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# RULES TO BIND YOU: PROBLEMS WITH THE USPTO'S PTAB RULEMAKING PROCEDURES

Andrew Dietrick and Jonathan Stroud

*"You don't need to accept everything as true, you only have to accept it as necessary . . . .  
The lie made into the rule of the world."<sup>1</sup>*

## INTRODUCTION

Despite its size and economic impact, the United States Patent and Trademark Office (USPTO) has historically been recognized as less than a full administrative agency possessing substantive rulemaking authority—unlike, say, the Food and Drug Administration, the Environmental Protection Agency, or the Securities and Exchange Commission.<sup>2</sup> Following the passage of the sweeping America Invents Act (AIA) in 2011 and the Supreme Court's decisions in *Cuozzo Speed Technologies, LLC v. Lee*<sup>3</sup> and *SAS Institute, LLC v. Iancu*,<sup>4</sup> it is clear that the USPTO is no exception and is an agency like any other. It has Congressional authority to promulgate substantive rules and is bound to the same Administrative Procedures Act (APA) procedural safeguards as any other arm of the administrative state.<sup>5</sup> Yet the USPTO has continued to routinely issue precedential rules and take

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1. FRANZ KAFKA, *THE TRIAL* 263 (1925).

2. See *infra* note 35; see also, S. Jay Plager, *An Interview with Circuit Judge S. Jay Plager*, 5 J. PROPRIETARY RTS. 2, 5 (1993) (Circuit Judge, Court of Appeals for the Federal Circuit) ("I came from an administrative law background. I thought the PTO was an administrative agency. But we don't review it as if it is. There is no other administrative agency in the United States that I know of in which the standard of review over the agency's decisions gives the appellate court as much power over the agency as we have over the PTO."); Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415, 1416–17 (1995) (arguing "scholarship has never fully addressed the relationship between the Court of Appeals for the Federal Circuit and the Patent and Trademark Office (PTO) . . . due in part to the highly specialized character of the patent system and esoteric nature of its rules and regulations.").

3. 136 S.Ct. 2131, 2134 (2016) (establishing that the USPTO has the power to promulgate substantive rules).

4. 138 S.Ct. 1348, 1358 (2018) (stating that § 318 does not provide the Director partial institution power).

5. In 2011, Congress enacted the AIA, which radically altered and expanded many of the core procedures run by the USPTO. Included in the AIA was the rebranding and expansion of the existing Board of Patent Appeals and Interferences (BPAI) called the Patent Trial and Appeal Board (PTAB). The PTAB is a panel of technically trained administrative judges that hear appeals from patent applicants and challenges to existing patents and can render decisions that are appealable to the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), and thus up to the Supreme Court of the United States (Supreme Court). See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); see generally

significant action with substantive effect, calling them guidance, policy documents, or administrative rulings. It has done so without fully complying with the APA's notice and comment requirements, seeking stakeholder input, or properly notifying the business communities those rules are set to affect.<sup>6</sup> That must change. Like any agency, it cannot act against the will of Congress, stakeholders, or the Courts without observing the strictures and constraints required by law.

This Article analyzes some of the recent rules, guidance documents, policy-based administrative decisions, and rulemaking procedures used by the USPTO, and concludes that the USPTO is improperly promulgating substantive rules *sub rosa* via, *inter alia*, updates to the Trial Practice Guide (TPG), an ostensibly nonbinding document that controls many broad substantive and procedural aspects of the Patent Trial and Appeal Board (PTAB), and in doing so, avoids appellate, Congressional, and stakeholder review of such decisions.<sup>7</sup>

Part I will review the established law of administrative agencies' rulemaking authority and procedures, specifically reviewing formal rulemaking, "informal" notice and comment rulemaking, guidance documents, and policy statements.<sup>8</sup> Part II will talk about the three recent Supreme Court challenges to the AIA. It will introduce the TPG and how it has been and continues to be updated by the USPTO piecemeal and through the Federal Register without any public notice or comment, or much stakeholder input in general.<sup>9</sup> Part III will analyze whether there is a requirement for various updates to the TPG to be held out to the public for notice and comment and other input, and whether any of it has (or should have) the force and effect of law. This Article will also analyze USPTO compliance with Congressional safeguards and Executive Orders.<sup>10</sup> Part III will also demonstrate that the rules presented in these guidance documents are given precedential treatment—by both the USPTO and the courts—and are thus noncompliant with the relevant APA requirements. In Part IV, this Article will explain possible consequences of that unlawful promulgation and offer recommendations for how to appropriately comply and not run afoul of due process notice and comment concerns. Part V will briefly conclude.

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Christopher J Walker & Melissa F. Wasserman, *The New World of Agency Adjudication*, 107 CALIF. L. REV. 141 (2019) (comparing PTAB adjudication with other forms of administrative adjudication and suggesting alternative forms of administrative review).

6. See generally, PATENT TRIAL & APPEAL BD., TRIAL PRACTICE GUIDE UPDATE (2018), [https://www.uspto.gov/sites/default/files/documents/2018\\_Revised\\_Trial\\_Practice\\_Guide.pdf](https://www.uspto.gov/sites/default/files/documents/2018_Revised_Trial_Practice_Guide.pdf) [<https://perma.cc/NG4B-49GG>].

7. *Id.*

8. See ANDREW F. POPPER, GWENDOLYN M. MCKEE, ANTHONY E. VARONA, PHILIP J. HATER, MARK C. NILES & FRANK A. PASQUALE, *ADMINISTRATIVE LAW: A CONTEMPORARY APPROACH* 72 (3d ed. 2010).

9. See, e.g., Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756 (Aug. 14, 2012) (to be codified at 37 C.F.R. § 42); Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018); see also *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S.Ct. 1365 (2018) (declaring the AIA constitutional); *SAS Inst., LLC v. Iancu*, 138 S.Ct. 1348 (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131 (2016).

10. This section will also introduce and analyze the PTO's compliance with the Paperwork Reduction Act of 1995, and Executive Orders 12,866 and 13,771, all of which would apply if the TPG were deemed substantive. See Paperwork Reduction Act of 1995, 44 U.S.C. §§ 3501–3521 (2018); Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sept. 30, 1993); Exec. Order No. 13,771, 82 Fed. Reg. 9,339 (Jan. 30, 2017).

## PART I: THE RISE OF THE ADMINISTRATIVE STATE

Administrative agencies, such as the Environmental Protection Agency (EPA)<sup>11</sup> and Food and Drug Administration (FDA),<sup>12</sup> are governmental entities that do the day-in, day-out work of government; they carry out Congress' legislation and its wishes,<sup>13</sup> monitoring and ensuring the safety and security of the everyday lives of Americans.<sup>14</sup> Administrative agencies were largely formed in response to a series of crises caused by the unregulated rise of industry in the 19th Century,<sup>15</sup> though scholars and political commentators often assume they are products of the Franklin Delano Roosevelt Administration and the New Deal of the 1940s.<sup>16</sup> The large-scale social and economic problems caused by the rise of industry were not easily

11. See Richard N. L. Andrews, *The EPA at 40: An Historical Perspective*, 21 DUKE ENV'T. L. & POL'Y F. 223, 228 (2011) (detailing the history of the EPA and its creation by executive fiat under the Nixon administration, noting "the EPA was thus created simply by pulling into one new agency an array of environmental health regulatory and technical assistance functions, and their associated statutory authorities, that were previously spread across multiple existing agencies.").

12. Originally the Food, Drug, and Insecticide Administration, it was expanded and reorganized in 1938 in largely modern form, though other forms and bodies of regulation predate it. See Federal Food, Drug, & Cosmetic Act (FDCA), Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

13. See Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2255 (2001) ("Congress, of course, must delegate certain tasks relating to the implementation of these laws to the administration . . ." and Congress does so when it "delegates specifically and clearly to administrative agencies" via legislation.).

