (proposing that Congress restructure the patent system to allow the Patent Office to engage in full substantive rulemaking so that the Agency could tailor patentability to diverse circumstances); John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1041 (2011) (arguing "that the enterprise of regulating patentable subject matter should be primarily entrusted to the USPTO, rather than, as it is now, to the courts"); Jonathan S. Masur, *Regulating Patents*, 2010 SUP. CT. REV. 275, 279 (proposing that Congress endow the USPTO with substantive rulemaking authority so that the Agency could craft "intelligent patent policy . . . [and] design rules that respond to particular technological developments in specific fields"); 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 towards bringing substantive patent law into conformity with administrative law could be mirrored in the area of procedure).

19. See, e.g., Joseph Scott Miller, *Substance, Procedure, and the Divided Patent Power*, 63 ADMIN. L. REV. 31 (2011) (embracing the Federal Circuit's distinction between valid USPTO procedural rules and invalid substantive ones); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1659 (2003) (asserting that the courts, rather than the USPTO, are most efficient at dealing with "bad patents").

20. See, e.g., Clarisa Long, *The PTO and the Market for Influence in Patent Law*, 157 U. PA. L. REV. 1965, 1973 (2009) (discussing the Agency's efforts to increase its influence by having administrative law principles govern patent law); Jonathan S. Masur, *Patent Inflation*, 121 YALE L.J. 470 (2011) (suggesting that the structural relationship between the USPTO and the Federal Circuit has inflated the boundaries of patentability); Melissa F. Wasserman, *The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379, 382–83 (2011) (arguing that, despite the substantive limitation

scholarship, I contributed to the debates about the proper relationship between patent law and administrative law by demonstrating that the Federal Circuit has never provided a coherent rationale for its limited view of USPTO authority.<sup>21</sup> I further demonstrated that the Federal Circuit's approach has generated a confusing and normatively dysfunctional distinction between valid procedural rules and invalid substantive rules.<sup>22</sup>

Despite the scrutiny the relationship between the USPTO and the Federal Circuit has received, no scholar has yet identified how the recent reforms to the patent system affect the power dynamic between these two governmental bodies. This Article provides the first comprehensive analysis of how the America Invents Act fundamentally alters both the USPTO's authority and its relationship with the courts. In doing so, this Article makes three primary contributions to the literature.

This Article first demonstrates that the enactment of the America Invents Act should not be viewed as a stand-alone event but rather must be viewed in light of the historical interactions between Congress, the Supreme Court, the Federal Circuit, and the USPTO. Viewed through this lens, it becomes apparent that the America Invents Act continues the trend since 1999 of shifting control and influence over patent law from the courts to the USPTO. Indeed, the America Invents Act serves as the latest and most clear-cut victory for the Patent Office vis-à-vis the courts in the struggle for power over patent law.

The Article's second contribution is to show that a number of the USPTO's new powers conflict irreconcilably with the Federal Circuit's traditional view of USPTO authority. Far beyond promulgating procedural rules — what the Federal Circuit has pronounced is the extent of the USPTO's rulemaking authority<sup>23</sup> — setting standards for patent proceedings and prioritizing technologies on the basis of their national importance requires that the Agency engage in complex, policy-based decisions that may carry profound implications for inventors, patent law practitioners, and society at large. For instance, for the USPTO to set “standards for the conduct of derivation proceedings, including requiring parties to provide sufficient evidence to prove and

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on its authority, the Patent Office has played a pivotal role in developing substantive patent law standards).

21. Sarah Tran, *Administrative Law, Patents, and Distorted Rules*, 80 GEO. WASH. L. REV. 831 (2012) [hereinafter *Distorted Rules*].

22. *See id.* at 845–54.

23. *See, e.g.,* *Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009) (holding that the USPTO has the authority to promulgate procedural rules but not substantive rules); *see also* *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335 (Fed. Cir. 2008) (“To comply with section 2(b)(2)(A), a Patent Office rule must be ‘procedural’ — i.e., it must ‘govern the conduct of proceedings in the Office.’” (quoting 35 U.S.C. § 2(b)(2)(A) (2006))).

rebut a claim of derivation,”<sup>24</sup> the USPTO is arguably empowered to define what it means for one invention to derive from another.<sup>25</sup> Patent holders who are found to have “derived” their inventions from another invention lose their patent rights, one of the harshest penalties possible in patent law. Thus the USPTO’s authority to set standards — such as the standards for derivation proceedings — appears to give it the power to shape substantive patent rights.

The America Invents Act provides almost no guidance as to what factors the USPTO should consider when it sets standards for its proceedings and prioritizes technologies of national importance, other than a few broad policy considerations. In promulgating rules for post-grant review and inter partes review, the USPTO must consider “the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete” the proceedings.<sup>26</sup> When the USPTO evaluates the national importance of applications for the purpose of prioritizing them in the review process, its sole required considerations are the impact of the applications on the national economy or national competitiveness.<sup>27</sup> Based on these two criteria for prioritization, how exactly should the USPTO rank the following inventions? (1) A device that generates energy from waves and could revolutionize the nation’s competitiveness in the clean energy industry. (2) A drug for erectile dysfunction that could create thousands of jobs; and (3) A videogame improvement that could produce billions of dollars in revenue for U.S. companies.<sup>28</sup> Judging the relative values of inventions requires a delicate balancing of social interests. Although the USPTO is limited in its powers to specific proceedings and is not specifically vested with the authority to issue any regulations that are “necessary or appropriate” to administer its organic act,<sup>29</sup> the Agen-

24. Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 3(i), 125 Stat. 284, 289 (2011) (to be codified at 35 U.S.C. § 135(b)) (replacing interference proceedings with derivation proceedings).

25. See discussion *infra* Part III.B.1.

26. America Invents Act sec. 6(a) (to be codified as amended in part at 35 U.S.C. § 316(b)); America Invents Act sec. 6(d) (to be codified as amended in part at 35 U.S.C. § 326(b)).

27. Thus, in prioritizing among patent applications, the USPTO could focus on job creation, revenue generation, a particular industry’s need for a regulatory boost, or the relative strength of competitor nations, among a whole host of other conceivable considerations.

28. To a large degree, this question oversimplifies the analysis as every invention has some effects on national competitiveness, revenue generation, and jobs.

29. A number of other institutional actors possess such authority. See Federal Trade Commission Act, 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); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 371 (2006) (“The authority to promulgate regulations for the efficient enforcement of this chapter . . . is vested in the Secretary [of Health and Human Services].”); 47 U.S.C. §§ 154(i), 303(r) (2006 & Supp. IV 2010) (providing that “[t]he [Federal Communications] Commission may perform any and all acts, make such rules and regulations, and issue such orders,

cy's new powers seem more like a cousin of the EPA's broad discretionary authority under environmental statutes to "protect human health and the environment"<sup>30</sup> than anemic, procedural powers entrusted to a ministerial agency. Indeed, it would appear to be a flagrant usurpation of executive and legislative authority for the Federal Circuit to superimpose a substantive restriction on the USPTO's new powers.

This Article's third contribution is to develop a straightforward framework for judicial review of all Patent Office regulations that could bring patent law into conformity with administrative law. Rather than apply an ill-defined distinction between valid procedural rules and invalid substantive rules, I propose a two-step framework to delineate the proper extent of the USPTO's authority under the Patent Act. First, consistent with the established administrative law principle that courts should interpret congressional delegations of authority broadly,<sup>31</sup> I propose the courts should broadly consider whether a USPTO rule is authorized by one of its specific rulemaking powers.<sup>32</sup> Second, the courts should ensure that the rule does not violate another portion of the Patent Act, such as its implicit delegation of authority to the courts in 35 U.S.C. §§ 101 ("Inventions patentable"),<sup>33</sup> 102 ("Conditions for patentability; novelty and loss of right to patent"),<sup>34</sup> 103 ("Conditions for patentability; non-obvious subject matter"),<sup>35</sup> and 112 ("Specification")<sup>36</sup> to determine certain standards for patentability that the Patent Office has not been directed to interpret. By using the specific language of the Patent Act to determine the proper extent of the Agency's rulemaking powers while respecting the role of the courts, this framework would restore the proper balance of power

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not inconsistent with this chapter, as may be necessary in the execution of its functions" and that "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").

30. Resource Conservation and Recovery Act § 9003(a), 42 U.S.C. § 6991b(a) (2006) (requiring the EPA to promulgate regulations for new and existing underground storage tanks and to establish technical requirements for leak detection and prevention "as may be necessary to protect human health and the environment"); see also *About EPA*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/aboutepa/index.html> (last visited May 3, 2012) ("EPA's mission is to protect human health and the environment.").

31. See Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 511–16.

32. A related issue is what level of deference the courts should give to decisions issued by the Patent Trial and Appeal Board when the Board is applying one of the USPTO's new rules, such as post-grant review rules. Although it is beyond the scope of this Article to address this issue, I intend to explore this issue in greater depth at a future time.

33. 35 U.S.C. § 101 (2006).

34. *Id.* § 102, amended by Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 2(b), 125 Stat. 284, 285–87 (2011).

35. *Id.* § 103, amended by America Invents Act sec. 2(c).

36. *Id.* § 112, amended by America Invents Act sec. 4(c).

between the congressional, judicial, and executive branches of government. It would also enhance the effectiveness of the USPTO, increase certainty in the patent system, and promote uniformity in administrative law.

The remainder of this Article expands upon these arguments. Part I describes the long-standing power struggle between the USPTO and Federal Circuit for control over substantive patent law. It reveals that the America Invents Act continues the trend since 1999 of shifting power from the courts to the USPTO. Part II delves deeper into the specific reforms embodied in the America Invents Act. It demonstrates how the America Invents Act grants the USPTO more resources, more flexibility, and more powers to combat the notorious speed and quality deficiencies in the patent system. It then reveals that these reforms require an end to the Federal Circuit's monopoly over substantive interpretations of the Patent Act. In Part III, I introduce a normatively attractive framework for judicial review of decisions by the Patent Office. Specifically, I propose that the courts should deferentially uphold any USPTO rules falling within one of the Agency's specific rulemaking powers unless the rule conflicts with another portion of the Patent Act, such as the provisions that have traditionally delegated authority to the courts to set certain core standards for patentability. This approach eliminates the incoherent and troublesome distinction between invalid substantive rules and valid procedural rules, furthers congressional intent, gives the PTO flexibility to promote innovation and commercialization of valuable technologies, and brings greater uniformity to administrative law. With major judicial and regulatory reforms to the patent system underway, now is the best time for the Federal Circuit to fix its overly narrow view of USPTO authority.

## II. POWER STRUGGLE

To understand how the America Invents Act alters the relationship between the courts and the USPTO, it is necessary to understand the status of the power dynamic before the Act. The Federal Circuit has developed for itself an enviable role in patent law. It has assumed exclusive responsibility for making substantive interpretations of the Patent Act and "has historically chosen not to defer to agencies on issues of patent law."<sup>37</sup> It achieved these feats by asserting, quite unexpectedly and without any coherent justification, that the Agency

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37. Sapna Kumar, *Expert Court, Expert Agency*, 44 U.C. DAVIS L. REV. 1547, 1550 (2011); see generally Ryan Vacca, *Acting Like an Administrative Agency: The Federal Circuit En Banc*, 76 MO. L. REV. 733, 733 (2011) (asserting that the Federal Circuit has been making substantive rules and setting patent policy like an administrative agency).



lacks substantive rulemaking authority.<sup>38</sup> The USPTO has not been complacent. It has pushed for greater autonomy and has achieved some success.<sup>39</sup> This Article demonstrates that the America Invents Act continues the trend since 1999 of shifting power from the courts to the USPTO.

*A. The Origins of an Administrative Law Anomaly*

The substantive restriction on the USPTO's rulemaking authority has an unusual history. It emerged out of a few loose lines of dicta in *Animal Legal Defense Fund v. Quigg*,<sup>40</sup> a 1991 Federal Circuit case that had little relevance to the question of the appropriate extent of the Agency's authority. Although it has been "widely recognized that the Judiciary, and in particular the Federal Circuit, . . . has played a salient role in" interpreting the Patent Act,<sup>41</sup> no court or statutory language imposed a "substantive" limit on the USPTO's authority prior to this decision.

The roots of the Patent Office's statutory authority go back to the late eighteenth century.<sup>42</sup> The Patent Act of 1790 gave the Secretary of State, the Secretary of War, and the Attorney General the authority to examine patent applications and issue patents.<sup>43</sup> Almost half a century later, in 1836, Congress created the Patent Office and charged it with the seemingly broad authority

under the direction of the Secretary of State, to superintend, execute, and perform, all such acts and things touching and respecting the granting and issuing of patents for new and useful discoveries, inventions, and improvements, as are herein provided for, or shall hereafter be, by law, directed to be done and performed . . . .<sup>44</sup>

Congress did not tamper with the USPTO's responsibilities for over one hundred years. Then, in 1952, Congress gave the USPTO the power to promulgate rules "for the conduct of proceedings in the Patent Office"<sup>45</sup> and rules "governing the recognition and conduct" of

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38. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996).

39. See Long, *supra* note 20, at 1966.

40. 932 F.2d 920, 930 (Fed. Cir. 1991).

41. Wasserman, *supra* note 20, at 387.

42. For an informative discussion of the early development of patent law up until the mid-1960s, see generally *Graham v. John Deere Co.*, 383 U.S. 1, 5–10 (1966).

43. Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 109–10 (1790).

44. Patent Act of 1836, ch. 357, § 1, 5 Stat. 117, 117–18 (1836).

45. Patent Act of 1952, Pub. L. No. 82-593, § 6, 66 Stat. 792, 793.

patent practitioners.<sup>46</sup> Although these powers are not as broad as the rulemaking powers certain other agencies enjoy, they could readily be interpreted as encompassing the authority to promulgate some substantive rules,<sup>47</sup> such as a rule rendering a patent invalid if a patent practitioner withheld a key fact from the Patent Office during prosecution of the underlying patent application.

The language of the Patent Act of 1952 was still in effect when the Federal Circuit took the first step in *Animal Legal Defense Fund v. Quigg*<sup>48</sup> towards stripping the USPTO of substantive rulemaking authority. In *Animal Legal*, the USPTO had issued a notice stating that non-human organisms, such as animals, were patentable under 35 U.S.C. § 101.<sup>49</sup> Various animal rights organizations and individuals filed suit arguing that the USPTO had failed to comply with the APA's notice and comment procedures when it issued the notice.<sup>50</sup> The Federal Circuit sided *in favor* of the USPTO,<sup>51</sup> concluding that the notice was an interpretive rule, which the APA exempts from its notice and comment requirements, rather than a substantive rule that represents "a change in existing law or policy."<sup>52</sup> After reaching this holding, the court noted in dicta: "A substantive declaration with regard to the Commissioner's interpretation of the patent statutes . . . does not fall within the usual interpretation" of the Patent Office's authority to only promulgate rules governing the conduct of its proceedings.<sup>53</sup>

For a number of reasons, this decision should not have formed a basis for eliminating the USPTO's authority to promulgate substantive rules for the next two decades. First, the court had not been called on to consider the validity of a USPTO rule or even the extent of the USPTO's authority. It was merely asked whether the USPTO had followed the appropriate procedures for issuing the notice. Had the court determined that the USPTO had not complied with the APA, the USPTO would have been free to promulgate the exact same rule again if it did so in compliance with the APA. The court's vague statement about the USPTO's authority was pure dicta.<sup>54</sup> To the extent the Federal Circuit did contemplate crafting any sweeping limitations on the Patent Office's substantive rulemaking authority, the court failed to delineate the limits of such a doctrine or articulate a clear rationale for

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46. *Id.* § 31.

47. Tran, *supra* note 21, at 857–62.

48. 932 F.2d 920 (Fed. Cir. 1991).

49. *Id.* at 922.

50. *Id.* at 923–24.

51. *Id.* at 931.

52. *Id.* at 927.

53. *Id.* at 930.