14. See Lawrence M. Friedman, *Legal Rules and the Process of Social Change*, 19 STAN. L. REV. 786, 793 (1967) (noting that "in the development of American labor law, factory regulation began with vague general rules requiring employers to maintain a 'safe' place to work; these rules were fitfully enforced through the medium of tort law when employees sued for personal injury damages and complained that the employers had failed in their safe-place duty[.] until "factory regulation was vested in an administrative agency . . .").

15. See Mark Fenster, *The Birth of A "Logical System": Thurman Arnold and the Making of Modern Administrative Law*, 84 OR. L. REV. 69, 75 (2005) (citing WILLIAM J. NOVAK, *THE PEOPLE'S WELFARE: LAW AND REGULATION IN NINETEENTH-CENTURY AMERICA* (1996)) ("Significant federal statutory mandates for regulatory programs whose implementation was overseen by administrative agencies (as well as myriad state regulatory agencies overseeing state programs) had been in place since the late nineteenth century during the Populist and Progressive Eras."); Jonathan Stroud, *The Illusion of Interchangeability: The Benefits And Dangers Of Guidance-Plus Rulemaking In The FDA'S Biosimilar Approval Process*, 63 ADMIN. L. REV. 599, 608 (2011) (citing FRAN HAWTHORNE, *INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT* 36 (2005)) (noting that "small patent medicine makers rushed to produce . . . products that often had little or no effect, or were in fact harmful to consumers' health"); cf. Eric A. Posner & Adrian Vermeule, *Crisis Governance in the Administrative State: 9/11 and the Financial Meltdown of 2008*, 76 U. CHI. L. REV. 1613, 1614 (2009) ("Broad political processes and constraints . . . create a generally similar pattern of crisis governance and emergency lawmaking . . . . In the modern administrative state, it is practically inevitable that legislators, judges, and the public will entrust the executive branch with sweeping power to manage serious crises . . ."); see generally ROBERT H. WIEBE, *THE SEARCH FOR ORDER, 1877-1920* (1967)).

16. See, e.g., Sandra B. Zellmer, *The Devil, the Details, and the Dawn of the 21st Century Administrative State: Beyond the New Deal*, 32 ARIZ. ST. L.J. 941, 942 (2000) ("More than half a century has passed since the New Deal, the era known for ushering in the modern administrative state, where broad-sweeping regulatory powers were delegated to over a dozen new executive agencies pursuant to a raft of social legislation.").

addressed by common or state law,<sup>17</sup> and the Congress and the Federal government were too slow and removed to effectively police the grosser excesses of industry.<sup>18</sup> By the turn of the 20th Century, these problems included everything from people being injured and killed by unsafe workplace conditions, dangerous products, and patent medicines to market inefficiencies caused by the formation of monopolies, cartels, and trusts that stifled competition.<sup>19</sup> Administrative agencies were created to solve these problems by actively regulating industry and proactively anticipating and preventing future problems from coming into existence in the first place.<sup>20</sup>

Agencies are necessary to properly regulate industry.<sup>21</sup> Congress, on its own, was, and still remains, ill-equipped to articulate with great detail or precision all the standards with which the public must comply. Furthermore, as technology and industry evolve, rules and legal standards must adapt to accommodate changes. Legislators also generally lack the technical expertise to police certain technical subject matters themselves,<sup>22</sup> like patent applications, drug approvals, or complex financial regulations. The legislative process is not designed to address these daily demands. Rather, Congress relies upon the expertise of agency officials to create detailed regulatory standards that can be updated when necessary.

### 1. Administrative Rulemaking Authority<sup>23</sup>

Due process protections are used to ease concerns for administrative agency accountability. Due process protections became attached to rulemaking first through the common law, then, at the federal level, through the Administrative Procedure Act (APA).<sup>24</sup> In 1908, the Supreme Court addressed the issue of due process protection in rulemaking by a non-legislative governmental body in *Londoner v. City & County of Denver*.<sup>25</sup> There, the Court found that due process violations arose when a subordinate body—delegated authority by the state legislature to set taxes—failed to

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17. Stroud, *supra* note 15, at 608 (noting “the regulation of drugs was widely thought to be a state law matter, and states were reluctant to spend money on something that was widely perceived as encroaching on personal liberties.”).

18. See *supra* note 12 and accompanying text.

19. Stroud, *supra* note 15, at 608 (citing Linda Bren, *The Road to the Biotech Revolution: Highlights of 100 Years of Biologics Regulation*, FDA CONSUMER MAG., Jan.-Feb. 2006, at 50–51 (“Without regulation of the sources of these treatments, mislabeling, fraud, and deaths were inevitable. For instance, in 1901 thirteen children died from tetanus. . . . a similar tragedy occurred in New Jersey around the same time—nine children died from tetanus after receiving a contaminated smallpox vaccine.”)).

20. For an authoritative historical review of roughly a century of administrative law, see Robert Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189, 1193 (1986) (reviewing a “century of regulatory expansion”).

21. See Emily Hammond, *Double Deference in Administrative Law*, 116 COLUM. L. REV. 1705, 1706 (2016) (describing a tradition of creating self-regulating organizations for industry while noting that “[a]dministrative law’s familiar narrative contemplates that agencies, empowered by their statutory mandates, carry out their delegated duties subject to the check of judicial review and political oversight”).

22. See Kagan, *supra* note 13, at 2261 (“The need for expertise emerged as the dominant justification for this enhanced bureaucratic power.”).

23. For an excellent review of these administrative law principles, see generally TODD GARVEY, CONG. RESEARCH SERV., A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW (2017), [hereinafter GARVEY].

24. Administrative Procedure Act of 1946, Pub. L. No. 79–404, 60 Stat. 237.

25. 210 U.S. 373 (1908).

(1) give proper notice to prospective taxpayers and (2) hold a hearing for those prospective taxpayers to give them an opportunity to be heard before the tax was irrevocably fixed.<sup>26</sup>

In 1946, the ruling in *Londoner* was made federal law when, after a decade of consideration by Congress, the APA was enacted.<sup>27</sup> The APA governs the ways in which federal administrative agencies must propose and establish regulations. The APA requires agencies to give notice of proposed rulemaking and give interested persons an opportunity to participate in the rulemaking.<sup>28</sup>

Thus, when delegated authority by Congress, federal agencies can impose substantive regulations that have the force and effect of binding law.<sup>29</sup> They must do so, however, subject to the umbrella safeguards of the APA, primarily to avoid abuse of their delegated authority (and to protect the citizens' due process rights).<sup>30</sup> Rules enacted through formal and informal rulemaking pursuant to that delegated authority are generally recognized as having the force and effect of law.<sup>31</sup> In contrast, agency guidance documents are not afforded the same weight, do not equally protect individual rights, and are considered optional. Thus, they are afforded little deference on appeal.<sup>32</sup> When enacting new rules through informal rulemaking, agencies must follow the procedural safeguards that Congress and the Courts have together established and interpreted—safeguards that allow the regulated industry, individuals, and other stakeholders to receive advance notice of the regulations, and to participate in formulating those regulations, before the individuals are bound by them.<sup>33</sup> To ensure the public is informed on how the agency plans to enforce these rules, the agency will often release generalized guidance documents explaining their planned execution and implementation of their binding rules, and guiding the public on how best to comply. These documents cannot and should not dictate parties' behavior as they should not have the "force and effect of law."<sup>34</sup>

The category of rulemaking an agency must use to promulgate a rule is determined by its type: substantive, procedural, or interpretive.<sup>35</sup> If the agency's rule

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26. *Id.* at 386.

27. H.R. REP. NO. 79-1980, at 233 (1946).

28. Administrative Procedure Act, 5 U.S.C. § 553(b)-(c).

29. *See generally*, Administrative Procedure Act, ch. 324, 60 Stat. 237 (1946), *repealed and replaced by* Pub. L. No. 89-554 (codified as 5 U.S.C. §§ 551-59).

30. Administrative Procedure Act, 5 U.S.C. §§ 551-59.

31. *Id.* (introducing the force of law given to rules promulgated through agency rulemaking).

32. *See* Exec. Order No. 13892, 84 Fed. Reg. 55, 239 (Oct. 9, 2019) (revoked by Exec. Order No. 13992, 86 Fed. Reg. 7,049 (Jan. 20, 2021)). Guidance documents are not held open to the public and are, therefore, not given precedential weight. Formal rulemaking is a cumbersome process largely abandoned by modern administrative agencies and is beyond the scope of this comment.

33. Doing so ensures the appropriate level of the public's Constitutionally safeguarded due process rights to notice and an opportunity to be heard before their government can adopt binding rules that have the force and effect of law. *See* 5 U.S.C. § 553(b) (outlining the requirements for notice-and-comment rulemaking).

34. *See* Stroud, *supra* note 15, at 629 (2011) (noting that the guidance documents are an agency's way of putting the public on notice of their intended interpretation of the law, but not offering a binding precedent to be followed by the public).

35. *See* Nat'l Org. of Veterans' Advocs. v. Sec'y of Veterans Affs., 260 F.3d 1365, 1374 (Fed. Cir. 2001) (holding that failure to allow notice and comment, where required, is grounds for invalidating a substantive rule), *superseded by regulation*, 38 C.F.R. § 20.1106, *recognized in* *Moffitt v. Shinseki*, 26

involves, affects, or creates an individual right or obligation, it is a substantive rule.<sup>36</sup> If the agency's rule solely governs the administration of the agency or outlines how an adjudication will operate, it is a procedural rule.<sup>37</sup> If the agency's rule clarifies an existing rule and does not create a new right or duty, it is an interpretive rule.<sup>38</sup> Rules do not always fit into a single type; they can affect one another and make a rule of one type look more like another type.<sup>39</sup> The APA requires agencies to promulgate substantive rules through informal or formal rulemaking, whereas procedural and interpretive rules can be issued using other means.<sup>40</sup>

Agency rulemaking can generally be broken into four process categories: formal rulemaking, informal rulemaking, guidance documents, and internal policy documents.<sup>41</sup> Formal and informal rulemaking are given the force and effect of law and are recognized as binding precedent.<sup>42</sup> Guidance documents can be precedential, but the APA does not explicitly grant them that weight, as they are implemented without being subject to public review.<sup>43</sup>

It is worth noting that most agencies have abandoned formal rulemaking as ossified beyond usefulness—i.e., as being procedurally too onerous to observe practically.<sup>44</sup> Congressional intent distinguishes formal and informal rulemaking.<sup>45</sup> Formal rulemaking is required when Congress explicitly requires the agency to promulgate rules in a trial-like hearing.<sup>46</sup> Informal rulemaking, on the other hand, governs procedures for when an agency independently decides to promulgate a rule.<sup>47</sup> In this informal “notice-and-comment” rulemaking, the agency must provide notice of proposed rulemaking to the public in the Federal Register, give the public an opportunity to comment on it before the rule is issued, and provide a concise statement of basis and purpose of the final rule before it is promulgated.<sup>48</sup> There is no requirement that the final rule be identical to the proposed rule—indeed, it is better if it conforms to the public's input and responds to their concerns—as long as there is some logical connection or “logical outgrowth” from the notice of proposed

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Vet. App. 424, 428 (2014); *see also* Am. Hosp. Assoc. v. Bowen, 834 F.2d 1037 (D.C. Cir. 1987) (providing exceptions to the notice and comment requirement).

36. *Nat'l Org. of Veterans' Advocs.*, 260 F.3d at 1365.

37. *Am. Hosp. Assoc.*, 834 F.2d at 1037 (defining procedural rules).

38. *Nat'l Org. of Veterans' Advocs.*, 260 F.3d at 1365.

39. For example, a procedural rule that makes a case outcome determinative, thus affecting a substantive right, making the rule look more substantive instead of procedural. *Id.*

40. *See* 5 U.S.C. § 553(d).

41. Internal policy documents have less authority than guidance documents and are not within the scope of this comment. *See* POPPER, *supra* note 8, at 72.

42. *Id.*

43. Administrative agencies have the ability to produce guidance to give the public notice on the internal expectations of statutory interpretation, but these guidance documents are not afforded the force and effect of law because of the absence of public contribution. *Id.*

44. *Id.*

45. *See* *City of West Chi. v. U.S. Nuclear Regul. Comm'n*, 701 F.2d 632, 644–45 (7th Cir. 1983).

46. 5 U.S.C. § 553(d); *see also* POPPER, *supra* note 8, at 66.

47. Informal rulemaking is typically known as notice-and-comment rulemaking. 5 U.S.C. § 553(b).

48. *Id.* (outlining the requirements for notice-and-comment rulemaking).

rulemaking.<sup>49</sup> Agencies prefer informal rulemaking because they can control the process closely and give the public notice of the new rule; formal rulemaking is generally considered too burdensome and inefficient today to be a useful mechanism of regulation.<sup>50</sup>

Guidance documents give general statements that “advise the public on how the agency proposes to exercise discretion or interpret law.”<sup>51</sup> An agency guidance document can be binding in some respects if it is either a “general statement of policy” (a.k.a., policy statement) or an interpretative rule of general applicability formulated and adopted by the agency (a.k.a., interpretive rule) that was published in the Federal Register.<sup>52</sup> Policy statements are advisory statements issued by the agency to inform the public of the agency’s intent to enforce the policy, while interpretive rules are advisory statements issued by the agency to inform the public of the agency’s interpretation of the rules and statutes that they issue.<sup>53</sup> Of course, Congress can require more or less procedure for any particular agency procedure, and can abrogate (or enhance) parts of the APA requirements whenever it sees fit.<sup>54</sup>

When agencies impose regulations that officially bind the agency and public (known as legislative rules), there are safeguards in place for how they do it—mainly the expensive, time-consuming processes of the APA, including notice-and-comment rulemaking, in which the parties who will be bound by a policy can participate in its formulation before it is set in stone.<sup>55</sup> By contrast, agencies can issue guidance or policy documents without any such process, because of the APA’s exemptions for “general statements of policy” and “interpretative rules,” which together cover guidance in all its forms.<sup>56</sup> Guidance or policy is merely a suggestive announcement of the agency’s current thinking about how to proceed in individual proceedings, not something the agency will follow in an automatic, ironclad manner as it would a legislative rule.<sup>57</sup> Guidance should leave space for the regulated party to argue for flexible treatment and for officials to be open to that argument.<sup>58</sup> It typically encompasses procedural and interpretive rules, and can vary from how administrative judges should interpret a law to changes in approval procedures,

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49. See *Chocolate Mfrs. Ass’n of U.S. v. Block*, 755 F.2d 1098, 1103–05 (4th Cir. 1985) (“There is no question that an agency may promulgate a final rule that differs in some particulars from its proposal.”).

50. Formal rulemaking is ossified and has been largely abandoned; most laws do not require it anymore. Aaron L. Nielson, *IN DEFENSE OF FORMAL RULEMAKING*, 75 OHIO ST. L.J. 237, 246 (2014).