54. See Tran, *supra* note 21, at 842–45.

it.<sup>55</sup> Second, the court appeared to evidence some confusion as to the distinction between interpretive rules and substantive rules. Interpretive rules, like legislative rules and policy statements, are a type of substantive rule, not a distinct category of rule as the court suggested.<sup>56</sup> Finally, in 1999 Congress expanded the USPTO's rulemaking powers,<sup>57</sup> rendering judicial decisions issued prior to that date of limited precedential value with respect to the scope of the Agency's authority.

Despite its limitations, *Animal Legal* has become one of the most frequently cited cases for restricting the USPTO's authority.<sup>58</sup> *Animal Legal* rose to prominence in 1996 in *Merck & Co. v. Kessler*. At issue in *Merck* was whether *Chevron* deference should be given to a Patent Office legal interpretation of the Hatch-Waxman and Uruguay Rounds Agreement Acts.<sup>59</sup> In *Chevron*, the Supreme Court had held that courts have a duty to 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>60</sup> In *Merck*, the Patent Office sought *Chevron* deference for interpreting the relevant statutes as limiting the length of potential patent term extensions for patents granted before June 8, 1995.<sup>61</sup> The unanimous panel rejected the Patent Office's claim for deference with a single damning statement: "As we have previously held, the broadest of the [Patent Of-

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55. Moreover, as highlighted by both the majority and dissenting opinions in *Tafas v. Doll*, it is questionable whether the court's efforts to distinguish "substantive" from "interpretative" rules for APA notice and comment clarifies the distinction between "substantive" and "procedural" rules. See *Tafas v. Doll*, 559 F.3d 1345, 1355 (Fed. Cir. 2009) ("While this court has previously evaluated USPTO rules in terms of whether they 'affect individual rights and obligations,' it has done so [while] distinguishing between 'interpretive' and 'substantive' rules . . . [This] is not dispositive on the issue of whether the Final Rules are procedural." (citation omitted)); *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").

56. 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).

57. See American Inventors Protection Act, Pub. L. No. 106-113, § 4711–12, 113 Stat. 1501A-552, at 1501A-572 to 1501A-575 (1999); discussion *infra* Part II.B.

58. See *supra* note 14.

59. *Id.* at 1546–50.

60. See *Chevron U.S.A., Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). After the *Merck* decision, the Supreme Court narrowed the grounds for agencies to receive *Chevron* deference. See *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (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 Subheading 4820.10.20 of the Harmonized Tariff Schedule of the United States); see also *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000) (holding that agency opinion letters are not entitled to *Chevron* deference).

61. 80 F.3d at 1548–49.

office's] rulemaking powers . . . authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [Patent Office]'; it does NOT grant the Commissioner the authority to issue substantive rules."<sup>62</sup> Although *Merck* was limited to the question of what deference to apply to the USPTO's interpretation, not whether the USPTO had the authority to promulgate a rule at all, *Merck* became the impetus for depriving the USPTO of all substantive rule-making authority in its patent law affairs<sup>63</sup> — a doctrine that has isolated patent law from administrative law.<sup>64</sup>

### B. Pushback

The Patent Office has not witnessed its power wane without a fight. After *Merck*, the USPTO proactively pushed for more influence over patent law.<sup>65</sup> Just three years after *Merck*, Congress and the Supreme Court both attempted to redistribute power to the USPTO from the courts. The America Invents Act continues this trend of shifting power to the USPTO.

In 1999, the Supreme Court made the first move toward redistributing power to the USPTO in *Dickinson v. Zurko*.<sup>66</sup> There, the Court held that the APA provides the governing standards for review of Patent Office fact-finding.<sup>67</sup> In so holding, the Court reversed the Federal Circuit's view that the "clearly erroneous" standard, a less deferential standard than the APA's standard, applied.<sup>68</sup> Prior to this case, the Federal Circuit had denied that the APA had any relevance to its review of Patent Office fact-finding for patent denials.<sup>69</sup> Although the case has limited legal effect because it dealt with the narrow issue of the appropriate standard for review of Patent Office fact-finding,<sup>70</sup> eminent patent law scholars view the decision as a symbolic effort by the Supreme Court to redirect the Federal Circuit's general approach toward the Patent Office:

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62. *Id.* at 1549–50 (quoting *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991)).

63. *See* Tran, *supra* note 21, at 845–48.

64. *See* Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415, 1432–33 (1995) (describing the discrepancy between the Federal Circuit's treatment of the USPTO and other governmental bodies).

65. *See* Long, *supra* note 20, at 1966 (discussing how "the PTO has been vying to gain more influence in the market for supplying legal rules and norms").

66. 527 U.S. 150, 153, 156 (1999) (holding that the standard now required is the APA's "substantial evidence" standard instead of the stricter review standard imposed by the Federal Circuit).

67. *Id.* at 165.

68. *See id.* at 164–65.

69. *See id.* at 152–54.

70. Orin S. Kerr, *Rethinking Patent Law in the Administrative State*, 42 WM. & MARY L. REV. 127, 128–29 (2000).

[T]he symbolic importance of *Zurko* looms large . . . . *Zurko* [was] the first major [Patent Office] 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>71</sup>

*Zurko* was the first of many decisions in which the Supreme Court expressed its disapproval of the Federal Circuit's efforts to craft special rules in patent cases.<sup>72</sup> As recently as 2011, the Court has condemned efforts by the appellate courts to create anomalies in administrative law.<sup>73</sup>

Just five months after the Supreme Court chastised the Federal Circuit in *Zurko*, Congress passed the American Inventors Protection Act ("AIPA") in November of 1999 to further redistribute power to the USPTO.<sup>74</sup> This Act expanded the USPTO's specific rulemaking powers to include:

establish[ing] regulations, not inconsistent with law, which —

- (A) shall govern the conduct of proceedings in the Office;
- . . . .
- (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 qualita-

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71. Long, *supra* note 20, at 1978–79.

72. *See, e.g.,* *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 118 (2007) (rejecting the Federal Circuit's declaratory judgment test); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 388 (2006) (rejecting the Federal Circuit's special test for issuing permanent injunctions in patent cases). The Supreme Court will likely address the relationship between the Federal Circuit and the USPTO again in 2012. *See Hyatt v. Kappos*, 625 F.3d 1320 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 3064 (2011).

73. *See Mayo Found. for Med. Educ. & Research v. United States*, 131 S. Ct. 704, 713 (2011) (rejecting efforts to craft special administrative law rules in tax cases).

74. The AIPA was a part of the Intellectual Property and Communications Omnibus Reform Act of 1999. *See* American Inventors Protection Act, Pub. L. No. 106-113, § 4711–4712, 113 Stat. 1501A-552, at 1501A-572 to 1501A-575 (1999).

tive measures and standards for evaluating cost-effectiveness and is consistent with the principles of impartiality and competitiveness . . . .<sup>75</sup>

Pursuant to 35 U.S.C. § 132(b), the Patent Office could also “prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.”<sup>76</sup> While the new powers did not empower the Patent Office to promulgate regulations on any subject it pleased, certain of these powers, such as the power to facilitate and expedite the processing of patent applications, appeared to exceed procedural limits.<sup>77</sup> Additionally, Congress created a new proceeding, *inter partes* reexamination, in which the USPTO could reexamine the validity of issued patents, but Congress did not create any rulemaking powers specifically designed for this proceeding.<sup>78</sup> The availability of *inter partes* reexamination and need for the USPTO to promulgate regulations implementing it suggested that the USPTO’s power to govern the conduct of its proceedings was broader than the Federal Circuit had assumed. This interpretation was supported by another new provision. Congress required in § 2(b)(2)(B)<sup>79</sup> that the Patent Office promulgate its rules in accordance with § 553 of the APA.<sup>80</sup> This provision articulates the procedures that agencies must follow when they promulgate substantive, but not procedural, rules to allow for public participation in the agencies’ decision-making processes.<sup>81</sup> The reforms to the USPTO’s authority were supported by legislative history that further signaled Congress’ intent for the Agency to promulgate some substantive rules.<sup>82</sup>

The Federal Circuit took little notice of the efforts by the Supreme Court and Congress to increase the USPTO’s authority. It continued to apply its substantive restriction on the USPTO’s authority

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75. *Id.* § 4712. While most of these powers were new, the USPTO’s powers to “govern the conduct of proceedings in the Office” and to “govern the recognition and conduct” of patent practitioners were not. *Compare id.*, with Patent Act of 1952, Pub. L. No. 82-593, §§ 6, 31, 66 Stat. 792, 793, 795.

76. 35 U.S.C. § 132(b) (2006).

77. Tran, *supra* note 21, at 857–62.

78. AIPA §§ 4601–4604.

79. 35 U.S.C. § 2(b)(2)(B) (2006).

80. 5 U.S.C. § 553 (2006).

81. Section 553(b) 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 requirement of publication more than thirty days before its effective date). The only aspect of § 553 that may have relevance to procedural rules is subsection (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 Patent Office to *make* rules in accordance with § 553. *Id.* § 2(b)(2)(B). Subsection (e) does not relate to the *making* of rules, although the other requirements for substantive rules in § 553 do. *See id.* § 553.

82. Tran, *supra* note 21, at 857–62.

without considering whether the USPTO's reformed authority encompassed substantive rulemaking. But applying the substantive restriction proved to be exceptionally trying for the Federal Circuit. In an attempt to respond to concerns about its mounting backlog of unreviewed patent applications and the unpredictable quality of issued patents, the Patent Office initiated a number of creative programs that have tested the boundaries of the Agency's rulemaking authority.<sup>83</sup> The Federal Circuit has failed to review the legality of these programs in a coherent manner. Instead, it adopted a murky distinction between valid procedural rules and invalid substantive ones. This problematic doctrine prompted the USPTO to renew its efforts to lobby Congress to give it a larger say over substantive patent law, efforts that appear to have paid off with the enactment of the America Invents Act.

The Federal Circuit's difficulty in differentiating valid procedural rules from invalid substantive rules became clear in 2009. The three judges on the Federal Circuit panel in *Tafas v. Doll*<sup>84</sup> 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. Among other things, the rules would have retroactively limited the ability of a patent applicant to file continuation or continuation-in-part applications, increased the burdens on applicants to disclose information about their inventions,<sup>85</sup> and required patent applicants to submit an examination support document if more than five independent or twenty-five total claims were included in certain sets of co-pending applications.<sup>86</sup>

Although Judge Prost did "not purport to set forth a definitive rule for distinguishing between substance and procedure,"<sup>87</sup> her majority opinion classified rules as procedural as opposed to substantive when they do not "'foreclose effective opportunity' to present patent applications for examination."<sup>88</sup> Judge Rader disagreed, asserting that it was more a question of degree with substantive rules having substan-

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83. See, e.g., Patent Application Backlog Reduction Stimulus Plan, 74 Fed. Reg. 62,285, at 62,286–87 (Nov. 27, 2009) (enabling small entities that expressly abandon a co-pending, unexamined application to have another application advanced out of turn); 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 three different processing tracks are "prioritized examination" (Track I), "traditional examination" (Track II), and examination allowing "applicant-controlled delay for up to 30 months prior to docketing for examination" (Track III)).

84. 559 F.3d 1345 (Fed. Cir. 2009).

85. *Id.* at 1350, 1363.

86. *Id.* at 1350. 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.*

87. *Id.* at 1356.

88. *Id.* (quoting *JEM Broad. Co. v. FCC*, 22 F.3d 320, 326, 328 (D.C. Cir. 1994)).

tive effects that are sufficiently grave.<sup>89</sup> Judge Bryson rejected the procedural/substantive distinction altogether.<sup>90</sup> The judges then failed to agree whether the four rules at issue were procedural or substantive. Judge Prost classified all of the rules as procedural.<sup>91</sup> Judge Rader contended that all the rules were substantive.<sup>92</sup> Judge Bryson refused to classify the rules, instead concluding that the rules fell within the Patent Office's statutory authority to establish rules governing the conduct of its proceedings regardless of how the rules were classified.<sup>93</sup>

The awkward *Tafas* decision attracted the attention of the full court, and the Federal Circuit agreed to rehear the case en banc. But before the en banc court could deliver a potentially adverse decision, the new Patent Office Director, David Kappos,<sup>94</sup> took the drastic measure of rescinding the rules that formed the basis of the litigation.<sup>95</sup> Upon a joint motion by the parties, the Federal Circuit held the appeal moot and ordered the dismissal of the appeal.<sup>96</sup> The inharmonious opinions in *Tafas* have stifled regulatory efforts to improve the patent system and have made it difficult for the USPTO, patent practitioners, and judges to predict ex ante the extent of the USPTO's rule-making authority.

Shortly after the *Tafas* decision issued, the Department of Commerce pointedly expressed its desire for Congress to fix the Federal Circuit's narrow view of USPTO authority. In October of 2009, Secretary of Commerce Gary Locke wrote to high-ranking members of Congress complaining about the *Tafas* and *Merck* decisions:

[T]he U.S. Court of Appeals for the Federal Circuit has ruled that "Congress has not vested the [USPTO Director] with any general substantive rulemaking power . . ." *Merck v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). Substantive rulemaking authority would remove doubt raised regarding the PTO Di-

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89. *Id.* at 1369 (Rader, J., concurring in part and dissenting in part).

90. *See id.* at 1366 (Bryson, J., concurring) ("I do not think it necessary, or particularly helpful, to consider whether those regulations would be deemed 'substantive,' 'interpretive,' or 'procedural' . . .").

91. *Id.* at 1356 (citing *JEM*, 22 F.3d at 326, 328).

92. *Id.* at 1368, 1371 (Rader, J., concurring in part and dissenting in part). Judge Rader concurred with the majority's "conclusion that the [Patent Office] is not entitled to *Chevron* deference with respect to its own rulemaking authority." *Id.* at 1368. However, because he viewed the rules as substantive, not procedural, he concluded that the Patent Office had exceeded its statutory rulemaking authority in promulgating the rules. *Id.*

93. *See id.* at 1366 (Bryson, J., concurring).

94. Biography of *David Kappos*, U.S. PAT. & TRADEMARK OFFICE, <http://www.uspto.gov/about/bios/kapposbio.jsp> (last visited May 3, 2012).

95. *See Tafas v. Kappos*, 586 F.3d 1369, 1371 (Fed. Cir. 2009).

96. *See id.*



rector's authority to adopt rules in light of [*Tafas*]. Furthermore, substantive rulemaking authority would give the PTO Director the ability to provide flexibility in the administration of patent rules and procedures.<sup>97</sup>

The USPTO Director also participated actively in the lobbying efforts.<sup>98</sup> Congress listened closely to the USPTO's and Secretary of Commerce's recommendations<sup>99</sup> and responded by granting the USPTO more resources, more responsibility, and, for the first time since the USPTO's founding, explicit authority to set patent law standards.<sup>100</sup> Although nowhere in the America Invents Act did Congress specify that the Act grants the USPTO substantive rulemaking authority, the Department of Commerce now appears to be quite content with the new powers and responsibilities bestowed upon the USPTO. Secretary of Commerce Gary Locke commented on one of the final reform proposals: "We believe that the provisions contained in H.R. 1249 — including those covering regulatory authority . . . — will adequately address" concerns about delays in the patent application review process and the proliferation of low quality patents.<sup>101</sup> He further noted that "[v]arious safeguards and flexibilities are included in the proposed [post-grant review and inter partes] proceedings to enable the USPTO to effectively implement and manage them."<sup>102</sup>

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97. Letter from Gary Locke, Secretary of Commerce, U.S. Dep't of Commerce, to Patrick J. Leahy, Chairman, Comm. on the Judiciary, U.S. Senate, and Jefferson B. Sessions, III, Ranking Member, Comm. on the Judiciary, U.S. Senate, at 3 (Oct. 5, 2009), available at [http://www.uspto.gov/aia\\_implementation/locke-letter-oct-05-2009.pdf](http://www.uspto.gov/aia_implementation/locke-letter-oct-05-2009.pdf).

98. See, e.g., *U.S. Patent and Trademark Office: Hearing Before the H. Comm. on the Judiciary*, 111th Cong. 57 (2010) (statement of David Kappos, Director, U.S. Patent and Trademark Office) (stating that Congress should press for comprehensive patent reform that includes all the "changes needed for the PTO, including fee-setting authority and the others, but also all the other important changes that will move the U.S. patent system back to the gold standard of patent systems and will advantage U.S. innovators for many, many years, and hopefully generations to come").

99. See 157 CONG. REC. S936-02 (daily ed. Feb. 28, 2011) (statement of Sen. Patrick Leahy) ("Commerce Secretary Locke has been a strong partner in our efforts [to enact a patent reform bill], and Director Kappos of the Patent and Trademark Office has been an indispensable source of wise counsel."); PATRICK LEAHY, *THE PATENT REFORM ACT OF 2009*, S. REP. NO. 111-18, at 16 (2009) (discussing how the proposed post-grant review proceeding "improves upon the current inter partes reexamination process, in a manner consistent with the USPTO's recommendations, to provide a more efficient mechanism to challenge patents that should not have issued and are, therefore, not promoting the purpose of the patent laws" (emphasis added)).

100. See discussion *infra* Part III.A.2.

101. Letter from Gary Locke, Secretary of Commerce, U.S. Dep't of Commerce, to Lamar Smith, Chairman, Comm. on the Judiciary, House of Representatives, at 3 (May 31, 2011), available at [http://www.uspto.gov/aia\\_implementation/viewshr1249-america-invents-act.pdf](http://www.uspto.gov/aia_implementation/viewshr1249-america-invents-act.pdf).

102. *Id.*

Thus, the relationship between the Federal Circuit and the USPTO has been profoundly influenced by a struggle for power and influence over substantive patent law. The America Invents Act continues the trend since 1999 of shifting power over patent law from the courts to the USPTO. While no governmental body has yet expressed an official view as to whether the America Invents Act granted the USPTO substantive rulemaking authority, the next Part demonstrates that there are compelling reasons to believe it did.

### III. NEW PATENT POWERS

After decades of debate about patent reform, on September 8, 2011, Congress passed the America Invents Act,<sup>103</sup> and on September 16, 2011, President Obama signed it into law.<sup>104</sup> The Act expands the scope of the USPTO's authority and, in so doing, reshapes the relationship between the Patent Office and the courts.

This Part first describes the impetus for reform — namely, excessive delays in a patent review process that has systematically failed to weed out low-quality patents — then briefly discusses some of the specific reforms that have expanded the USPTO's rulemaking powers. The Article next analyzes the USPTO's new powers and reveals that the Agency now appears to have substantive rulemaking authority, a reform that will likely require the Federal Circuit to share its influence over substantive patent law with the USPTO.

#### *A. Patent Reform*

The America Invents Act grants the USPTO a slew of new responsibilities and powers that elevate its status as an administrative agency. The purpose behind these reforms was to rectify notorious problems in the patent system, including lengthy delays in a review process that has produced a proliferation of low quality patents. In essence, the Act gives the USPTO more resources, more flexibility, and more powers to tackle the deficiencies in the patent system. By doing so, the Act appears to vest the USPTO with substantive rule-making authority.

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103. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

104. Press Release, The White House, Office of the Press Secretary, President Obama Signs America Invents Act (Sept. 16, 2011), *available at* <http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim>.

## 1. Impetus for Reform

Over the last decade, countless commentators have identified deficiencies in the patent system,<sup>105</sup> and Congress has flirted with about a dozen patent reform proposals.<sup>106</sup> The most infamous problems with the patent system have been its failure “to provide consistent timeliness and quality. To the contrary, the current U.S. system [has been] highly prone to delay and uncertainty as well as inconsistent quality.”<sup>107</sup> Other noted problems with the patent system have included excessive litigation, damage awards, and royalty payments.<sup>108</sup> There has also been uncertainty about patent scope, validity, and overlapping rights.<sup>109</sup> The amalgamation of these problems prompted Professors Burk and Lemley to assert in 2009 that “[t]he patent system is in crisis.”<sup>110</sup>

The primary impetus for reform was the recognition that delays in the review process were imposing considerable costs on patentees and society at large. Whereas Alexander Graham Bell received a patent for the telephone less than one month after submitting an application to the Patent Office in 1876,<sup>111</sup> in recent times applicants have waited

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105. See, e.g., Brief of 37 Law, Business, and Economics Professors as Amici Curiae Supporting Petitioner at 3–6, *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238 (2011) (No. 10-290), 2011 WL 380832, at \*3–6 [hereinafter Brief of 37 Professors]; 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, 316–322 (identifying the social costs of the Patent Office’s improvident issuance of many low-quality patents); Sarah Tran, *Expediting Innovation: The Quest for a New Sputnik Moment*, 36 HARV. ENVTL. L. REV. 123 (2012) [hereinafter *Expediting Innovation*] (arguing that the Patent Office greenwashed itself by initiating a so-called “green” program that did not provide meaningful opportunities for applications pertaining to green technologies to be expedited).

106. See Patent Lawsuit Reform Act of 2010, H.R. 6352, 111th Cong. (2010); Patent Reform Act of 2009, S. 610, 111th Cong. (2009); Patent Reform Act of 2009, S. 515, 111th Cong. (2009); Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009); Patent Reform Act of 2008, S. 3600, 110th Cong. (2008); Patent Reform Act of 2007, S. 1145, 110th Cong. (2007); Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2006); U.S. Patent and Trademark Fee Modernization Act of 2005, H.R. 2791, 109th Cong. (2005); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

107. ARTI RAI, STUART GRAHAM & MARK DOMS, PATENT REFORM: UNLEASHING INNOVATION, PROMOTING ECONOMIC GROWTH & PRODUCING HIGH-PAYING JOBS: A WHITE PAPER FROM THE U.S. DEPARTMENT OF COMMERCE 4 (2010) [hereinafter UNLEASHING INNOVATION], 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)

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

109. *Id.*

110. *Id.* at 1.

111. *Id.* at 22.

almost three years on average to receive their patents.<sup>112</sup> The speed of the review process is significant. The patent system rewards inventors by giving them the right to exclude others from engaging in various competitive activities for a limited time.<sup>113</sup> But because the patent monopoly exists for only a limited time after an application is filed,<sup>114</sup> long pendency times reduce the opportunities for applicants to gain an early competitive advantage from acquiring a patent.<sup>115</sup> The delays in the review process impede the ability of startup companies and other businesses to attract venture capital investment, develop additional products and services, and create new jobs.<sup>116</sup> At the same time, parties may postpone commercializing a technology until a patent is granted because it may be difficult to predict *ex ante* the precise scope of any patent rights that will be granted.<sup>117</sup> Although some patent applicants may appreciate a long review process so they can focus their resources on other endeavors, it is generally believed that these applicants are the exception, not the rule.<sup>118</sup> Reports “conclude that the U.S. backlog could ultimately cost the U.S. economy billions of dollars annually in ‘foregone innovation.’”<sup>119</sup>

An abundance of low quality patents issued by the Patent Office provided another motivation for patent reform.<sup>120</sup> To evaluate a single patent application, an examiner must review documentation submitted by the applicant, which is frequently complex and voluminous, use

112. See U.S. PATENT & TRADEMARK OFFICE, 2010-2015 STRATEGIC PLAN 10 fig.3 (2010), [http://www.uspto.gov/about/stratplan/USPTO\\_2010-2015\\_Strategic\\_Plan.pdf](http://www.uspto.gov/about/stratplan/USPTO_2010-2015_Strategic_Plan.pdf) (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).

113. 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 2010).

114. See *id.* § 154(a)(2). The term of a patent usually ends twenty years from the date on which the patent application 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.* However, 37 C.F.R. § 1.701 (2011), which was promulgated in accordance with 35 U.S.C. § 154, provides several bases for patent term extensions. Patent term extensions do not make up for the loss of an early competitive advantage or lack of clarity surrounding the scope of inventors’ property rights.

115. See UNLEASHING INNOVATION, *supra* note 107, at 3–4.

116. See *Expediting Innovation*, *supra* note 105, at 138–42.

117. See UNLEASHING INNOVATION, *supra* note 107, at 5.

118. See, e.g., Angus Loten, *Expediting U.S. Innovation Comes at a Cost*, WALL ST. J. (Feb. 3, 2011), <http://online.wsj.com/article/SB10001424052748704358704576118672311596138.html> (“Exclusivity to an idea is crucial to convincing backers to fund your idea. So by and large, 80% of applicants need to get patents fast.” (quoting Ted Weisz, a patent lawyer and partner at Gottlieb, Rackman, and Reisman, P.C.)).

119. UNLEASHING INNOVATION, *supra* note 107, at 1.

120. See, e.g., Brief of 37 Professors, *supra* note 105, at 3–6 (discussing how resource limitations at the USPTO have resulted in poor patents); UNLEASHING INNOVATION, *supra* note 107, at 2–4; Osenga, *supra* note 105, at 132–33; Thomas, *supra* note 105, at 316–22.

computerized databases and other available sources to search for invalidating prior art, and correspond with the applicant's lawyers.<sup>121</sup> But the Patent Office has had scarce resources to dedicate to the onerous task of reviewing patent applications. While the processing of a patent occurs over a period of several years, examiners typically receive only sixteen to seventeen hours to work on a single patent application.<sup>122</sup> The imbalance between the USPTO's workload and resources has enabled patents that probably should not have been granted to slip through the system. As a result, "[p]atent owners — and the Federal Circuit itself — [have been] beset on all sides by those complaining about the proliferation of bad patents and the abuse of those patents in court."<sup>123</sup> And litigating patent suits is costly: "The average patent litigation lasts about two years and costs about \$3 million. An appeal can add another \$2 million and one year to that estimate."<sup>124</sup>

In summary, the Patent Office has lacked the resources to review applications in a timely manner. It has also lacked the resources to review applications well. These problems have generated substantial social costs in the forms of excessive litigation, reduced innovation, and delayed commercialization of technologies that could have generated substantial economic benefits for the nation if a better system had been in place.

## 2. More Resources, More Flexibility, More Power

Congress designed the America Invents Act to rectify the two most blatant deficiencies in the patent system — its speed and quality problems. To address these problems, the America Invents Act grants the USPTO fee setting authority as well as the authority to prioritize technologies of national importance. It further gives the USPTO more tools (in the form of new proceedings) to weed out low-quality patents. The USPTO's arsenal of new or fortified proceedings now includes post-grant review, inter partes review, supplemental examination, and derivation proceedings, as well as a transitional post-grant review program for certain business method patents.<sup>125</sup> For

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121. See 37 C.F.R. § 1.104 (2011) (setting out the general duties of a patent examiner).

122. Brief of 37 Professors, *supra* note 105, at 3–5; Thomas, *supra* note 105, at 314.

123. BURK & LEMLEY, *supra* note 108, at 1.

124. Richard D. Margiano, *Cost and Duration of Patent Litigation*, MANAGING INTELLECTUAL PROPERTY: THE GLOBAL IP RESOURCE (Feb. 1, 2009), <http://www.managingip.com/Article/2089405/Cost-and-duration-of-patent-litigation.html>; see also Sarah Tran, *Experienced Intellectual Property Mediators: Increasingly Attractive in Times of "Patent" Unpredictability*, 13 HARV. NEGOT. L. REV. 313, 314 (2008) (asserting that mediation with an expert well versed in IP law provides a robust alternative because of the high cost of patent litigation).

125. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 6, 125 Stat. 284, 299–313 (2011); *id.* sec. 18. The USPTO's ex parte reexamination proceeding, in which a

each of these new responsibilities, Congress has given the USPTO broad powers to set patent standards and make policy choices. To understand how these reforms empower the Patent Office to alter, change, and directly influence substantive law, it is necessary to have a general understanding of each of these reforms.

#### *A. Funding*

One of the most monumental reforms of the America Invents Act is the change in how the USPTO is funded. Historically, Congress dictated what fees the USPTO could charge and diverted fees collected by the USPTO to the nation's general budget for uses unrelated to intellectual property, including deficit reduction,<sup>126</sup> subsidies to the steel, coal, and oil industries,<sup>127</sup> and appropriations for homeland security programs.<sup>128</sup> Even though fee diversion became less frequent in recent years,<sup>129</sup> Congress' practices left the USPTO with a dearth of resources to tackle its mounting log of patent applications as well as a constantly lurking threat that what money the Agency did have might be taken away for other purposes. In response to these perceived problems, the inventive community lobbied Congress for greater USPTO control over its finances.<sup>130</sup>

The America Invents Act responds to the calls for financial reform of the patent system. The Act grants the USPTO the authority to set its own fees in consultation with the Patent Public Advisory Committee and the Trademark Public Advisory Committee by rule-making to cover its costs.<sup>131</sup> Although annual appropriations remain

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party may request that the USPTO reexamine a patent but not participate in the proceeding after filing the request, remains essentially unchanged. *Compare* 35 U.S.C. § 302 (2006) ("Request for reexamination"), *and id.* § 303 ("Determination of issue by Director"), *with* America Invents Act sec. 6(d) (making no changes to 35 U.S.C. § 302 but changing § 303 to allow the Director to use information from reexamination proceedings in determining "[o]n his own initiative . . . whether a substantial new question of patentability is raised").

126. *See* Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 112 Stat. 2681, 2681-1 to -2 (1998).

127. *See* Emergency Oil and Gas Guaranteed Loan Program Act of 1999, Pub. L. No. 106-51, § 202(a), 113 Stat. 252, 258.

128. *See* 2002 Supplemental Appropriations Act for Further Recovery From and Response to Terrorist Attacks on the United States, Pub. L. No. 107-206, § 1403(a), 116 Stat. 820, 898.

129. *See* Long, *supra* note 20, at 1987 ("The combination of the PTO and the inventive community lobbying has succeeded in convincing Congress each year since 2005 to refrain from diverting fees for that year.").

130. *See, e.g.,* Long, *supra* note 20, at 1987-88 ("[T]he inventive community came to support the PTO as it advocated hard to end fee diversion."); Rai, *supra* note 18, at 2067 ("[E]nsuring a permanent end to fee diversion would be a significant improvement over the current system of cross-subsidy and year-by-year assessment of the fee-diversion question.").

131. Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 10, 125 Stat. 284, 316-20 (2011).

necessary to approve USPTO spending, Congress may not divert USPTO revenues to the general treasury.<sup>132</sup> Additionally, the Act provides for prompt increases in the fees for processing a patent, including an interim, fifteen percent surcharge on most patent and trademark fees, patent maintenance fees,<sup>133</sup> an additional \$400 fee for most applications not electronically filed after November 14, 2011,<sup>134</sup> and a \$4800 fee for filing most applications for prioritized review.<sup>135</sup>

The financial reforms to the patent system should not be taken lightly. With increased resources at its disposal, the USPTO can hire more examiners to tackle the speed and quality problems in the patent review process. It can also devote itself to activities that go beyond the rudimentary task of reviewing patent applications, like setting patent policy and establishing substantive patent law standards.

### *B. New and Modified Proceedings*

Supported by financial reforms, the America Invents Act drastically expands the USPTO's set of tools for reviewing the validity of patents. By giving the USPTO broad control over its new trial-like proceedings, Congress has shifted responsibility for defining patent law standards from the courts to the USPTO, and, in doing so, has given the USPTO a much bigger say in the development of substantive patent law.<sup>136</sup>

#### *i. Post-Grant Review*

The creation of post-grant review provides the USPTO with a key opportunity to set substantive patent law standards and make patent policy. Of all the USPTO's proceedings, this proceeding constitutes its most powerful tool for invalidating patents. This new trial-like proceeding conducted at the Patent Trial and Appeal Board (the "Board") provides third parties with an opportunity to challenge the validity of claims in a recently-issued patent on any ground relating to the statutory requirements for patentability, including invalidating prior art,

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132. *Id.* sec. 22.

133. *See id.* sec. 11(b). The Act reduces the fees for small and micro entities and gives the USPTO the discretion to define who constitutes a micro entity. *Id.* sec. 10(b), (g); *id.* sec. 10(g) (to be codified at 35 U.S.C. § 123).

134. *See id.* sec. 10(h).

135. *See id.* sec. 11(h)(1)(A)(i).