51. Nicholas R. Parrillo, *Should the Public Get to Participate Before Federal Agencies Issue Guidance? An Empirical Study*, 71 ADMIN. L. REV. 57, 59 (2019).

52. 5 U.S.C. §§ 552(a)(1)(D), 553(b)(A). This is sometimes referred to as “guidance plus” rulemaking; i.e., guidance documents that nonetheless observe some—but not all—of the procedural safeguards of full informal notice-and-comment rulemaking. See Stroud, *supra* note 15, at 630 (discussing “Good Guidance Practices” at the FDA and “guidance plus” at the FDA requiring further public input).

53. See Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 168 (2000).

54. Stroud, *supra* note 15, at 630.

55. See *generally id.* at 628–33 (describing the various avenues of agency rulemaking).

56. 5 U.S.C. § 553(b)(A) (2018).

57. See Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 383–84, 388 (1985).

58. *Id.* at 388.

depending on the agency.<sup>59</sup> This is a viable, efficient form of policymaking, but Congress, and by extension the APA, did not intend for guidance documents to be binding.<sup>60</sup> Scholars have observed that agencies may be employing guidance documents to circumvent the cumbersome procedural safeguards other avenues provide.

## 2. Judicial Review of Agency Action

*“You must not pay too much attention to opinions. The written word is unalterable, and opinions are often only an expression of despair.”<sup>61</sup>*

Discussions, scholarship, and instruction on the doctrines of judicial deference to agency action, criticism of it, and countercriticism thereof, is well-trod ground and we will not bore readers with a lengthy review of it.<sup>62</sup> Suffice it to say that *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,<sup>63</sup> and its companions *Auer v. Robbins*,<sup>64</sup> *United States v. Mead Corp.*,<sup>65</sup> *National Cable & Telecommunications Ass’n v. Brand X Internet Services*,<sup>66</sup> *Skidmore v. Swift & Co.*,<sup>67</sup> all denote when and how an Article III court can or should defer to an agency—or when review should be more searching. Importantly, however, most of these doctrines recognize that to obtain any form of judicial deference, rules must be properly implemented via notice-and-comment rulemaking, thereby attaining the force and effect of law. It is relatively common, nonetheless, for significant agency action to be miscast as a guidance document—as Stroud has noted, “guidance

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59. When an agency publishes an order as precedential or uses it to create an intra-agency common law, it is issuing an interpretive rule. See David L. Cavanaugh & Jonathan R. Stroud, *Precedent, Persuasion, and the PTAB*, 8 LANDSLIDE MAG., Mar. & Apr. 2016; see also PATENT TRIAL & APPEAL BD., STANDARD OPERATING PROCEDURE 2, PUBLICATION OF OPINIONS AND DESIGNATION OF OPINIONS AS PRECEDENTIAL, INFORMATIVE, REPRESENTATIVE, AND ROUTINE, <https://www.uspto.gov/sites/default/files/documents/sop2-revision-9-dated-9-22-2014.pdf> [<https://perma.cc/BLF2-XUAL>]

60. The efficiency provided by guidance documents is attractive for agencies to be able to inform the public of statutory interpretation, but because of the lack of public notice they are not afforded the force and effect of law. See generally Sarah Tran, *Patent Powers*, 25 HARV. J. L. & TECH. 609, 658–59 (2012).

61. Cf. FRANZ KAFKA, *THE TRIAL* 260 (1925).

62. Scholarship on these doctrines is legion—it seems every administrative law professor’s rite of passage to comment on their interplay, and even meta-studies of the studies are plentiful. See, e.g., Michael P. Healy, *The Past, Present and Future of Auer Deference: Mead, Form and Function in Judicial Review of Agency Interpretations of Regulations*, 62 U. KAN. L. REV. 633 (2014); John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 COLUM. L. REV. 612 (1996); Kevin M. Stack, *Interpreting Regulations*, 111 MICH. L. REV. 355 (2012); Bradley George Hubbard, Comment, *Deference to Agency Statutory Interpretations First Advanced in Litigation? The Chevron Two-Step and the Skidmore Shuffle*, 80 U. CHI. L. REV. 447 (2013); Connor N. Raso & William N. Eskridge, Jr., *Chevron as a Canon, Not a Precedent: An Empirical Study of What Motivates Justices in Agency Deference Cases*, 110 COLUM. L. REV. 1727 (2010); Christopher J. Walker, *Attacking Auer and Chevron Deference: A Literature Review*, 16 GEO. J.L. & PUB. POL’y 103 (2018).

63. 467 U.S. 837 (1984).

64. 519 U.S. 452 (1997).

65. 533 U.S. 218 (2001).

66. 545 U.S. 967, 982–83 (2005).

67. 323 U.S. 134 (1944).

documents may claim to lack the force and effect of law but may *de facto* have significant legal impact.”<sup>68</sup> If they do not use and comply with notice and comment, at best they are afforded *Skidmore* respect in judicial review, which is at bottom a *de novo* review—a searching look at whether the agency pronouncement has any basis in law or is even reasonable, or if the Courts would have ruled differently. Such guidance documents and policy statements would also not bind the parties—and an agency suggesting they do, relying on them, or forcing parties into a particular posture based on them would run afoul of the Court’s review and risk widespread reversal.<sup>69</sup>

### 3. Is the USPTO an Administrative Agency or a Clerical Office?

*“There are no conditions to which a man cannot become used, especially if he sees that all around him are living in the same way.”*<sup>70</sup>

The USPTO has sometimes been treated by its reviewing court as an administrative law anomaly.<sup>71</sup> The Federal Circuit Court of Appeals, the federal appellate court with jurisdiction over virtually all appeals related to patents, has held that the USPTO has only procedural rulemaking powers.<sup>72</sup> In the 1996 case *Merck & Co. v. Kessler*, the Federal Circuit stripped the USPTO of substantive rulemaking powers, ruling that the Commissioner of the USPTO has authority “to promulgate regulations directed only to ‘the conduct of proceedings in the [PTO]’; it does not grant the Commissioner the authority to issue substantive rules.”<sup>73</sup> The Supreme Court has never reviewed the Federal Circuit on that point—until *Cuozzo*, as discussed below.

Yet, even as Congress regularly expanded the USPTO’s responsibility, scope, size, and rulemaking authority with various acts and procedures, and as the fee-driven Office ballooned in workforce, output, revenue, budget, and economic impact, the Federal Circuit continued to apply a substantive restriction on the USPTO’s authority. When *Merck* was decided, the USPTO was operating primarily under the authority of the Patent Act of 1952, in which Congress granted the USPTO powers “for the conduct of proceedings in the Patent Office”<sup>74</sup> and rules “governing the recognition and conduct” of patent practitioners.<sup>75</sup> In 1999, Congress passed the American Inventors Protection Act; in it, they added to the USPTO’s list of specific rulemaking powers and responsibility, including the addition of rulemaking for a

68. Stroud, *supra* note 15, at 628.

69. See Gwendolyn McKee, *Judicial Review of Agency Guidance Documents: Rethinking the Finality Doctrine*, 60 ADMIN. L. REV. 371, 372 (2008) (“Agencies increasingly issue guidance documents . . . in lieu of engaging in the more costly, and binding, informal rulemaking process that ultimately affords regulatees with opportunities for judicial review.”).

70. LEO TOLSTOY, ANNA KARENINA 1667 (Constance Garnett trans., The Floating Press 2008) (1877).

71. See *supra* note 2.

72. See discussion *infra* Part IV and accompanying text and notes.

73. 80 F.3d 1543, 1549–50 (quoting *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991)).

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

75. *Id.* at § 31.

new proceeding called “*inter partes* reexamination.”<sup>76</sup> As part of the American Inventors Protection Act, Congress also amended 35 U.S.C. § 2(b)(2)(B), requiring the USPTO’s rulemaking to be in accordance with § 553 of the APA, which articulates the procedure that agencies must follow when making substantive rules.<sup>77</sup> This was a clear indicator that Congress intended for the USPTO to have substantive rulemaking power; but USPTO’s rulemaking practice did not significantly change.

The Federal Circuit also took little notice, continuing to deny the USPTO had any substantive rulemaking power; it struggled to clearly delineate the line between substantive and procedural rulemaking. This struggle was most clearly expressed in *Tafas v. Doll*, where each Federal Circuit panel judge expressed conflicting views over what makes a rule substantive or procedural and even whether the rule at issue in the case was substantive or procedural.<sup>78</sup> After the *Tafas* decision issued, the Department of Commerce and the USPTO Director pushed Congress to explicitly give the USPTO substantive rulemaking authority.<sup>79</sup> Since then, the battle has raged on and extended all the way up to the Supreme Court.

## PART II: THE USPTO/PTAB AND THE PTAB TRIAL PRACTICE GUIDE

Amid that confusion, in 2011 Congress enacted the America Invents Act (AIA), the most sweeping reforms and expansions of substantive rulemaking authority for USPTO since the 1952 Act; among other things, it rechristened the old Board of Patent Appeal and Interference the Patent Trial and Appeal Board (PTAB) and expanded its authority as the primary adjudicative body for patent post-issuance reviews.<sup>80</sup> The PTAB is a panel of technically trained administrative judges that hear appeals from patent applicants and challenges to existing patents and can render decisions that are appealable to the U.S. Court of Appeals for the Federal Circuit, and thus up to the Supreme Court of the United States.<sup>81</sup> The AIA also vastly expanded the policymaking powers of the USPTO by, among other things, allowing it to promulgate sweeping rules governing proceedings in the PTAB.<sup>82</sup> It gave the USPTO explicit authority to guide patent law standards.<sup>83</sup> The AIA granted the USPTO authority to articulate substantive standards and prescribe regulations for several new proceedings, including *inter partes* review,<sup>84</sup> derivation proceedings,<sup>85</sup>

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76. American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 311, 113 Stat. 1501A-552–67.

77. See 5 U.S.C. § 553 (2018) (outlining the rule making procedures under the APA).

78. 559 F.3d 1345 (Fed. Cir. 2009).

79. Letter from Gary Locke, Sec’y of Com., U.S. Dep’t of Com., 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 (Oct. 5, 2009), at 3.

80. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6, 125 Stat. 284, 313–14 (2011) (enacting the PTAB and describing its formation, duties, and procedures).

81. See generally 35 U.S.C. § 6 (2018) (describing the appointment of the administrative patent judges and the appeal process); Walker & Wasserman, *supra* note 5 (describing and analyzing PTAB adjudication within administrative law’s larger landscape of agency adjudication).

82. See Walker & Wasserman, *supra* note 5, at 181–82.

83. See § 31, 125 Stat. at 338–39.

84. See § 6, 125 Stat. at 301

85. See § 3, 125 Stat. at 289.

and post-grant review.<sup>86</sup> The AIA distinguished between “setting forth standards” as it was now doing, “and procedures,”<sup>87</sup> as it had done in the past.

The PTAB continues to hear appeals regarding patent applications, appeals from *ex parte* reexaminations, and hears three additional types of post-grant proceedings created by the AIA: post-grant review, *inter partes* review (IPR), and transitional covered business method post-grant review.<sup>88</sup> The procedural differences in these proceedings have made them favorable for the different objectives of third parties.<sup>89</sup> To date, there have been more than 11,000 petitions to the PTAB since the creation of the proceedings, with over 5,000 trials instituted—roughly 60%.<sup>90</sup> Of the approximately 3,000 written final decisions of those instituted proceedings, 63%, or about 1,900, have found all challenged claims unpatentable, which shows both that frivolous patent claims are being cancelled, and also that roughly two-thirds of all challenges fail on the merits, either at institution or at final written decision.<sup>91</sup>

### 1. The PTAB in the Supreme Court

The surprising speed, effectiveness, and popularity of these proceedings have already led PTAB decisions to be appealed to the Supreme Court three times in its first six years of existence.<sup>92</sup> But what sort of rulemaking authority does the USPTO have over them, and what does that authority require? To answer that question, we must look to the holding of the 2016 case, *Cuozzo*, which recognized that AIA granted substantive rulemaking authority to the USPTO.<sup>93</sup> Also, in the 2018 Supreme Court case, *Oil States v. Greene’s Energy Group*, the Court held that the PTAB does not violate Constitutional separation of powers concerns when it administratively reviews patentability post-issuance; and the companion *SAS Institute, LLC v. Iancu*—decided the same day—held that the USPTO lacked the ability to promulgate a regulation inconsistent on its face with the governing statute.<sup>94</sup>

In *Cuozzo*, the earliest of the three, the Supreme Court considered, as a preliminary question, whether the USPTO had the power to promulgate a rule that

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86. See § 6, 125 Stat. at 308–09.

87. See § 6, 125 Stat. at 302.

88. These third-party challenges of patents are not without precedent; they replaced *inter partes* reexamination and are a supplement to *ex parte* reexamination. The previous avenues for post-grant review were both less adversarial in nature, and had fewer streamlining procedural constraints, such as the one-year statutory requirement for completion. 35 U.S.C. §§ 314–25.

89. Such as the requirement to file a PGR within nine months of issuance of a patent and the ability to file an IPR only after nine months or the expiration of a PGR. See Tran, *supra* note 60, at 631–37.

90. PAT. TRIAL & APPEALS BD., TRIAL STATISTICS, at 10 (Jan. 2020), [https://www.uspto.gov/sites/default/files/documents/trial\\_statistics\\_01312020.pdf](https://www.uspto.gov/sites/default/files/documents/trial_statistics_01312020.pdf) [<https://perma.cc/M55D-3SXH>].

91. *Id.* at 11.

92. See *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S.Ct. 1365 (2018) (declaring the AIA constitutional); *SAS Inst., LLC v. Iancu*, 138 S.Ct. 1348 (2018) (stating that § 318 does not provide the Director partial institution power); *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131 (2016) (establishing the USPTO has the power to promulgate substantive rules).

93. *Cuozzo*, 136 S.Ct. at 2142.

94. See *Oil States*, 138 S.Ct. at 1370; *SAS Institute*, 138 S.Ct. at 1352–53.

concerned the standard of review during an IPR.<sup>95</sup> The Court held that 35 U.S.C. § 316(a)(4) provides for the USPTO to issue “regulations . . . establishing and governing inter partes review . . . ,” giving the USPTO the power to promulgate substantive rules.<sup>96</sup> It found explicitly that the claim construction standard regulation it had then issued was a substantive rule. It is worth noting that the substantive rules allowed by § 316 may only be issued regarding the establishment and governance of IPR, and are not related to substantive patent law, such as 35 U.S.C. § 101.<sup>97</sup>

In the second case, *Oil States*, the Supreme Court declared that even though IPR proceedings are somewhat adjudicative in nature, patent rights—limited in both time and scope, and granted solely by the Federal government—are more akin to franchise rights than other forms of common-law rights, and thus, PTAB proceedings do not run afoul of separation of powers concerns.<sup>98</sup> Put simply, Congress can delegate to entities other than Article III courts the ability to adjudicate these types of federally granted rights.<sup>99</sup> Hence, IPRs fall squarely on one side of the public/private rights doctrine, as the decision to grant a patent is a matter involving so-called public rights.<sup>100</sup>

In the third case, *SAS Institute, Inc.*—heard and decided the same day as *Oil States*—the Supreme Court considered whether deference should apply to regulations promulgated by the Director of the USPTO.<sup>101</sup> While the Court dodged the ultimate issue of agency deference, a 5–4 majority of the Court reversed the PTAB’s interpretation of their governing statute, and held that the PTAB must issue a decision on all challenged claims and that the director cannot partially institute petitions, thus limiting the authority of a Director to guide the PTAB via *ultra vires* regulation.<sup>102</sup>

## 2. The Trial Practice Guide

In 2011, the AIA set forth considerations for USPTO’s new patent review proceedings, and asked the Director (or, one assumes, their workaday delegates) to promulgate rules governing those proceedings.<sup>103</sup> These concerns prompted USPTO to publish a series of proposed rules and request public comments regarding the substantive and procedural aspects of the then-new proceedings.<sup>104</sup> The original TPG

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95. See *Cuozzo*, 136 S.Ct. at 2136.