136. This Part discusses only the reforms that have resulted in both new responsibilities and new rulemaking powers for the USPTO. That is not to suggest that the USPTO's other new responsibilities, such as its responsibility for reviewing submissions by third parties that are provided before a patent issues, are insignificant. *See, e.g., id.* sec. 8. But those responsibilities simply do not play as big a role in reshaping the scope of the USPTO's authority and relationship with the courts.

prior public use, lack of enablement, lack of written description, lack of utility, lack of obviousness, and lack of novelty.<sup>137</sup>

The grounds for petitioning for post-grant review are substantially broader than for other USPTO proceedings, new and old. In essence, post-grant review gives parties the ability to challenge a patent at the Board instead of in court. The availability of post-grant review, which will become available for patents with an effective filing date on or after September 16, 2012,<sup>138</sup> may provide a real benefit to parties of limited financial means, such as individual inventors, small business owners, and start-up companies, who cannot afford litigation in court. That is not to say that the availability of the post-grant review proceeding precludes parties from bringing actions in court. An interesting feature of USPTO's new post-grant reviews, as well as other proceedings, is that they function as an alternative, not an outright replacement, to litigation in court. For instance, a party may either file a petition for inter partes review or post-grant review, or file a suit in a district court. However, there are limits on the ability of parties to use both forums. For instance, if a challenger alleges invalidity in a district court before filing a petition for post-grant or inter partes review, the USPTO proceedings will not be available to the challenger.<sup>139</sup> Additionally, third parties have only nine months from the time a patent is granted or a reissue patent is issued to petition for a post-grant review of the patent.<sup>140</sup> During this window, the USPTO may grant a review upon a showing that it is "more likely than not that at least 1 of the claims challenged in the petition is unpatentable" or that "the petition raises a novel or unsettled legal question that is important to other patents or patent applications."<sup>141</sup>

As depicted in the chart in the Appendix, the America Invents Act grants the USPTO Director seventeen rulemaking powers over post-grant reviews, including a number of powers that appear to clearly encompass substantive rulemaking.<sup>142</sup> Among other things, the powers broadly require the USPTO to promulgate regulations:

- setting standards for the showing of sufficient grounds to institute a post-grant review;
- establishing and governing post-grant reviews and their relationship to other proceedings;
- setting standards and procedures for discovery of relevant evidence;

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137. *See id.* sec. 6(d) (to be codified at 35 U.S.C. § 321(b)).

138. *See id.* sec. 6(f).

139. *See id.* sec. 6(a) (to be codified at 35 U.S.C. § 315); *id.* sec. 6(d) (to be codified at 35 U.S.C. § 325).

140. *See id.* sec. 6(d) (to be codified at 35 U.S.C. § 321(c)).

141. *Id.* sec. 6(d) (to be codified at 35 U.S.C. § 324(a), (b)).

142. *See discussion infra* Part III.B.1.



- prescribing sanctions for any improper uses of post-grant review proceedings;
- setting forth standards and procedures for allowing patent owners to move to amend their patents; and
- setting fees for the requests for post-grant reviews.<sup>143</sup>

In using the majority of its new rulemaking powers for post-grant review, the USPTO must consider policy-oriented factors such as “the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings.”<sup>144</sup>

Many of the standards the USPTO sets for post-grant review will directly affect whether parties can retain their core patent rights. For instance, if the USPTO crafts liberal standards for initiating a post-grant review, many patents may be challenged and potentially invalidated in a post-grant review proceeding. Even without this proceeding, parties could challenge patents in court, but parties who would forego litigation due to financial, time, or other constraints may be willing to challenge a patent at the USPTO. As such, post-grant review exposes owners of low-quality patents to a greater risk of losing their patent rights. The USPTO has the ultimate say over how much greater this risk is when it promulgates the standards for post-grant reviews.

Thus, the USPTO’s new responsibilities and accompanying powers over post-grant review require it to weigh competing policy considerations when establishing regulations that alter the standards by which patent rights may be terminated or strengthened. This institutional structure leaves the USPTO considerable discretion to implement and set patent policy.

## ii. Inter Partes Review

After a post-grant review terminates or the window in which such a review could have been instituted passes, third parties may petition for inter partes review,<sup>145</sup> a proceeding that will replace inter partes reexamination.<sup>146</sup> In some ways, inter partes review could be viewed as an extension of post-grant review. Like post-grant review (and inter partes reexamination), inter partes review is a trial-like proceeding in which the Board reviews the patentability of one or more claims in a

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143. America Invents Act sec. 6(d) (to be codified at 35 U.S.C. §§ 321, 326).

144. *Id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(b)).

145. *Id.* sec. 6 (to be codified at 35 U.S.C. §§ 311–319).

146. Inter partes reexamination previously enabled parties to challenge the validity of a patent if the request for reexamination raised a substantial new question of patentability affecting any claim of the patent. *See* 35 U.S.C. § 312(a) (2006), *amended by* America Invents Act sec. 6(a).

patent.<sup>147</sup> And, just as Congress granted the USPTO broad powers over post-grant review proceedings, it granted the USPTO broad powers over inter partes review proceedings.<sup>148</sup> Indeed, the USPTO's rulemaking powers for inter partes review and post-grant review are virtually identical.<sup>149</sup>

Despite the similarities between inter partes review and post-grant review, there are several key distinctions between the two proceedings. The USPTO may institute an inter partes review upon a showing "that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged."<sup>150</sup> In contrast, the standard for post-grant review is that it must be "more likely than not that at least 1 of the claims challenged in the petition is unpatentable"<sup>151</sup> or that "the petition raises a novel or unsettled legal question that is important to other patents or patent applications."<sup>152</sup> These new standards differ from the traditional standard for inter partes reexamination as well, which required that requests for reexamination raise "a substantial new question of patentability" affecting any claim of the patent.<sup>153</sup> The USPTO will need to discern the legal significance between the "reasonable likelihood," "more likely than not," and "substantial new question of patentability" standards. It will also need to weigh the relative importance of issues when it determines whether a "petition raises a novel or unsettled legal question that is important to other patents or patent applications,"<sup>154</sup> which is a ground for granting post-grant but not inter partes review. What constitutes an "important" issue is not readily apparent. Another key difference between inter partes review and post-grant review is that inter partes review is a weaker sword to challenge a patent than post-grant review. The party requesting an inter partes review may only challenge a patent on the grounds that the claimed invention lacked novelty in violation of 35 U.S.C. § 102 or that it was obvious in violation of 35 U.S.C. § 103.<sup>155</sup>

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147. America Invents Act sec. 6.

148. See Chart of New Patent Office Powers, *infra* Appendix.

149. See Chart of New Patent Office Powers, *infra* Appendix. The minor exception is that the Act requires the USPTO to promulgate rules providing a timeframe for persons to request that they be joined as a party to an inter partes review. See America Invents Act sec. 6 (to be codified at 35 U.S.C. § 316(a)(12)). This authority was not granted to the USPTO with respect to post-grant review. See *id.* § 6 (to be codified at 35 U.S.C. § 326(a)). The USPTO's extensive array of rulemaking powers over inter partes review is particularly astonishing given that the USPTO had no rulemaking powers geared specifically for its predecessor, inter partes reexamination, but had to rely on its generic power to "govern the conduct of proceedings in the Office." See 35 U.S.C. § 2(b)(2)(A) (2006), *amended by* America Invents Act sec. 20.

150. America Invents Act sec. 6 (to be codified at 35 U.S.C. § 314(a)).

151. *Id.* sec. 6 (to be codified at 35 U.S.C. § 324(a)).

152. *Id.* sec. 6 (to be codified at 35 U.S.C. § 324(b)).

153. 35 U.S.C. § 312(a) (2006), *amended by* America Invents Act sec. 6(a).

154. America Invents Act sec. 6 (to be codified at 35 U.S.C. § 324(b)).

155. *Id.* sec. 6 (to be codified at 35 U.S.C. § 311(b)).

Moreover, the party petitioning for inter partes review may only submit patents or printed publications to be considered as potentially invalidating prior art.<sup>156</sup>

In summary, parties participating in an inter partes review have less flexibility in challenging a patent than if they had acted fast enough to avail themselves of post-grant review. However, the USPTO's authority over inter partes review is just as broad as over post-grant review. For both proceedings, the USPTO possesses broad statutory authority to set standards that affect patent rights and alter patent policy.

### iii. Derivation Proceedings

Derivation proceedings constitute a third trial-like proceeding conducted at the Board.<sup>157</sup> Derivation proceedings will replace the USPTO's interference proceedings, which the USPTO has used to determine which of two or more parties is entitled to a patent for a single invention.<sup>158</sup> The purpose of the new proceeding is to prevent copycats from owning patent rights. In a derivation proceeding, the Board will determine (1) whether an inventor named in an earlier application derived a claimed invention from an inventor named in the petitioner's application, and (2) whether the earlier application was filed without authorization.<sup>159</sup> If a patent holder is found to have derived his or her invention from an earlier invention without authorization, the patent holder may lose his or her patent rights.<sup>160</sup> Congress restricted the availability of derivation proceedings to a narrow window, perhaps because of the potential strength of derivation proceedings. A challenger may only petition for a derivation proceeding within one year after "the first publication of a claim to an invention that is the same or substantially the same as the earlier application's claim to the invention."<sup>161</sup> Additionally, the petition must be supported by substantial evidence.<sup>162</sup>

Derivation proceedings, like inter partes and post-grant review proceedings, shift considerable power onto the USPTO's shoulders. Although the USPTO only has two rulemaking powers with regard to derivation proceedings instead of over a dozen for each of the other

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156. *Id.*

157. *Id.* sec. 3 (to be codified at 35 U.S.C. §§ 135, 146, 291).

158. The new proceedings will apply to patent applications with initial filing dates of March 16, 2013 or later and will be instituted in the sole discretion of the Director of the USPTO, whose decision will be final and not appealable. *See id.* sec. 3(j) (to be codified at 35 U.S.C. §§ 134, 145, 146, 154, 305) (eliminating references to interferences).

159. *Id.* sec. 3(i) (to be codified at 35 U.S.C. § 135(b)).

160. *See id.* sec. 3(i) (to be codified at 35 U.S.C. § 135).

161. *Id.* sec. 3(i) (to be codified at 35 U.S.C. § 135(a)).

162. *Id.*

proceedings, one of the USPTO's powers for derivation proceedings is considerably broad. Specifically, the USPTO must "prescribe regulations setting forth standards for the conduct of derivation proceedings, including requiring parties to provide sufficient evidence to prove and rebut a claim of derivation."<sup>163</sup> A key ambiguity in derivation proceedings is the term "derives." As I show *infra* in Part III.B.1, the statute appears to assign the USPTO the role of defining "derives." How the USPTO does so will directly affect whether patent holders retain or lose their patent rights. Thus, while the USPTO possesses fewer rulemaking powers over derivation proceedings than over inter partes or post-grant review proceedings, the powers it does have over derivation proceedings appear to give it a major role in determining the validity of patents.

#### iv. Transitional Program for Business Method Patents

In addition to the USPTO's permanent proceedings, the America Invents Act creates a transitional program for business method patents that will be in effect for eight years between September 16, 2012 and September 16, 2020.<sup>164</sup> This new trial proceeding provides third parties who have been sued or charged with infringement of a covered business method patent with the ability to challenge the patentability of one or more claims in the patent at the Board.<sup>165</sup> The proceeding resembles post-grant review with several exceptions. Unlike post-grant review proceedings, transitional proceedings can be instituted at any point in the life of a patent,<sup>166</sup> not just within nine months of a patent's issuance. This timeframe provides a considerable benefit to patent challengers. However, petitioners may only use a subset of prior art for these petitions. To support a petition when the validity of a "covered business method patent" is at issue, a person may only use art showing prior publication, use, or knowledge of the invention.<sup>167</sup>

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163. *Id.* sec. 3(i) (to be codified at 35 U.S.C. § 135(b)). Additionally, the USPTO must specify a time period in which parties may resolve derivation disputes by arbitration. *Id.* sec. 3(i) (to be codified at 35 U.S.C. § 135(f)).

164. *Id.* sec. 18.

165. *Id.* sec. 18(a).

166. *See id.* sec. 18(a)(1)(A).

167. *Id.* sec. 18(a)(1)(C). This section limits the prior art available in a transitional proceeding to:

- (i) prior art that is described by [35 U.S.C. § 102(a)] (as in effect on the day before such effective date); or
- (ii) prior art that —
  - (I) discloses the invention more than 1 year before the date of the application for patent in the United States; and
  - (II) would be described by section 102(a) of such title (as in effect on the day before the effective date set forth in section 3(n)(1)) if the disclosure had been made by another before the invention thereof by the applicant for patent.

Further, a person may not file a petition “unless the person or the person’s real party in interest or privy has been sued for infringement of the patent or has been charged with infringement under the patent.”<sup>168</sup> Finally, unlike post-grant review, the program is available only for patents that claim “a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.”<sup>169</sup>

Congress delegated to the USPTO two broad powers over the transitional program. First, it required the USPTO to “issue regulations establishing and implementing a transitional post-grant review proceeding for review of the validity of covered business method patents” within one year of the enactment of the America Invents Act.<sup>170</sup> Then, perhaps in recognition of the ambiguity inherent in the term “technological invention,” Congress provided: “To assist in implementing the transitional proceeding authorized by this subsection, the Director shall issue regulations for determining whether a patent is for a technological invention.”<sup>171</sup> How the USPTO defines “technological invention” will affect whether parties interested in challenging a patent may take advantage of the transitional program. Congress has thus given the USPTO a lead role in determining the eligibility of inventions for a program that has profound implications on patent rights.

#### v. Supplemental Examination

Not all of the USPTO’s new proceedings that shift greater power to the Agency constitute administrative trials. The America Invents Act also establishes a new supplemental examination proceeding in which a patent owner may request that the USPTO “consider, reconsider, or correct information believed to be relevant to the patent.”<sup>172</sup> For instance, if a patentee realizes he has failed to disclose relevant prior art to the USPTO of which he was aware, the patentee could submit the prior art to the USPTO and ask the Agency to consider its relevance. If the USPTO determines that the submission raises a “substantial new question of patentability,” the Agency must order reexamination of the patent.<sup>173</sup> This mechanism provides patent owners with a way to cure errors made during the course of prosecuting the underlying patent application.

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*Id.* sec. 18(a)(1)(C).

168. *Id.* sec. 18(a)(1)(B).

169. *Id.* sec. 18(d)(1).

170. *Id.* sec. 18(a)(1).

171. *Id.* sec. 18(d)(2).

172. *Id.* sec. 12 (to be codified at 35 U.S.C. § 257(a)).

173. *Id.* sec. 12 (to be codified at 35 U.S.C. § 257(b)).

The purpose of supplemental examination is to reduce patent holders' exposure to inequitable conduct claims. Patent applicants have "a duty of candor and good faith in dealing with the [Patent] Office, which includes a duty to disclose to the [Patent] Office all information known to that individual to be material to patentability."<sup>174</sup> Breach of this duty 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> In recent years, the Federal Circuit has called the inequitable conduct doctrine a "plague" on the patent system and has "tighten[ed] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public."<sup>176</sup> With supplemental examination, Congress has provided a potential means of further reducing the incidence of inequitable conduct claims in court. If a patent survives reexamination, it cannot "be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent."<sup>177</sup> However, parties may not request supplemental examination after a challenger has already alleged inequitable conduct in court.<sup>178</sup>

Unlike the USPTO's powers over derivation, inter partes review, and post-grant review proceedings, Congress did not state that the USPTO has the authority to "set standards" for supplementary examination. Instead, Congress provided that the USPTO must "by regulation, establish fees for the submission of a request for supplemental examination of a patent, and . . . consider each item of information submitted in the request."<sup>179</sup> The USPTO must also "issue regulations governing the form, content, and other requirements of requests for supplemental examination, and establishing procedures for reviewing information submitted in such requests."<sup>180</sup> The USPTO's authority to issue regulations governing the content and other requirements of requests for supplemental examination could broadly be interpreted as empowering it to set standards for such requests. Alternatively, it

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174. 37 C.F.R. § 1.56(a) (2011).

175. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (en banc).

176. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289–90 (Fed. Cir. 2011) (en banc).