96. *Id.* (quoting 35 U.S.C. § 316(a)(4)).

97. See 35 U.S.C. § 316, which does not allow the USPTO to promulgate substantive rules that could define subject matter under § 101 or enablement under § 112. 35 U.S.C. § 316(a)(4).

98. See *Oil States*, 138 S.Ct. at 1370 (declaring the AIA constitutional).

99. See *Exec. Benefits Ins. Agency v. Arkison*, 134 S.Ct. 2165 (2014).

100. Judicial precedent recognizes that the decision to grant a patent is a matter involving public rights, specifically, the grant of a public franchise. *Oil States*, 138 S.Ct. at 1373. It follows that Congress secures inventors the exclusive right to their discoveries. *United States v. Duell*, 172 U.S. 576, 583 (1899).

101. *SAS Inst. Inc. v. Iancu*, 138 S.Ct. 1348, 1358 (2018).

102. *Id.* at 1353.

103. See 35 U.S.C. §§ 316(b), 326(b).

104. See, e.g., Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 Fed. Reg. 6879 (proposed Feb. 9, 2012) (to be codified at 37 C.F.R. §§ 42, 90); Changes to Implement *Inter Partes* Review Proceedings, 77 Fed. Reg. 7041 (proposed Feb. 10, 2012) (to be codified at 37 C.F.R. § 42); Changes to Implement Post-Grant

was created in parallel to govern the procedures of the PTAB, laid out timelines, briefing schedules, and other details, and has since been revised and updated by the USPTO via the Federal Register.<sup>105</sup> It was intended to apprise the public of standard practices before PTAB during AIA trial proceedings, including IPR, Post-Grant Review, Covered Business Method Post-Grant Review, and derivation proceedings, and included detailed procedural rules for how contested proceedings should be administered.<sup>106</sup> The TPG was also envisioned to encourage consistency of procedures among panels of the PTAB.<sup>107</sup>

The 2012 TPG was nominally held open for notice and comment;<sup>108</sup> the USPTO published the original TPG in the Federal Register concurrently with the promulgation of the AIA, but not itself as a notice of proposed rulemaking.<sup>109</sup> “The TPG was intended to inform the public of standard practices during AIA trials before the [PTAB] and encourage consistency of procedures among panels of the [PTAB],” and also lay out detailed briefing schedules and proposed discovery and evidentiary rules governing the procedure.<sup>110</sup> It was published in large part to provide guidance on the general framework and structure of the PTAB proceedings.<sup>111</sup> It did not suggest the rule was economically significant (as required by multiple Executive Orders, *see infra* note 190 and accompanying text) and did not seek to comply with the Paperwork Reduction Act of 1995 (PRA).

The USPTO received 251 public comments both supporting and opposing the original proposed rules package, which at the time was considered substantial.<sup>112</sup> Comments received covered a wide range of substantive subject matter affecting users’ legal rights, including proposed page limits, discovery requirements, and video testimony.<sup>113</sup> After considering the comments, the USPTO modified the rules to provide clarity and to balance the interests of the public, patent owners, and patent challengers in light of the statutory requirements and considerations presented in the comments.<sup>114</sup> Final rules were published in August 2012, along with the USPTO

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Review Proceedings, 77 Fed. Reg. 7060 (proposed Feb. 10, 2012) (to be codified at 37 C.F.R. § 42); Changes to Implement Transitional Program for Covered Business Method Patents, 77 Fed. Reg. 7080 (proposed Feb. 10, 2012) (to be codified at 37 C.F.R. § 42); Transitional Program for Covered Business Method Patents—Definition of Technological Invention, 77 Fed. Reg. 7095 (proposed Feb. 10, 2012) (to be codified at 37 C.F.R. § 42).

105. *See, e.g.*, Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756 (Aug. 14, 2012) (to be codified at 37 C.F.R. § 42); Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018).

106. PAT. TRIAL & APPEAL BD., *supra* note 6.

107. *Id.*

108. Practice Guide for Proposed Trial Rules, 77 Fed. Reg. 6868 (Feb. 9, 2012) (to be codified at 37 C.F.R. § 42).

109. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756; Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 317–18 (2011).

110. USPTO, *PTAB Trial Practice Guide Update* (Aug. 2018), <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/ptab-trial-practice-guide-august-2018> [<https://perma.cc/C7M6-TSC9>].

111. Practice Guide for Proposed Trial Rules, 77 Fed. Reg. at 6868.

112. Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,756.

113. Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 Fed. Reg. 48,612, 48612 (Aug. 14, 2012).

114. *Id.*

responses to the comments and the explanations for the changes made that justified its position for maintaining the rules.<sup>115</sup>

The TPG was again updated in 2015, though not via notice and comment rulemaking.<sup>116</sup> In June 2014, the USPTO asked for a general, open-ended public comment on how the AIA proceedings were working under the TPG.<sup>117</sup> The PTAB reviewed thirty-seven comments regarding all PTAB procedures with the intentions of improving them, especially for the patent owners.<sup>118</sup> The USPTO announced a three-part plan to revise and improve the PTAB proceedings on March 27, 2015, based on the generalized comments they received.<sup>119</sup> The first part of the revision, effective immediately upon announcement, was called the Director's "quick-fixes."<sup>120</sup> One of the most attractive and impactful procedural aspects of these quick fixes for patent owners was an increase to the page limits for certain briefs and motions.<sup>121</sup> These changes were not put into the Federal Register at the time. The second part of the revision was a proposed rule package in the Federal Register later that year.<sup>122</sup> The USPTO received twenty-eight comments on the August 2015 proposal to the rules of practice and in response, considered and implemented more significant modifications to the proceedings.<sup>123</sup> In April 2016, the USPTO released the Update as a final rule and addressed all comments received from the public pursuant to APA requirements.<sup>124</sup>

In August 2018, the USPTO again updated the TPG, but this time only published a notice in the Federal Register, without accepting or soliciting any public comment.<sup>125</sup> The 2018 Update was published, according to the USPTO, to provide updated guidance to the public on standard practices before the PTAB in the post-

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115. *See id.*

116. *See* Michelle K. Lee, *PTAB's Quick-Fixes for AIA Rules Are to Be Implemented Immediately*, USPTO: DIRECTOR'S F.: A BLOG FROM USPTO'S LEADERSHIP (Mar. 27, 2015), [https://www.uspto.gov/blog/director/entry/ptab\\_s\\_quick\\_fixes\\_for](https://www.uspto.gov/blog/director/entry/ptab_s_quick_fixes_for) [<https://perma.cc/3V3W-MNZP>].

117. *See* Request for Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 79 Fed. Reg. 36,474, 36,476 (June 27, 2014); *see also* USPTO, *Comments on Trial Proceedings Under the American Invents Act Before the Patent Trial and Appeal Board*, <https://www.uspto.gov/page/comments-trial-proceedings-under-america-invents-act-patent-trial-and-appeal-board/> [<https://perma.cc/XW68-VYAL>].

118. Lee, *supra* note 116; Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750 (April 1, 2016).

119. Lee, *supra* note 116.

120. *Id.*

121. Ryan J. Gatzemeyer, *Are Patent Owners Given a Fair Fight? Investigating the AIA Trial Practices*, 30 BERKELEY TECH. L. J. 531, 535 (2015).

122. Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 80 Fed. Reg. 50,720 (proposed Aug. 20, 2015) (to be codified at 37 C.F.R. pt. 42).

123. USPTO, *Comments to the Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board*, <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/comments-amendments-rules-practice-trials> [<https://perma.cc/WBJ5-7SUH>].

124. Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750 (April 1, 2016).

125. Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018); *see also* Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750 (Aug. 20, 2015).

grant trial procedures implemented following the AIA.<sup>126</sup> It noted that the USPTO publishes the TPG to provide practitioners with guidance on typical procedures and times for taking action in AIA trials, as well as to ensure consistency of procedure among panels of PTAB.<sup>127</sup>

The 2018 Update covered, “among other things, the [updated] sections of the TPG including guidance on: (1) the use of expert testimony;” (2) new factors PTAB must consider when determining whether to institute a trial; (3) “providing for sur-replies to principal briefs as a matter of right” rather than request; (4) “the distinction between motions to exclude and motions to strike, and the proper use of each; (5) procedures for oral hearing before [PTAB], including the use of live testimony, sur-rebuttal, and default time for the hearing; and (6) providing for a pre-hearing conference and potential early resolution of issues.”<sup>128</sup> Among the changes made in the August 2018 Update, the most relevant to this Article are the sections regarding new considerations in instituting a review and page limits.<sup>129</sup> These amendments affect claim amendments, patentability analyses, and outline the scope of the Director’s delegated institution discretion, among other substantive areas, many of which by their nature cannot be put into place through a guidance document and must be held out to the public for comment.

Then, in June of 2019, the USPTO again amended the TPG piecemeal, again without notice and comment rulemaking—they simply filed a brief notice in the Federal Register without accepting any commentary, circulating the Update among stakeholders, or publishing a notice of proposed rulemaking.<sup>130</sup> These amendments went further, enacting rules prohibiting *ex parte* communications, revising the default protective orders, modifying the rules on additional discovery, live testimony, claim construction, the substantive Patent Owner Preliminary Response, requiring new substantive “Considerations in Instituting a Review,” limiting the number of petitions that will normally be appropriate, dictating the content on whether to institute, modifying a “pilot program” on motions to amend practice, and modifying all procedures associated with motions to amend, among other things.<sup>131</sup>

Of particular note, the admonishments to petitioners, citing nothing, that “[b]ased on the Board’s prior experience, one petition should be sufficient to challenge the claims of a patent in most situations” was a radical departure from the previous seven years of PTAB practice, when parties often filed multiple petitions at the same time based on page limits or a substantial number of patent claims challenged, as allowed under the statute. Indeed, just months previously, a panel had

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126. Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018).

127. *Id.* Consistency among the more than 270 administrative law judges and various panels is certainly a difficult task to achieve.

128. USPTO, *supra* note 110.

129. PAT. TRIAL & APPEAL BD. *supra* note 6. The 2018 update revises sections: I.G. (Expert Testimony); II.A.3. (Word Count and Page Limits); II.D.2. (Considerations in Instituting a Review); II.I. (Reply to Patent Owner Response and Reply for a Motion to Amend; Sur-Replies); II.K. (Challenging Admissibility; Motions to Exclude; Motions to Strike); II.M. (Oral Hearing); and Appendix A (Sample Scheduling Order). *Id.*

130. Office Patent Trial Practice Guide, July 2019 Update, 84 Fed. Reg. 33,925 (July 16, 2019).

131. *Id.*

noted in *Apple Inc. v. Qualcomm Inc.*<sup>132</sup> that “there is nothing *per se* improper with filing multiple petitions at the same time to avoid issues associated with the word limit,” citing PTAB’s prior guidance that “[p]etitioners should consider filing multiple petitions if exceeding word or page limits were of concern.”<sup>133</sup> What changed in those five months? The public could not ask; they were denied the opportunity to comment and meaningfully participate in the “rulemaking” process. The amendments also make Federal review difficult, as the changes lack citation or justification, and, as those changes were not properly rules under the APA, Article III courts need not defer to them other than for their reasonability.

While beyond the focus of this article, these changes were even more problematic given that PTAB instituted other procedural hurdles via a steady stream of “precedential” adjudicative orders starting with *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*<sup>134</sup> and continuing with *NHK Spring Co., LTD., v. Intri-plex Technologies, Inc.*,<sup>135</sup> and the precedential decision in *Apple v. Fintiv*,<sup>136</sup> all of which introduced legal tests that shortened the available window in which to file IPRs. For example, a study of early decisions related to the July 2019 TPG Update demonstrated that regardless of couching such factors in permissive or optional language, the Updates created a *de facto* rule applied almost uniformly, where multiple petitions were denied for almost all second and all third petitions filed.<sup>137</sup>

Notably, the USPTO then tried to use this *de facto* rulemaking as support for retroactive *de jure* rulemaking and submitted what appeared by its title to be a codification of the same in the summer of 2020.<sup>138</sup> They sought neither public comment nor did they release a draft of the rules, instead proposing some unknown codification months before the end of the four-year Presidential term. In October of 2020, while the rule was under prepublication consideration from the Office of Information and Regulatory Affairs for compliance with executive orders, the APA, and other regulatory concerns, more than twenty-five stakeholder groups scheduled and held meetings with Office of Information and Regulatory Affairs to express concerns at the scope, speed, and propriety of the unreleased proposed rule, and to express further concerns that such a rule was

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132. No. IPR2018-01279 (P.T.A.B. Feb. 1, 2019).

133. *Id.* at 8 (noting where petitions are filed near in time, the policy concerns related to multiple petitions filed on the same patent claims were not salient).

134. No. IPR2016-01357, § II.B.4.i (P.T.A.B. Sept. 6, 2017) (precedential).

135. No. IPR2018-00752 (P.T.A.B. Sep. 12, 2018) (precedential). Note the parallel district court trial date over which this case was denied quite predictably never materialized.

136. No. IPR2020-00019 (P.T.A.B. Mar. 20, 2020) (precedential).

137. See generally Monica Grewal, Heather Petruzzi & Wenli Gu, *Ranking Parallel Petitions Before the PTAB: A Survey*, 19 CHI.-KENT J. INTELL. PROP. 523 (2020).

138. See OIRA, Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board (unpublished) (withdrawn), (July 22, 2020), <https://www.reginfo.gov/public/do/eoDetails?trid=130908> [<https://perma.cc/2DX4-9M5L>]. The rule contents were never made public, but after a fair number of complaints from stakeholder groups, the rule was withdrawn in favor of the more generic request for comments.

submitted without first seeking stakeholder input.<sup>139</sup> Responding to such concerns, the USPTO withdrew the rule and instead filed a Request for Comments (RFC) that sought such input prior to moving forward with codification.<sup>140</sup> That RFC resulted in over 800 comments submitted, many quite substantive—826, to be exact—setting a record for comments to a USPTO rulemaking.<sup>141</sup> The comments broke down relatively evenly both for and against codification of the rules. The Presidential election of 2020 resulted in a changeover of Administration, and any further attempt to codify those procedures was apparently abandoned at the end of the term.