177. America Invents Act sec. 12(a) (to be codified at 35 U.S.C. § 257(c)(1)).

178. *Id.* sec. 12(a) (to be codified at 35 U.S.C. § 257(c)(2)(A)). There are other situations where a supplemental examination is not allowed. For example, patent holders may not supplement their patents after an allegation has been pled "with particularity in a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act." *Id.*

179. *Id.* sec. 12(a) (to be codified at 35 U.S.C. § 257(d)(1)).

180. *Id.* sec. 12(a) (to be codified at 35 U.S.C. § 257(d)(2)).

could be viewed as a merely procedural power. As will later be discussed, the uncertain classification of this delegation of authority highlights the need to reform the Federal Circuit's traditional approach to USPTO authority.<sup>181</sup>

### C. Prioritization

Beyond the new and modified proceedings, another reform that carries substantial implications with respect to the question of the USPTO's ability to engage in substantive rulemaking is the Agency's new authority to prioritize inventions of national importance. Specifically, the USPTO

may, subject to any conditions prescribed by the Director and at the request of the patent applicant, provide for prioritization of 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, notwithstanding section 41 or any other provision of law.<sup>182</sup>

While any "nonprovisional application for an original utility or plant patent" is now eligible to receive expedited processing upon the payment of a fee of \$4800,<sup>183</sup> the USPTO's Prioritization Authority enables it to prioritize certain categories of inventions, which may then receive expedited processing without the payment of any additional fees.<sup>184</sup>

Recognizing the delays in the patent review process that had become the norm, Senator Robert Menendez, the Democrat from New Jersey who introduced the Amendment, wanted to make sure that key technologies, particularly environmentally-beneficial inventions, were not getting stuck behind bureaucratic tape. He explained: "Our country is at risk of having vital new technologies buried in a sea of paperwork at the Patent Office. We want to make sure patents that are important to our national economy are fast-tracked rather than sidelined."<sup>185</sup>

Menendez envisioned his proposed Amendment as a "good commonsense policy that can help America propel forward in the 21st

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181. See discussion *infra* Part IV.B.1.

182. America Invents Act sec. 25 (to be codified at 35 U.S.C. § 2(b)(2)(G)).

183. *Id.* sec. 11(h)(1)(A)(i).

184. See *id.* sec. 25 (to be codified at 35 U.S.C. § 2(b)(2)(G)).

185. 157 CONG. REC. S1052 (daily ed. Mar. 1, 2011) (Amendment No. 124 and statement of Sen. Robert Menendez).

century.”<sup>186</sup> But what is so striking about the new authority is its policy-focused nature. The provision provides the USPTO with almost unlimited flexibility to rank the relative importance of patent applications in the review process.<sup>187</sup>

In summary, the reforms embodied in the America Invents Act give the USPTO greater financial autonomy, require the Agency to set standards that affect core patent rights, and empower the Agency to make patent policy. With more resources, more flexibility, and more powers, the Agency can now go beyond the rudimentary task of reviewing patent applications and play a more definite and sizable role in shaping patent law.

### *B. Power Redistribution*

While the America Invents Act clearly expands the scope of the USPTO’s authority, there is no way yet of knowing how the Federal Circuit will interpret these reforms. This Article demonstrates that the new powers granted by the America Invents Act to the USPTO appear to conflict irreconcilably with the Federal Circuit’s traditional view of USPTO authority. Far beyond promulgating procedural rules, the measures that direct the USPTO to set standards for patent proceedings and prioritize technologies on the basis of their national importance require that the Agency engage in complex, policy-based decisions that may carry profound implications for inventors, patent law practitioners, and society at large. The USPTO’s new financial independence ensures that the Agency has the resources to take on this expanded role.

#### 1. Standard-Setting Authority

The most potent evidence that Congress intended to grant the USPTO substantive rulemaking authority is its use of the term “standard.” The USPTO now has broad rulemaking powers to set forth “standards” for inter partes review, post-grant review, and derivation proceedings on top of more limited powers to establish “procedures” for certain of these proceedings. This delegation of authority appears to be incompatible with the Federal Circuit’s traditional view of USPTO authority as limited to procedural rulemaking.

Congress sprinkled the terms “standards” and “procedures” throughout the USPTO’s new rulemaking powers. The USPTO must “prescribe regulations setting forth *standards* for the conduct of derivation proceedings, including requiring parties to provide sufficient

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186. *Id.*

187. See discussion *infra* Part III.B.2.



evidence to prove and rebut a claim of derivation.”<sup>188</sup> For inter partes review, the Act requires the USPTO to set “forth the *standards* for the showing of sufficient grounds to institute” the review,<sup>189</sup> set “forth *standards and procedures* for discovery of relevant evidence, including that such discovery shall be limited to . . . what is otherwise necessary in the interest of justice,”<sup>190</sup> and set “forth *standards and procedures* for allowing the patent owner to move to amend the patent.”<sup>191</sup> Similarly, for post-grant review, the Act requires the USPTO to prescribe regulations “setting forth the *standards* for the showing of sufficient grounds to institute a [post-grant] review,”<sup>192</sup> “setting forth *standards and procedures* for discovery of relevant evidence,”<sup>193</sup> and “setting forth *standards and procedures* for allowing the patent owner to move to amend the patent.”<sup>194</sup> In promulgating these rules for post-grant review and inter partes review, the USPTO must consider broad policy concerns such as “the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings.”<sup>195</sup>

It would make little sense for the Federal Circuit to interpret the USPTO’s powers to set forth “standards and procedures” as the power to set forth “only procedures.” Such an interpretation would violate 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>196</sup> Moreover, the plain meanings of the terms are distinct. Black’s Law Dictionary defines “standard” broadly as “[a] criterion for measuring acceptability, quality, or accuracy.”<sup>197</sup> It defines “procedure” as “[a] specific method or course of action.”<sup>198</sup> Applying these definitions to proceedings where the USPTO has the authority to set forth procedures and standards, the USPTO thus has the procedural authority to guide the manner in which the proceedings occur and the broader authority to dictate the standards for measuring whether a petitioner’s filing is of adequate

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188. America Invents Act sec. 3(i) (to be codified at 35 U.S.C. § 135(b)) (emphasis added).

189. *Id.* sec. 6(a) (to be codified at 35 U.S.C. § 316(a)(2)) (emphasis added).

190. *Id.* sec. 6(a) (to be codified at 35 U.S.C. § 316(a)(5)) (emphasis added).

191. *Id.* sec. 6(a) (to be codified at 35 U.S.C. § 316(a)(9)) (emphasis added).

192. *Id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(a)(2)) (emphasis added).

193. *Id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(a)(5)) (emphasis added).

194. *Id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(a)(9)) (emphasis added).

195. *Id.* sec. 6(a) (to be codified at 35 U.S.C. § 316(b)); *id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(b)).

196. 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 . . .” (quoting 2A NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION § 46:6 (rev. 6th ed. 2000))).

197. BLACK’S LAW DICTIONARY 660 (2d pocket ed. 2001).

198. *Id.* at 558.

acceptability, quality, or accuracy in light of the policy factors that Congress instructed the USPTO to consider. The distinct meaning of “standards” should be interpreted consistently throughout the Act, including in provisions that mention standard-setting authority but not procedural rulemaking authority.

The legislative history for the America Invents Act supports a broad interpretation of the term “standard.” It shows that Congress deliberated over whether it should grant the USPTO the power to “set standards” for the first time, and, if so, how much. For instance, in April 2007, H.R. 1908 proposed to grant the USPTO the authority to “set[] forth the standards for showings of substantial reason to believe and significant economic harm under section 322(2) and sufficient grounds under section 325.”<sup>199</sup> Although the precise meaning of this poorly worded provision is not clear, it undeniably granted the USPTO the authority to set some standards related to post-grant review. But, six months later in September 2007, the House Bill no longer mentioned standard-setting authority.<sup>200</sup> Similarly, on March 3, 2009, S. 515 did not grant the USPTO standard-setting authority.<sup>201</sup> Two weeks later, S. 610 proposed to grant the USPTO the authority to set standards for the institution of post-grant review but not in other contexts.<sup>202</sup> The next month, there was no mention of standard-setting language in S. 515.<sup>203</sup> Subsequent proposals expanded the USPTO’s ability to set standards.<sup>204</sup> Ultimately, those in favor of giving the USPTO the authority to set standards for the new proceedings were the decisive winners in the debate as the USPTO’s new standard-setting authority appears not just in one or two of its new powers but in seven of its new powers.<sup>205</sup> Congress’ actions of putting in stand-

199. H.R. 1908, 110th Cong. § 6(e) (as introduced, Apr. 18, 2007).

200. *See, e.g.*, H.R. 1908, 110th Cong. § 6(f) (as reported by H. Comm. on the Judiciary, Sept. 4, 2007) (proposing to amend 35 U.S.C. § 326(a) to grant the USPTO certain powers to establish procedures, but not standards, for post-grant review).

201. *See, e.g.*, S. 515, 111th Cong. § 5(h) (as introduced, Mar. 3, 2009) (proposing to amend 35 U.S.C. § 326(a) to require the USPTO to “prescribe regulations, in accordance with section 2(b)(2)” that establish and govern post-grant review proceedings and their relationship to other proceedings, that establish procedures for the submission of supplemental information, and that set forth procedures for discovery of relevant evidence).

202. S. 610, 111th Cong. § 5(c) (as introduced, Mar. 17, 2009) (proposing to amend 35 U.S.C. § 329(a) to require the USPTO to “prescribe regulations . . . setting forth the standards for showings of sufficient grounds to institute a [post-grant review] proceeding” but only authorizing it to establish procedures, not standards, for the discovery of relevant evidence).

203. *See, e.g.*, S. 515, 111th Cong. § 5(f) (as reported by S. Comm. on the Judiciary, Apr. 2, 2009) (proposing to amend 35 U.S.C. § 326 to grant the USPTO certain powers to establish procedures, but not standards, for post-grant review).

204. *See, e.g.*, S. 23, 112th Cong. § 5(a) (as passed by Senate, Mar. 8, 2011) (proposing to amend 35 U.S.C. § 316 to grant the USPTO various powers to establish procedures and standards for inter partes review); *id.* § 5(d) (proposing to amend 35 U.S.C. § 326 to grant the USPTO various powers to establish procedures and standards for post-grant review).

205. *See* Chart of New Patent Office Powers, *infra* Appendix.

ard-setting language, taking it out and leaving the Agency with procedural authority, then putting the standard-setting authority back in suggests that Congress clearly did not intend for the USPTO's standard-setting authority to constitute a form of procedural rulemaking.

The Federal Circuit itself has recognized that setting standards constitutes substantive rulemaking. Indeed, Judge Prost wrote in the majority opinion in *Tafas* that she was "most persuaded" by the D.C. Circuit's approach in distinguishing procedural rules from substantive rules in *JEM*.<sup>206</sup> She emphasized that in *JEM* "[t]he 'critical fact' that was 'fatal to JEM's claim' . . . was that the 'hard look' rules 'did not change the *substantive standards* by which the FCC evaluates license applications."<sup>207</sup> In other words, rules that do not alter substantive standards are procedural. Congress has now explicitly given the USPTO the authority to change the substantive standards by which it evaluates patent applications. Under Judge Prost's rationale in *Tafas*, the America Invents Act thus provides concrete evidence that Congress granted the USPTO substantive rulemaking authority.

In other areas of administrative law, courts construe the power to set standards as a broad power that includes making substantive law. For instance, the Clean Air Act, a comprehensive statutory scheme designed to reduce air pollution, requires the EPA to set national ambient air quality standards for certain air pollutants.<sup>208</sup> Not only has the EPA set standards pursuant to this authority that have dramatically altered substantive law, but the D.C. Circuit has held that the EPA's power to set such standards was so broad that it lacked an intelligible principle to guide the Agency and thus constituted an unconstitutional delegation of legislative power.<sup>209</sup> The Supreme Court later disagreed and held that, despite the breadth of the EPA's authority, the Clean Air Act properly delegated legislative power to the EPA.<sup>210</sup> The USPTO's standard-setting authority is not perfectly analogous to the EPA's, as the USPTO's authority is limited to particular proceedings. Nonetheless, the EPA controversy demonstrates that the EPA's power to set standards encompasses substantive rulemaking and that standard-setting authority can be a very broad power indeed.

Empowering the USPTO to set standards for its proceedings enables the Agency to encroach on the Federal Circuit's traditional role as the sole expositor of substantive patent law standards. Although the America Invents Act does not invite the USPTO to challenge most of the core standards of patentability that have already been set by the

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206. *Tafas v. Doll*, 559 F.3d 1345, 1355 (Fed. Cir. 2009).

207. *Id.* at 1356 (emphasis added) (quoting *JEM Broad. Co. v. FCC*, 22 F.3d 320, 327 (D.C. Cir. 1994)).

208. 42 U.S.C. §§ 7401–7671q (2006).

209. *Am. Trucking Ass'ns, Inc. v. EPA*, 175 F.3d 1027, 1034 (D.C. Cir. 1999).

210. *See Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457 (2001).

Federal Circuit, such as obviousness or novelty, it leaves ample latitude for the USPTO to develop standards for other key terms that affect the patentability of inventions. For instance, section 3(i) of the America Invents Act requires the USPTO to “prescribe regulations setting forth standards for the conduct of derivation proceedings, including requiring parties to provide sufficient evidence to prove and rebut a claim of derivation.”<sup>211</sup> It is plausible that the Federal Circuit will narrowly interpret this provision as only giving the USPTO the authority to promulgate regulations to guide the conduct of derivation proceedings, which would include rules specifying which party may present first and what methods may be used to introduce evidence. But Congress intentionally gave the USPTO the power to set “standards” for this proceeding rather than the narrower power to establish “procedures.” As discussed earlier in the section, Congress purposefully gave the terms distinct meanings in the Act and deliberated over whether to give the USPTO standard-setting authority. Thus, as ultimately enacted, the language of section 3(i) of the America Invents Act appears to delegate to the USPTO, not to the courts, the role of setting a standard for determining whether one invention derives from another. How the USPTO defines derivation will determine whether some inventions are patentable.

The USPTO’s authority to set forth standards and procedures for allowing a patent owner to move to amend a patent<sup>212</sup> also affects parties’ fundamental patent rights. The USPTO’s rules will inevitably preclude some parties from amending their patents. When patents are held unenforceable due to defects in the patents that could have been fixed through amendment had the USPTO promulgated other rules, the USPTO will be responsible for this outcome. Indeed, virtually any rule limiting an inventor’s ability to amend a patent will affect the inventor’s core patent rights. Some of these rules would fall squarely within a procedural category, such as rules specifying postmarking dates, paper size, or the relevant address to send a motion to amend. But many conceivable rules would also fall definitely into the substantive category, which would be authorized under the USPTO’s standard-setting authority. For instance, the USPTO could set a standard providing that motions to amend a patent may be granted if the USPTO determines it is in the public interest to do so. Such a rule would leave considerable policy discretion in the USPTO’s control.

Using the *Tafas* precedent to analyze a hypothetical rule issued pursuant to the USPTO’s new authority to set standards further highlights the substantive nature of these powers. Assume that the USPTO

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211. Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 3(i), 125 Stat. 284, 289 (2011) (to be codified at 35 U.S.C. § 135(b)).

212. *See id.* sec. 6(d) (to be codified at 35 U.S.C. § 326).

promulgated a rule clarifying derivation as follows: “A party derives an invention from another, original invention when the party uses knowledge about the original invention to develop an invention that is substantially similar to the original invention.” Even though such a rule would fall within the USPTO’s statutory authority to set “standards for the conduct of derivation proceedings, including requiring parties to provide sufficient evidence to prove and rebut a claim of derivation,”<sup>213</sup> it would be invalid under the Federal Circuit’s procedural/substantive classification. Under the *Tafas* majority approach, a USPTO rule is substantive when it forecloses effective opportunity for a patent application to be examined.<sup>214</sup> The USPTO’s rule would be invalid because it would foreclose applicants from obtaining patents or retaining their patent rights if they had used knowledge about another’s invention to make substantially similar inventions. Under Judge Rader’s alternative formulation in *Tafas*, where a rule is substantive when it has effects that are “sufficiently grave,”<sup>215</sup> the court would also classify the rule as an invalid substantive rule. Certainly the ability of a party to lose his or her entitlement to a patent would qualify as a grave effect so as to preclude the classification of the rule as procedural. Indeed, extinguishing a party’s entitlement to obtain or retain a patent is probably one the gravest effects possible in patent law. Only Judge Bryson, who prefers to look exclusively to the statutory authority behind the rule rather than superimpose a procedural limitation upon the rule, would likely uphold the rule as valid.<sup>216</sup> Table 1 parses these legal arguments and their implications.

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213. *Id.* sec. 3(i) (to be codified at 35 U.S.C. § 135(b)).

214. *See Tafas v. Doll*, 559 F.3d 1345, 1356 (Fed. Cir. 2009).

215. *Id.* at 1371–72 (Rader, J., concurring in part and dissenting in part) (quoting *JEM Broad. Co. v. FCC*, 22 F.3d 320, 327 (D.C. Cir. 1994)).

216. *Id.* at 1365 (Bryson, J., concurring).

Table 1: Legal Arguments in *Tafas* and Their Implications

Source of definition	Definition of substantive rule	Does USPTO likely have authority to make hypothetical “derivation” rule?
Judge Prost’s majority opinion in <i>Tafas</i> .	A rule that forecloses effective opportunity to present patent applications for examination.	No because the hypothetical definition is substantive (i.e., it would foreclose applicants from receiving patent rights).
Judge Rader’s dissent in <i>Tafas</i> .	A rule that has substantive effects that are sufficiently grave.	No because the hypothetical definition is substantive (i.e., it has a grave effect, the denial of a patent).
Judge Bryson’s concurrence in <i>Tafas</i> .	Irrelevant because substantive/procedural distinction does not matter.	Yes because, regardless of how the rule is classified, it clearly falls under the Agency’s rulemaking authority.

The plain language of the America Invents Act, supported by its legislative history, Federal Circuit precedent, and the broad interpretation of similarly worded powers in other administrative law contexts, thus reveals that the USPTO appears to have the substantive rulemaking authority to set forth standards for certain proceedings. This reformation of the USPTO’s authority suggests, at a minimum, that the Federal Circuit should relinquish its substantive restriction on the USPTO’s powers to set standards. Failure to do so would seem to rep-

resent a brazen interference with a legislative delegation of authority to the executive branch.

## 2. Policymaking Authority

Beyond the USPTO's new authority to set standards, certain of the USPTO's new powers clash with a critical premise of the substantive restriction on the USPTO's authority. Implicit in the Federal Circuit's distinction between procedural and substantive rules is the assumption that the USPTO lacks policymaking authority. But the USPTO cannot prioritize technologies on the basis of their national importance or set standards that take into account "the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings"<sup>217</sup> without making core policy determinations. These policy-focused powers reveal that the Agency is not merely a rubberstamping, ministerial body as the Federal Circuit has traditionally assumed.

The Federal Circuit's efforts to segregate valid procedural rules from invalid substantive rules have served to limit the USPTO to a ministerial role rather than a policy-setting role. In *Tafas*, Judge Rader would classify the rules at issue as substantive because they "affect individual rights and obligations, and mark a startling change in existing law and patent policy."<sup>218</sup> This view comports with the APA.<sup>219</sup> Policy statements, like legislative rules and interpretive rules, are a type of substantive rule under the framework of the APA.<sup>220</sup> Judge Prost adopted a more cautious approach. She appeared to recognize "that substantive rules 'encode[] a substantive value judgment or put[] a stamp of approval or disapproval on a given type of behavior.'"<sup>221</sup> However, she thought rules involving only incidental policymaking discretion or substantive effects could be classified as procedural rules.<sup>222</sup>

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217. America Invents Act sec. 6(a) (to be codified at 35 U.S.C. § 316(b)); *id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(b)).

218. *Tafas*, 559 F.3d at 1371 (Rader, J., concurring in part and dissenting in part).

219. See Anthony, *supra* note 56, at 1321 n.37.

220. *Id.* at 1323.

221. *Tafas*, 559 F.3d at 1355 (quoting *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987) (alterations in the original)).

222. See *id.* at 1355–56. The idea that rules with merely "incidental" policy implications should be classified differently from rules with more consequential policy implications derives analogous support from the framework of the Rules Enabling Act ("REA"). See 28 U.S.C. § 2072 (2006). This Act provides: "The Supreme Court shall have the power to prescribe general rules of practice and procedure" for federal trial and appeals courts but these "rules shall not abridge, enlarge or modify any substantive right." *Id.* § 2072(a)–(b). This language has been interpreted as granting the Court the authority to make procedural rules with incidental impacts on substantive concerns but not substantive rules. See Martin H. Redish & Uma M. Amuluru, *The Supreme Court, the Rules Enabling Act, and the Politicization of the Federal Rules: Constitutional and Statutory Implications*, 90 MINN. L. REV.

Policymaking is not an incidental aspect of the Agency's reformed authority. Rather, at the very heart of any efforts to set standards for the Agency's proceedings or to expedite the review of technologies of national importance are complex, policy-loaded decisions that encode value judgments and put a stamp of approval on certain inventions. The policy-focused nature of the USPTO's powers is readily apparent in the USPTO's new Prioritization Authority.<sup>223</sup> To prioritize is to rank in importance.<sup>224</sup> Thus, to prioritize applications in the patent system, the USPTO must determine whether one type of patent application has greater importance for the national economy or national competitiveness than another. Is a new diaper design that could generate thousands of jobs and billions in revenue more important to the nation than a new windmill technology that could revolutionize the nation's competitiveness in the clean energy industry? Congress purposefully chose to be vague about which technologies should be expedited under the Prioritization Authority. The original proposal to grant the USPTO Prioritization Authority highlighted "green technologies designed to foster renewable energy, clean energy, biofuels, agricultural sustainability, environmental quality, conservation, or energy efficiency" as technologies that could be prioritized under the USPTO's proposed new authority based on their ability to create green jobs and reduce the nation's reliance on foreign oil.<sup>225</sup> Before Congress approved the amendment, however, it deleted the examples of technologies that could be prioritized from the text of

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1303, 1333 (2006) (describing the judicial interpretations of Rules Enabling Act). Prior to the enactment of the America Invents Act, Professor Miller argued compellingly that the REA could serve as a better model for ascertaining the distinction between procedural and substantive rules in the patent context than any of the rules proffered in *Tafas*. See Miller, *supra* note 19, at 57–58. However, given that such a distinction between substantive and procedural rules has proven to be one of the most incoherent legal principles in other areas of the law, inviting this doctrinal chaos into patent law seems ill advised. For instance, in the civil procedure context where federal courts sitting in diversity must apply state substantive law with federal procedural rules, a circuit split has arisen as to whether state affidavit-of-merit requirements are substantive laws or procedural rules. Compare *Chamberlain v. Giampapa*, 210 F.3d 154, 161 (3d Cir. 2000) (applying the state affidavit-of-merit requirement as substantive law in a medical malpractice diversity case), with *Long v. Adams*, 411 F. Supp. 2d 701, 709 (E.D. Mich. 2006) (excluding the state affidavit-of-merit requirement as a procedural matter in a medical malpractice diversity case). In any event, under either an "incidental" impacts test or Judge Rader's less flexible approach, it is clear that, due to their policymaking nature, the USPTO's new powers cannot be confined to procedural rulemaking.

223. Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 25, 125 Stat. 284, 337–38 (2011) (to be codified at 35 U.S.C. § 2(b)(2)(G)); see also discussion *supra* Part III.A.2.C.

224. See MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 988 (11th ed. 2004) (defining "prioritize" as "to list or . . . in order of priority" and "priority" as "superiority in rank, position, or privilege").

225. 157 CONG. REC. S1052–53 (daily ed. Mar. 1, 2011) (statement of Sen. Robert Menendez regarding Amendment No. 124) (applauding the USPTO for prioritizing green technologies in the review process).



the Amendment. As it currently stands, Congress has provided the USPTO with no guidance on the types of technologies that deserve prioritization other than that they must carry importance for the national economy or national competitiveness.<sup>226</sup> This structure gives the USPTO substantial discretion to choose how to implement the new power.

Among countless other potentially relevant factors, the USPTO could prioritize technologies on the basis of which technologies:

- Create the largest number of jobs in the United States;
- Generate the most revenue for U.S. companies; or
- Require a regulatory boost to become competitive with more established technologies.

But boiling down the USPTO's considerations to these factors oversimplifies the Agency's analysis. If the USPTO chooses to prioritize inventions based on their ability to promote job growth, should the USPTO consider which inventions:

- *Have* created the largest number of jobs in the United States;
- Are predicted to create the largest number of jobs in the United States *over the next year*; or
- Are predicted to create the largest number of jobs in the United States *over the next twenty years*?

Resolving these issues may involve some procedural rulemaking, but certainly the core purpose of prioritizing is to make value judgments and set policy — a purpose that defies procedural limitations.

Other powers granted by the America Invents Act also require the USPTO to engage in complex policy determinations. In promulgating rules for post-grant review and inter partes review, for instance, the USPTO must consider “the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings.”<sup>227</sup> Does this requirement authorize the USPTO to alter its standards if it concludes that doing so will help it complete reviews more quickly? Probably. Does this requirement authorize the USPTO to set standards for its proceedings on an industry-by-industry basis if it believes doing so would benefit the national economy? Probably. This is not to say that the USPTO should take such action but merely to point out the fact that it could potentially do so. By forcing the USPTO to incorporate broad policy determinations into its regulations, Congress has given the USPTO a key policymaking role in the patent system.

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226. See America Invents Act sec. 25 (to be codified at 35 U.S.C. § 2(b)(2)(G)).

227. *Id.* sec. 6(a) (to be codified at 35 U.S.C. § 316(b)); *id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(b)).

Although the USPTO's powers are limited to specific proceedings and it lack the authority that some agencies possess to issue regulations that are "necessary or appropriate" to administer their organic acts,<sup>228</sup> the USPTO seems more comparable to the EPA with its broad discretionary authority under environmental statutes to promulgate regulations that "protect human health and the environment"<sup>229</sup> than to a rubberstamping body without any policymaking powers. Congress tasked both the USPTO and the EPA with prioritizing public goods — the national economy and competitiveness for the USPTO and human health and the environment for the EPA. Congress provided little explanation on how to balance the sensitive policy concerns that come into play when trying to promote these public goods. And by ending fee diversion and granting the USPTO the authority to set its own fees, Congress has given the USPTO the financial means of carrying out this expanded policymaking role.<sup>230</sup> The Federal Circuit's assumption that the USPTO lacks policy-setting authority is incompatible with the powers delegated to the USPTO by the America Invents Act.

In summary, the Federal Circuit's traditional view of the USPTO as a rubberstamping agency with anemic powers is clearly out of date. By granting the Patent Office the power to set standards, prioritize technologies, and set its own fees, Congress has pumped up the USPTO's rulemaking muscles and invited it to flex them.

#### IV. A PROPOSAL

What would happen if the courts did eliminate the substantive restriction on the USPTO's authority? I propose that, in conformity with the practice of interpreting congressional delegations of authority broadly,<sup>231</sup> the USPTO should be allowed to promulgate any rules authorized by the plain language of the Patent Act without a murky and normatively defective distinction between invalid substantive rules and valid procedural rules.

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228. See *supra* note 29 and accompanying text.

229. *E.g.*, Resource Conservation and Recovery Act § 9003(a), 42 U.S.C. § 6991b(a) (2000) (requiring the EPA to promulgate regulations for new and existing underground storage tanks and to establish technical requirements for leak detection and prevention "as may be necessary to protect human health and the environment"); see also *About EPA*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/aboutepa/index.html> (last visited May 3, 2012) ("EPA's mission is to protect human health and the environment.").

230. America Invents Act secs. 10, 22; see also discussion *supra* Part III.A.2.A.

231. Scalia, *supra* note 31, at 511–16.

*A. Framework*

My framework to delineate the boundaries between the USPTO's authority and the Federal Circuit's authority requires a two-step analysis. First, the courts should consider deferentially whether a USPTO rule or interpretation is authorized by a specific rulemaking power in the Patent Act. This step represents a straightforward application of administrative law and principles of legislative interpretation. Second, the courts should ensure that the rule or interpretation does not violate the settled understanding of other sections of the Patent Act, such as the authority of the courts to determine certain core standards of patentability under 35 U.S.C. §§ 101, 102, 103, and 112.<sup>232</sup> The second step of this framework is necessary because the America Invents Act does not eradicate the Federal Circuit's well-established responsibility for setting certain core standards of patentability. Adopting this framework for judicial review, the courts would restore the proper balance of power between the congressional, judicial, and executive branches of government, enhance the efficiency of the USPTO, and improve agency accountability.

Taking a broad view of the USPTO's specific statutory powers would not undermine decades of decisions in which the Federal Circuit has established patent law standards. Prior to the enactment of the America Invents Act, the Patent Act did not delegate authority to the USPTO to set standards for ambiguous statutory terms like obviousness and novelty. Yet the patent system could never have functioned if some governmental institution had not interpreted these key terms of the Patent Act. It was incumbent upon the courts to do so. The America Invents Act does not undo this implicit delegation of authority. It delegates specific powers to the USPTO, such as the powers to set standards for inter partes review, post-grant review, and derivation proceedings, and implicitly leaves to the courts the responsibility of filling in gaps left by the statutory scheme. And as former Chief Judge Paul Michel of the Federal Circuit has observed, the America Invents Act is chock-full of ambiguity.<sup>233</sup> For instance, the America Invents Act has substantially altered 35 U.S.C. § 102,<sup>234</sup> creating new ambiguity in the statute. None of the USPTO's new or old powers grant it the authority to resolve this ambiguity.

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232. See Wasserman, *supra* note 20, at 387 (discussing the historical role of the courts in filling legislative gaps in the patent laws).

233. Jan Wolfe, *What Effects Will the America Invents Act Have on U.S. Patent Law?*, LAW.COM (Sept. 13, 2011), <http://www.law.com/jsp/cc/PubArticleCC.jsp?id=1202514170593> (quoting Chief Judge Michel as stating that “[t]he bill makes fundamental changes, and many sections are poorly written and ambiguous”).

234. See America Invents Act, sec. 3(b) (to be codified at 35 U.S.C. § 102(a)–(b)); 157 CONG. REC. S5431 (daily ed. Sept. 8, 2011) (statement of Sen. John Kyl) (discussing how public availability is now a prerequisite for all prior art).

Had Congress intended to remove the courts' traditional responsibility for making substantive interpretations of the Patent Act, it could have done so. Congress entertained and ultimately declined the possibility of giving the Patent Office 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>235</sup> Such language would have expanded the Patent Office's rulemaking authority to cover setting standards for all of the core standards for patentability, including novelty and obviousness, and would have obviated the need for the courts to engage in such standard setting. But the authority granted to the USPTO in the America Invents Act is more limited and leaves a gap for the courts to continue to fill.<sup>236</sup> Congress granted the USPTO general authority to "carry out" provisions of the Patent Act but (1) it only did so with respect to the post-grant review and inter partes review provisions and (2) Congress instructed the USPTO to carry out these provisions within one year of the enactment of the America Invents Act.<sup>237</sup> Since the post-grant review and inter partes review proceedings are of new vintage, there is little potential for the USPTO to intrude on the traditional role of the Federal Circuit in carrying out these provisions, even if the USPTO engages in substantive rulemaking with respect to these proceedings. The same is true with respect to the USPTO's other powers that are not time-limited and appear to encompass substantive rulemaking, such as its powers to set standards for inter partes review, post-grant review, and derivation proceedings. The fact that the USPTO can likely engage in substantive rulemaking does not oust the Federal Circuit from its role in setting certain patentability standards.

Given that the courts have played a prominent role in determining the core standards for patentability over the history of the patent system and that Congress has previously rejected proposals that would have obviated this role, the principle of *stare decisis* suggests Congress would need to speak clearly to remove this role.<sup>238</sup> Nothing in

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235. Long, *supra* note 20, at 1979 (quoting Letter from John J. Sullivan, Gen. Counsel of the U.S. Dep't of Commerce, to Howard L. Berman, Chairman, Subcomm. on Courts, the Internet, and Intellectual Prop., H. Comm. on the Judiciary, at 9 (May 16, 2007) (thanking Congress for including language in the house bill 1908, the Patent Reform Act, that would authorize the Patent Office "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"))).

236. *Cf.* *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000) (holding that when Congress repeatedly denies an agency the power to regulate in a particular area, and develops a comprehensive regulatory scheme outside the agency's control, the agency may not regulate in that area).

237. *See* America Invents Act sec. 6(c)(1) (to be codified at 35 U.S.C. § 317); *id.* sec. 6(f)(2)(A) (to be codified at 35 U.S.C. § 321).

238. *See* *Flood v. Kuhn*, 407 U.S. 258, 281–84 (1972) (finding heightened deference appropriate because Congress had considered and rejected proposals to overturn the Court's interpretation); *Toolson v. N.Y. Yankees, Inc.*, 346 U.S. 356, 357 (1953) (same).

the legislative history of the America Invents Act suggests Congress intended to do so. Instead, the America Invents Act appears to empower the USPTO to make some substantive interpretations of the Patent Act while respecting the Federal Circuit's traditional role of setting patentability standards like obviousness and novelty.

My proposal for judicial review respects the boundaries between the USPTO's and Federal Circuit's powers, as is best illustrated through a hypothetical. Assume the USPTO determined that business method patents were not producing much incentive for innovation or commercialization of new technologies. If the USPTO declared that business method inventions were no longer patentable subject matter, the USPTO could argue that such a declaration facilitated and expedited the processing of applications pursuant to 35 U.S.C. § 2(b)(2)(C). Getting rid of applications relating to business methods would arguably facilitate and expedite the USPTO's review of other applications as there would be fewer applications in the system overall, enabling the USPTO to redirect its workforce to other applications and cut down patent processing time. Nonetheless, the USPTO rule would be invalid.

The main problem with any USPTO effort to cut out a class of applications from its backlog is that such an interpretation would conflict with the language of 35 U.S.C. § 101, which provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."<sup>239</sup> Declaring that business method inventions are unpatentable would prevent inventors of "*any* new and useful"<sup>240</sup> invention from obtaining a patent. The USPTO could not get around this language by redefining "new" or "useful" to exclude business method inventions. Like 35 U.S.C. §§ 102, 103, and 112, § 101 does not delegate implementation to the USPTO. This provides a stark contrast to the specific rulemaking powers that Congress has carved out for the USPTO and indicates Congress intended for the courts to interpret and fill in the gaps with respect to these provisions, not the Agency.

Now assume that instead of declaring that business method inventions are not patentable, the USPTO promulgated a rule providing that the review of business method applications are its lowest priority.<sup>241</sup> This rule would fall within the USPTO's statutory authority to "facilitate and expedite" the review of patent applications,<sup>242</sup> as it would free

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239. 35 U.S.C. § 101 (2006).

240. *Id.* (emphasis added).

241. This would aggravate the delays in processing business method patents but would not have the same effect as completely denying that business methods were patentable.

242. 35 U.S.C. § 2(b)(2)(C) (2006).

up USPTO resources temporarily to attend to other patent applications. The rule would not conflict with any other provisions of the Patent Act. Under my proposed framework, it would therefore be valid without any consideration of whether the rule was procedural or substantive. In these examples, the two-step framework would ensure that the USPTO was not infringing on the Federal Circuit's turf while simultaneously giving the Agency flexibility to attend to what it considered more pressing applications.

A similar analysis can be performed with respect to the USPTO's new powers to set standards for its proceedings. Take, for instance, the Patent Office's authority to set standards for the showing of sufficient grounds to institute a post-grant review. The Agency cannot alter the statutory standard that post-grant review is only allowed if it is "more likely than not that at least 1 of the claims challenged in the petition is unpatentable" or "the petition raises a novel or unsettled legal question that is important to other patents or patent applications."<sup>243</sup> Altering such a standard would violate Congressional intent. But the Agency could set a standard clarifying that a petition "raises a novel or unsettled legal question that is important to other patents or patent applications"<sup>244</sup> when resolution of the petition will likely have a substantial impact on technologies of importance to the national economy. Filling in the gap as to what constitutes a "legal question that is important to other patents or patent applications"<sup>245</sup> is clearly within the USPTO's authority to set "set[] forth the standards for the showing of sufficient grounds to institute a [post-grant] review"<sup>246</sup> and does not conflict with any implied delegation of authority to the courts.

This two-step framework would have little effect on rules that are clearly procedural. If the substantive restriction was lifted from the USPTO's authority, all previous Federal Circuit decisions upholding rules as both procedural and within the USPTO's statutory authority — such as rules permitting conferences between an administrative patent judge and the parties to an interference proceeding; rules establishing that the movant in an interference proceeding has the burden of proof and duty of translating earlier filed documents into English; and rules defining the term "original application" in a statutory provision that established the procedures for inter partes reexamination<sup>247</sup> — would continue to be valid to the extent they fell within the

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243. Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 6(d), 125 Stat. 284, 306-07 (2011) (to be codified at 35 U.S.C. § 324(a), (b)).

244. *Id.*

245. *Id.*

246. *Id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(a)(2)).

247. *Tafas v. Doll*, 559 F.3d 1345, 1365-66 (Fed. Cir. 2009) (Bryson, J., concurring) (identifying the rules that have been upheld by the Federal Circuit).

USPTO's reformed statutory authority. Further, eight of the USPTO's new rulemaking powers extend exclusively to procedural rules, indicating their narrow scope. For example, pursuant to § 257(d)(2), the USPTO must "issue regulations . . . establishing *procedures* for reviewing information submitted in" requests for supplemental examination.<sup>248</sup> For post-grant review, the USPTO must establish *procedures* for the submission of supplemental information after petitions are filed.<sup>249</sup>

In summary, eliminating the substantive restriction on the Patent Office's authority would not empower the Agency to promulgate regulations on any subject it pleases, such as on core issues of patentability traditionally left to the courts. Instead, by employing a two-step framework for judicial review, the courts would satisfy congressional intent and give the USPTO the flexibility it needs to improve the patent system.

### B. Social Benefits

The Federal Circuit's decision to construe the Patent Act as prohibiting substantive rulemaking has made it difficult for the USPTO, patent practitioners, and even Federal Circuit judges to discern the precise scope of the Agency's authority.<sup>250</sup> Now that the America Invents Act endows the USPTO with several dozen new powers that are not readily classified as purely procedural or substantive powers, the importance of reforming this doctrine is more important than ever. Rather than enforcing a murky distinction between invalid substantive rules and valid procedural rules, the Federal Circuit should promote certainty, decrease needless litigation, and increase consistency in judicial review by eliminating the substantive restriction entirely and letting the USPTO use its full congressional delegation of authority.

Approximately thirty of the USPTO's new powers cannot readily be classified as either substantive or procedural rulemaking powers.<sup>251</sup> For instance, Congress chose to expressly exclude "technological inventions" from the transitional program for covered business method patents,<sup>252</sup> and Congress tasked the USPTO with promulgating "regulations for determining whether a patent is for a technological inven-

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248. America Invents Act sec. 12 (to be codified at 35 U.S.C. § 257(d)(2)) (emphasis added).

249. *Id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(a)(3)).

250. See Tran, *Distorted Rules*, *supra* note 21.

251. See Chart of New Patent Office Powers, *infra* Appendix.

252. America Invents Act sec. 18(d)(1) (providing that "the term 'covered business method patent' . . . does not include patents for technological inventions").

tion.”<sup>253</sup> By defining technological invention, the USPTO will determine which inventions will be eligible for the transitional program. The USPTO’s definition thus ultimately affects whether a party will keep or lose its patent rights in the transitional post-grant review proceeding. Whether the relationship between a USPTO rule defining technological invention and the ultimate invalidity of an invention affected by the regulation would motivate a Federal Circuit panel to categorize the regulation as substantive is difficult to predict.

Another group of new powers that resists classification as procedural or substantive are powers using the word “govern”:

- The USPTO must prescribe regulations “establishing and governing” inter partes review and post-grant review “and the relationship of such reviews to other proceedings.”<sup>254</sup>
- The USPTO must prescribe regulations “providing for protective orders governing the exchange and submission of confidential information.”<sup>255</sup>
- The USPTO must “issue regulations governing the form, content, and other requirements of requests for supplemental examination, and establishing procedures for reviewing information submitted in such requests.”<sup>256</sup>

On the one hand, the use of the word “govern” suggests these are purely procedural rulemaking powers because the Federal Circuit has consistently viewed the USPTO’s authority to govern the conduct of its proceedings as a procedural power.<sup>257</sup> On the other hand, these powers are susceptible to a broader interpretation. Take, for instance, the USPTO’s authority to govern the form, content, and other requirements for requests for supplemental examination.<sup>258</sup> This power appears to authorize the USPTO to promulgate procedural rules specifying the number of pages in a request for supplemental examination and the types of information the USPTO might find useful to add to its records. However, the power also seems to authorize the USPTO to issue a regulation providing the criteria for eligibility for supplemental examination, which could affect, for example, whether a patent is held unenforceable for inequitable conduct. In other words, this power could be viewed as authorizing the Agency to set standards for supplemental examination just as the statute grants the USPTO powers to set standards for its other proceedings. Additionally, like the

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253. *Id.* sec. 18(d)(2) (“To assist in implementing the transitional proceeding authorized by this subsection, the Director shall issue regulations for determining whether a patent is for a technological invention.”).

254. *Id.* sec. 6(a) (to be codified at 35 U.S.C. § 316(a)(4)); *id.* sec. 6(d) (to be codified at 35 U.S.C. § 326(a)(4)) (emphasis added).

255. *Id.* sec. 6(a) (to be codified at 35 U.S.C. § 316(a)(7)) (emphasis added).

256. *Id.* sec. 12(a) (to be codified at 35 U.S.C. § 257(d)(2)) (emphasis added).

257. *See supra* note 14.

258. *See supra* Part III.A.2.B.v.



USPTO's powers to set standards and procedures for its other proceedings, Congress gave the USPTO seemingly broad authority to govern the requests for supplemental examination in addition to a narrower procedural power to review the information submitted.

Many of the USPTO's powers that predate the America Invents Act also cannot readily be classified as procedural or substantive rulemaking powers. For instance, the tension between the broad discretionary authority of the Prioritization Authority and the narrow procedural limits on the USPTO's authority is not new. The USPTO's authority to prioritize inventions of national importance does not add much, if anything, to the USPTO's existing powers to "govern the conduct of proceedings in the Office" and to "facilitate and expedite the processing of patent applications."<sup>259</sup> Indeed, over the past fifty years, the USPTO has already used these powers to issue regulations prioritizing applications relating to counterterrorism,<sup>260</sup> the "safety of research in the field of recombinant DNA,"<sup>261</sup> HIV/AIDS and cancer,<sup>262</sup> certain biotechnology inventions by small entities,<sup>263</sup> and energy and environmental technologies.<sup>264</sup> These regulations have enabled certain applications to be processed more quickly than they would have otherwise and without the payment of supplemental fees. Although the USPTO's past prioritization efforts have never been challenged in the courts, the USPTO's decision to prioritize technologies reflected a core policy determination — that one particular class of technologies was more socially valuable than others. As a result, the USPTO's prioritization efforts have conflicted with the substantive limitation on the Patent Office's rulemaking authority,<sup>265</sup> as well as the Federal Circuit's failure to "recognize policy decisions as a separate category of PTO behavior."<sup>266</sup> In providing new legislative support to the USPTO's prioritization practices in a form that resists

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259. 35 U.S.C. § 2(b)(2) (2006).

260. 37 C.F.R. § 1.102(c)(2)(iii) (2011).

261. MPEP § 708.02(VII) (8th ed. Rev. 6, Sept. 2007) (justifying preferential treatment for inventions relating to recombinant DNA on the ground that "[r]ecombinant DNA research appears to have extraordinary potential benefit for mankind").

262. *See id.* § 708.02(X). The USPTO's reason for expediting these technologies is "[i]n view of the importance of developing [these technologies] . . . and the desirability of prompt disclosure of advances made in these fields." *Id.*

263. *See id.* § 708.02(XII).

264. *See* 37 C.F.R. § 1.102(c)(2)(i), (ii); Pilot Program for Green Technologies Including Greenhouse Gas Reduction, 74 Fed. Reg. 64,666, at 64,666–67 (Dec. 8, 2009) (providing for expedited review of certain environmentally-beneficial technologies).

265. *See* *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) ("[T]he broadest of the PTO's rulemaking powers . . . does NOT grant the Commissioner the authority to issue substantive rules."); Benjamin & Rai, *supra* note 15, at 301 (reviewing the Federal Circuit's case law and concluding that the Federal Circuit takes the position "that the PTO does not make [policy] determinations").

266. Benjamin & Rai, *supra* note 15, at 305.

classification as a procedural rulemaking power,<sup>267</sup> Congress has signaled that it supports a broader view of USPTO authority than the Federal Circuit has been willing to accept.

If the America Invents Act does not prod the courts to abandon the substantive restriction on the USPTO's authority entirely, the restriction would detrimentally impact the patent system. First, it would promote needless uncertainty. If the USPTO issued a rule that was not readily classifiable as procedural or substantive, neither the USPTO nor patent practitioners would know for sure if the rule would be upheld by the courts. The USPTO's ability to receive *Chevron* deference for any legislative interpretations embodied in such a rule would also be compromised. Such uncertainty would encourage litigation, as parties adversely impacted by a USPTO rule would hope to convince a court to invalidate the rule even if it fell clearly within the USPTO's statutory authority. The uncertainty would be aggravated by the fact that the courts would treat rules promulgated pursuant to certain of the USPTO's new powers differently than rules promulgated pursuant to the USPTO's other powers, requiring litigants to try to predict judicial outcomes under two quite different standards of review.

Second, continuing the restriction on the USPTO's authority would provide the Agency with a problematic incentive to make rules in a manner that produces little to no benefit to inventors, the patent system, and society at large. The surest way for the USPTO to avoid challenges to the substantive nature of its rules is to promulgate rules that have limited applicability or effect. Such rules likely would not foreclose effective opportunity to present patent applications for examination (Judge Prost's rule in *Tafas*) and would not create grave effects (Judge Rader's rule in *Tafas*).<sup>268</sup> Indeed, this may have been the USPTO's intention when it expedited via regulation the review of socially valuable applications in the past. These regulations did not trigger any legal challenges, most likely because the regulations only provided limited benefits to a narrow class of applications so that the disruption to normal, non-expedited applications was minimal. For instance, in December of 2009, the Patent Office initiated the Green Technology Pilot Program, which purported to provide opportunities for environmentally beneficial applications to receive expedited review.<sup>269</sup> But this program imposed a laundry list of restrictions on eligible applications and only provided a moderately faster review

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267. See discussion *supra* Part III.B.2.

268. See discussion *supra* Part III.B.1.

269. See Pilot Program for Green Technologies Including Greenhouse Gas Reduction, 74 Fed. Reg. at 64,666–67; see also 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).

process.<sup>270</sup> As a result, participation in the program was sub-optimal.<sup>271</sup>

Third, the restriction would discourage the USPTO from involving the public in its decision-making processes at a time when public input would be most valuable given the sheer amount of new regulations that are needed to fulfill the mandate of the America Invents Act. When agencies promulgate substantive rules, but not procedural rules, they must comply with 5 U.S.C. § 553 of the APA.<sup>272</sup> This provision includes various mechanisms that require agencies to inform the public about proposed substantive rules and to consider the public's comments on the proposed rules.<sup>273</sup> The USPTO has not needed to provide notice of proposed rules or opportunity for public participation when it promulgates rules because the Federal Circuit views the USPTO's authority as limited to procedural rules, which are exempt from these requirements.<sup>274</sup> Moreover, in *Tafas*, Judge Rader viewed the Patent Office's voluntary efforts to provide a notice and comment period for the rules at issue, as well as the overwhelming public participation that resulted, as evidence that the rules were invalid substantive rules rather than valid procedural ones.<sup>275</sup> As a result of this interpretation, in situations where the Patent Office might have been inclined to voluntarily solicit public participation,<sup>276</sup> it may be disinclined to do so as such action could suggest to the Federal Circuit that it is exceeding its rulemaking authority. Not surprisingly, the Patent Office was reticent to fulfill the public participation obligations of the APA on its own initiative prior to the enactment of the America In-

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270. See *Expediting Innovation*, *supra* note 105, at 154–62.

271. See *id.* at 143–47 (demonstrating that the Green Technology Pilot Program attracted little interest from inventors as it provided nominal benefits to participants).

272. See 5 U.S.C. § 553 (2006).

273. *Id.*

274. Section 553(b) explicitly does not apply to “interpretative rules, general statements of policy, or rules of agency organization, *procedure*, or practice.” *Id.* § 553(b) (emphasis added).

275. *Tafas v. Doll*, 559 F.3d 1345, 1370–71 (Fed. Cir. 2009) (Rader, J., concurring in part and dissenting in part).

276. One potential motivation for the Agency to use the notice and comment procedure is to receive *Chevron* deference. See *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). *Mead* stated that:

[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.

*Id.* Although it is not always necessary for an agency to use the notice and comment procedure to receive deference, doing so suggests that the agency interpretation was promulgated in the exercise of proper authority. *Id.*

vents Act.<sup>277</sup> However, in performing the monumental task of implementing the America Invents Act, a task that obviously benefits from public participation, the USPTO has sought public input and comments on the Act.<sup>278</sup> It would defy all reason if the fact that the USPTO took the commonsense action of soliciting public input on the far-reaching changes of the America Invents Act motivated the courts to hold the USPTO's regulations invalid.<sup>279</sup>

Thus, the Federal Circuit's fuzzy distinction between valid procedural rules and invalid substantive rules has placed a blanket of uncertainty over many, if not most, of the USPTO's powers. Such an approach had little merit before the America Invents Act went into effect.<sup>280</sup> However, now this approach is even more problematic as it creates an inconsistency in the treatment of USPTO rules, provides the USPTO with an incentive to curb the effects (and simultaneously the benefits) of the mass of new regulations it is obligated to promulgate in the wake of the America Invents Act, and reduces transparency in the patent system. By eliminating the substantive restriction on the USPTO's powers altogether, the courts will give the USPTO the flexibility and resources it needs to promote the goals of the patent system and reduce the risk of needless litigation.

## V. CONCLUSION

On September 7, 2011, Congress brought epic changes to the patent system by passing the America Invents Act. This historic Act allocates an array of broad powers, responsibilities, and resources to the USPTO. The new institutional design of the patent system appears to directly conflict with the Federal Circuit's entrenched view that the Agency lacks substantive rulemaking authority. The Federal Circuit's narrow interpretation of the USPTO's authority has contravened the basic principle of administrative law that courts should uphold congressional delegations of authority, has raised separation of powers concerns, has flouted the Supreme Court's efforts to eliminate anoma-

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277. See *Expediting Innovation*, *supra* note 105, at 143–47 (discussing how Patent Office officials have acknowledged that they solicited and received comments on the Green Technology Pilot Program but have not released the comments to the public).

278. Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees, 77 Fed. Reg. 3666 (Jan. 25, 2012); Changes To Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 982 (Jan. 6, 2012); Changes To Implement Miscellaneous Post Patent Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 442 (Jan. 5, 2012); Changes To Implement the Preissuance Submissions by Third Parties Provision of the Leahy-Smith America Invents Act, 77 Fed. Reg. 448 (Jan. 5, 2012).

279. Further examination of the ways in which compliance with the APA could reduce concerns about agency capture is beyond the scope of this Article, but I intend to explore this issue in greater depth at a future time.

280. See Tran, *Distorted Rules*, *supra* note 21.

lies in administrative law, and has stifled regulatory progress. With judicial and regulatory reforms underway, no time could be better to eliminate this ill-devised restriction and bring patent law into conformity with administrative law.

If the Federal Circuit acknowledges the breadth of the USPTO's new powers, the USPTO will be able to play a central role in setting substantive patent law standards and making patent policy alongside the courts. Although such a change would disrupt the longstanding power divide between the USPTO and the Federal Circuit, it would produce immense social and practical benefits. By recognizing the incompatibility between traditional judicial doctrines and the broad authority bestowed upon the USPTO by the America Invents Act, the courts could increase uniformity in administrative law while promoting the central goals of executive delegation: administrative efficiency, certainty, and agency accountability. As a result, applicants would likely experience fewer delays in waiting for a patent application to be reviewed, parties would waste less time and money litigating the validity of patents and USPTO regulations, and the general public would have more opportunities to participate in the USPTO's decision-making processes. Additionally, by having more freedom to prioritize socially valuable applications in the review process, the Patent Office could provide meaningful incentives for parties to innovate, and bring to market sooner, technologies of national importance, such as those relating to energy development, biomedical research, and information technology. Finally, concentrated authority at the USPTO would create benefits for inventors of limited financial means, like individual inventors, small business owners, and start-up companies. These parties might be able to challenge low-quality patents that harm their business interests in one of the USPTO's new or fortified proceedings even though litigation would be cost prohibitive for them. Thus, with the historic reform embodied in the America Invents Act comes an opportunity for historic social progress.

## APPENDIX

Table 2: New Patent Office Powers

Rulemaking Authority	America Invents Act Section	Patent Act Section Modified 35 U.S.C.
<p><b>Fees for Patent Services</b></p> <p>*The Director may by regulation provide for a refund of any part of the fee specified in subparagraph (A) for any claim that is canceled before an examination on the merits, as prescribed by the Director, has been made of the application under section 131. Errors in payment of the additional fees under this paragraph may be rectified in accordance with regulations prescribed by the Director.</p> <p>*The Director may by regulation provide for a refund of any part of the fee specified in this paragraph for any applicant who files a written declaration of express abandonment as prescribed by the Director before an examination has been made of the [patent] application under section 131.</p> <p>*Subject to [reductions for electronic filings], fees charged under subsections (a) [general fees], (b) [maintenance fees], and (d)(1) [patent search fees] shall be reduced by 50 percent with respect to their application to any small business concern</p>	11(a)	§ 41(a)(2)(C)
	11(c)	§ 41(d)(1)(D)
	11(d)	§ 41(h)(1)

as defined under section 3 of the Small Business Act, and to any independent inventor or nonprofit organization as defined in regulations issued by the Director.

\*[Under the transition provisions, t]he Director may by regulation prescribe conditions for acceptance of a request [for prioritized examination of a nonprovisional application for an original utility or plant patent] and a limit on the number of filings for prioritized examination that may be accepted.

11(h)(1)(B)(i)

\*[Under the transition provisions, u]ntil regulations are prescribed under clause (i), no application for which prioritized examination is requested may contain or be amended to contain more than 4 independent claims or more than 30 total claims.

11(h)(1)(B)  
(ii)

\*[Under the transition provisions, t]he Director may not accept in any fiscal year more than 10,000 requests for prioritization until regulations are prescribed under this subparagraph setting another limit.

11(h)(1)(B)  
(iii)

### **General Fee Setting**

#### **Authority**

The Director may set or adjust by rule any fee established, authorized, or charged under title 35, United States Code, or the Trademark Act of 1946 (15 U.S.C. 1051 et seq.), for any services performed by or materials furnished by, the Office, subject to paragraph (2).

10(a)(1)

**Post-Grant Review**

\*The Director shall establish, by regulation, fees to be paid by the person requesting the [post-grant] review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the post-grant review.

6(d) § 321(a)

\*A petition filed [for post-grant review] may be considered only if . . . the petition provides such other information as the Director may require by regulation.

6(d) § 322(a)(4)

\*The Director shall prescribe regulations [for post-grant review] . . . providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion . . . .

6(d) § 326(a)(1)

\*The Director shall prescribe regulations [for post-grant review] . . . setting forth the standards for the showing of sufficient grounds to institute review . . . .

6(d) § 326(a)(2)

\*The Director shall prescribe regulations [for post-grant review] . . . establishing procedures for the submission of supplemental information after the petition is filed . . . .

6(d) § 326(a)(3)

\*The Director shall prescribe regulations [for post-grant review] . . . establishing and governing a post-grant review

6(d) § 326(a)(4)



<p>under this chapter and the relationship of such review to other proceedings under this title . . . .</p> <p>*The Director shall prescribe regulations [for post-grant review] . . . setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to evidence directly related to factual assertions advanced by either party in the proceeding . . . .</p>	6(d)	§ 326(a)(5)
<p>*The Director shall prescribe regulations [for post-grant review] . . . prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding . . . .</p>	6(d)	§ 326(a)(6)
<p>*The Director shall prescribe regulations [for post-grant review] . . . providing for protective orders governing the exchange and submission of confidential information . . . .</p>	6(d)	§ 326(a)(7)
<p>*The Director shall prescribe regulations [for post-grant review] . . . providing for the filing by the patent owner of a response to the petition . . . after a post-grant review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response . . . .</p>	6(d)	§ 326(a)(8)

<p>*The Director shall prescribe regulations [for post-grant review] . . . setting forth standards and procedures for allowing the patent owner to move to amend the patent . . . to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any amendment . . . is made available to the public as part of the prosecution history of the patent . . . .</p>	6(d)	§ 326(a)(9)
<p>*The Director shall prescribe regulations [for post-grant review] . . . providing either party with the right to an oral hearing as part of the proceeding . . . .</p>	6(d)	§ 326(a)(10)
<p>*The Director shall prescribe regulations [for post-grant review] . . . requiring that the final determination in any post-grant review be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 325(c) . . . .</p>	6(d)	§ 326(a)(11)
<p>*The Director shall prescribe regulations [for post-grant review] . . . providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.</p>	6(d)	§ 326(a)(12)

*The Director shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out [post-grant review].	6(d)	§ 329(f)(1)
*The Director shall determine, and include in the regulations issued [for post-grant review], the procedures under which an interference commenced before [one year after the enactment of the Act] is to proceed, including whether such interference — (i) is to be dismissed without prejudice to the filing of a petition for a post-grant review . . . ; or (ii) is to proceed as if this Act had not been enacted.	6(d)	§ 329(f)(3)(A)
<b>Inter Partes Review</b>		
*The Director shall establish, by regulation, fees to be paid by the person requesting the [inter partes] review . . . considering the aggregate costs of the review.	6(a)	§ 311(a)
*A petition filed [for inter partes review] may be considered only if . . . the petition provides such other information as the Director may require by regulation . . . .	6(a)	§ 312(a)(4)
*The Director shall prescribe regulations [for inter partes review] . . . providing that the file of any proceeding . . . shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the	6(a)	§ 316(a)(1)

<p>motion . . . .</p> <p>*The Director shall prescribe regulations [for inter partes review] . . . setting forth the standards for the showing of sufficient grounds to institute [an inter partes review] . . . .</p>	6(a)	§ 316(a)(2)
<p>*The Director shall prescribe regulations [for inter partes review] . . . establishing procedures for the submission of supplemental information after the petition is filed . . . .</p>	6(a)	§ 316(a)(3)
<p>*The Director shall prescribe regulations [for inter partes review] . . . establishing and governing inter partes review . . . and the relationship of such review to other proceedings under this title . . . .</p>	6(a)	§ 316(a)(4)
<p>*The Director shall prescribe regulations [for inter partes review] . . . setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to — (A) the deposition of witnesses submitting affidavits or declarations; and (B) what is otherwise necessary in the interest of justice . . . .</p>	6(a)	§ 316(a)(5)
<p>*The Director shall prescribe regulations [for inter partes review] . . . prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding . . . .</p>	6(a)	§ 316(a)(6)
<p>*The Director shall prescribe regulations [for inter partes review] . . . providing for pro-</p>	6(a)	§ 316(a)(7)

protective orders governing the exchange and submission of confidential information . . . .

\*The Director shall prescribe regulations [for inter partes review] . . . providing for the filing by the patent owner of a [preliminary response to a petition for inter partes review] after an inter partes review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response . . . .

6(a)

§ 316(a)(8)

\*The Director shall prescribe regulations [for inter partes review] . . . setting forth standards and procedures for allowing the patent owner to move to amend the patent . . . to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any [such] amendment . . . is made available to the public as part of the prosecution history of the patent . . . .

6(a)

§ 316(a)(9)

\*The Director shall prescribe regulations [for inter partes review] . . . providing either party with the right to an oral hearing as part of the proceeding . . . .

6(a)

§ 316(a)(10)

<p>*The Director shall prescribe regulations [for inter partes review] . . . requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 315(c) . . . .</p>	6(a)	§ 316(a)(11)
<p>*The Director shall prescribe regulations [for inter partes review] . . . setting a time period for requesting joinder under section 315(c) . . . .</p>	6(a)	§ 316(a)(12)
<p>*The Director shall prescribe regulations [for inter partes review] . . . providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.</p>	6(a)	§ 316(a)(13)
<p>*Additional motions to amend [a patent during inter partes review] may be permitted . . . by regulations prescribed by the Director.</p>	6(a)	§ 316(d)(2)
<p>The Director shall, not later than the date that is 1 year after the date of the enactment of this Act, issue regulations to carry out [inter partes review].</p>	6(c)(1)	
<p><b>Derivation Proceedings</b></p>		
<p>*The Director shall prescribe regulations setting forth standards for the conduct of derivation proceedings, including requiring parties to provide</p>	3(i)	§ 135(b)

sufficient evidence to prove and rebut a claim of derivation.

\*Parties to a [derivation] proceeding . . . may, within such time as may be specified by the Director by regulation, determine such contest or any aspect thereof by arbitration.

3(i)

§ 135(f)

**Transitional Program for Covered Business Method Patents**

\*Not later than the date that is 1 year after the date of the enactment of this Act, the Director shall issue regulations establishing and implementing a transitional post-grant review proceeding for review of the validity of covered business method patents.

18(a)(1)

\*[T]he term “covered business method patent” . . . does not include patents for technological inventions. . . . To assist in implementing the transitional proceeding authorized by this subsection, the Director shall issue regulations for determining whether a patent is for a technological invention.

18(d)(1), (2)

**Supplemental Examination**

\*The Director shall, by regulation, establish fees for the submission of a request for supplemental examination of a patent, and to consider each item of information submitted in the request. If reexamination is ordered under subsection (b), fees established and applicable to ex parte reexamination proceedings under chapter 30 shall

12(a)

§ 257(d)(1)

be paid, in addition to fees applicable to supplemental examination.

\*The Director shall issue regulations governing the form, content, and other requirements of requests for supplemental examination, and establishing procedures for reviewing information submitted in such requests.

12(a)

§ 257(d)(2)

**Prioritized Examination for Important Technologies**

The [Patent] Office . . . may establish regulations, not inconsistent with law, which . . . may, subject to any conditions prescribed by the Director and at the request of the patent applicant, provide for prioritization of 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, notwithstanding section 41 or any other provision of law . . . .

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§ 2(b)(2)(G)

**Study on Implementation**

The Director shall, not later than the date that is 4 years after the date of the enactment of this Act, submit to the Committees on the Judiciary of the House of Representatives and the Senate a report on the results of the [PTO Study] conducted under subsection (a),

26(b)



including recommendations for any changes to laws and regulations that the Director considers appropriate.		
<b>Inventor's Oath or Declaration</b>		
*The Director may specify additional information relating to the inventor and the invention that is required to be included in an oath or declaration . . . .	4(a)(1)	§ 115(c)
*In lieu of executing an oath or declaration . . . , the applicant for patent may provide a substitute statement under the circumstances described in paragraph (2) and such additional circumstances that the Director may specify by regulation.	4(a)(1)	§ 115(d)(1)
<b>Definition of Micro-Entity</b>		
For purposes of this title, the term 'micro entity' means an applicant who makes a certification that the applicant . . . qualifies as a small entity, as defined in regulations issued by the Director . . . .	10(g)	§ 123(a)(1)
<b>NOTE</b>		
In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.	6(a), (d)	§§ 316(b) 326(b)