### PART III: THE USPTO IS NOT COMPLYING WITH APA REQUIREMENTS AND THIS FAILURE WILL HAVE FAR-REACHING CONSEQUENCES.

*“Voids can’t be filled.”*<sup>142</sup>

The USPTO complied with the APA rulemaking requirements in the 2012, 2014, and (nominally) 2015 Updates to the TPG by proposing rules, receiving public comments, and revising the proposed rules based on the feedback into the final rules.<sup>143</sup> In 2012, the public comments on the proposed rules covered many substantive areas which were considered and used to modify the final published rules.<sup>144</sup> In 2014, the USPTO asked the public how the new procedures were working, and received comments on both substantive and procedural aspects of the proceedings the AIA put into place, which were then used to create a plan to further modify the PTAB.<sup>145</sup> While generalized, the notice nominally complied with the requirement to solicit public input on proposed rule changes and allowed parties’ voices to be heard. The three-part plan included a rule proposal in 2015 and received public comments that were considered when enacting the final rule.<sup>146</sup> However,

139. See OIRA, EO 12866 Meetings Search Results, <https://www.reginfo.gov/public/do/eom12866SearchResults?pubId=&rin=0651-AD47&viewRule=true> [<https://perma.cc/C5D4-2ZKE>]. One of the author’s employer, Unified Patents, LLC, was one of the parties that requested the meeting.

140. Request for Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 79 Fed. Reg. 36,474, 36,476 (June 27, 2014); see also, USPTO, Comments on Trial Proceedings Under the American Invents Act Before the Patent Trial and Appeal Board, (Oct. 18, 2014), <https://www.uspto.gov/page/comments-trial-proceedings-under-america-invents-act-patent-trial-and-appeal-board/> [<https://perma.cc/5G5E-Y5H2>].

141. See USPTO, *supra* note 140; see also Comments to Discretion to Institute Trials Before the Patent Trial and Appeal Board, REGUL.’S GOV., <https://beta.regulations.gov/document/PTO-C-2020-0055-0001/comment> [<https://perma.cc/RR63-DQ4J>].

142. ROBERTO BOLAÑO, 2666 at 657 (2006).

143. See Practice Guide for Proposed Trial Rules, 77 Fed. Reg. 6868 (Feb. 9, 2012) (to be codified at 37 C.F.R. § 42); Request for Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 79 Fed. Reg. at 36,476; Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 80 Fed. Reg. 50,720 (Aug. 20, 2015).

144. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756 (Aug. 14, 2012) (to be codified at 37 C.F.R. § 42).

145. See Request for Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 79 Fed. Reg. at 36,476; see also USPTO, *supra* note 140.

146. See Lee, *supra* note 116; see also Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 80 Fed. Reg. at 50,720.

inconsistent with the prior updates to the TPG and noncompliant with APA rulemaking procedures, the USPTO published the 2018 Update as a final rule in the Federal Register with no call for public comment.<sup>147</sup> They did so again with the July 2019 Update and for the adjudicative rules in *NHK* and *Fintiv*, as well.

For the USPTO to now suggest that the 2018 and 2019 Updates do not cover substantive aspects of the PTAB would be entirely inconsistent with the past actions of the agency. The 2012 Update received hundreds of comments, many regarding proposed page limits, discovery requirements, and video testimony.<sup>148</sup> The 2015 Update, based on comments received during the prior year, included an increase to the page limits on briefs and motions.<sup>149</sup> The USPTO then said that the 2018 and 2019 Updates, which include updates to testimony, page limits, limits on the number of petitions, claim construction standards, and motions to amend, were not substantive.<sup>150</sup> Yet in the past, the same areas of PTAB proceedings were included in proposed rules that *were* subject to public notice and comment, and those specific areas were revised based on the considerations presented in the comments.<sup>151</sup> Again, what changed?

It is worth noting that the USPTO, like other agencies, has sought to avoid notice-and-comment requirements in the past, ostensibly to save the time and money required to comply or to avoid addressing expected criticism or scrutiny.<sup>152</sup> In May 2018, the USPTO changed its claim construction rule from a “broadest reasonable interpretation” standard to an “ordinary meaning” standard.<sup>153</sup> There, they did file a notice of proposed rulemaking and nominally followed notice and comment rulemaking procedures. Nonetheless, the change included caveat language in the notice of proposed rulemaking and final rule that stated prior notice and opportunity for public comment *were not* required pursuant to 5 U.S.C.A. § 553(b) or (c) because of the statement “[t]he changes set forth in this final rule will not change the substantive criteria of patentability,” and mentioned that the changes are to agency procedure and interpretation.<sup>154</sup> This is deeply perplexing, as the Supreme Court had earlier, in reviewing the predecessor of this rule, explicitly found the Director’s substantive rulemaking authority was invoked.<sup>155</sup> The USPTO’s notice was thus insufficient as substantive on its face, according to the clear ruling of the Supreme

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147. Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018).

148. Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 Fed. Reg. 48,612, 48,613, (Aug. 14, 2012).

149. See Gatzemeyer, *supra* note 121 at 535.

150. See Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989; Office Patent Trial Practice Guide, July 2019 Update, 84 Fed. Reg. 64,280. See also USPTO, 1449 CNOG 3090 (Dec. 31, 2019).

151. See David Boundy, *An Administrative Law View of the PTAB’s Ordinary Meaning Rule*, WESTLAW J. INTELL. PROP., Jan. 30, 2019, at 1, 2.

152. See *id.* at 6.

153. *Id.* at 1.

154. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,357 (Oct. 11, 2018). In the absence of other law, “procedural” rules and “interpretive” rules are exempt from notice-and comment rulemaking. See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 21,221, 21,224 (May 9, 2018).

155. *Cuozzo Speed Techs. v. Lee*, 136 S.Ct. 2131, 2142 (2016).

Court.<sup>156</sup> It was noncompliant at least because: (1) the rule is clearly substantive and not procedural, despite the disclaimer; (2) the rule was not eligible for the interpretive exemption; and (3) notice and comment was required under at least the Patent Act.<sup>157</sup>

First, the rule is plainly substantive. By stating that this “final rule will not change the substantive criteria of patentability,” the USPTO sought to categorize the rule as procedural and avoid having to comply with APA requirements.<sup>158</sup> But even in the notice itself, the USPTO acknowledges that the purpose of this rule is to change substantive criteria of patentability by including the language, “the office has determined that the same claim construction *standard* should apply to both a patentability determination at the PTAB and determinations in federal court *on issues related to infringement or invalidity*.”<sup>159</sup> The rule directly and plainly affects the substantive law of the proceedings, as the Supreme Court recognized when analyzing the predecessor rule; to say otherwise strains credulity.

Nor does an “interpretive” exemption apply. To qualify for the “interpretation” exemption, a rule must “interpret” an unclear portion of a statutory grant.<sup>160</sup> In the final rule notice, the USPTO directly concedes that “there is no statute applicable to either the PTAB or federal courts that requires any different standards . . . for claim construction.”<sup>161</sup> The Supreme Court had earlier noted the same. There is no ambiguity to interpret, just a standard left to the agency to set; the “interpretation” exception does not apply.<sup>162</sup>

Lastly, the Patent Act itself grants the Director of the USPTO the express and limited authority to prescribe regulations to act in this area.<sup>163</sup> A regulation, as opposed to a guidance document, requires public notice and comment.<sup>164</sup> Therefore, any rule or regulation that is prescribed by the Director of the USPTO must comply with APA notice and comment rulemaking procedures, or it has violated the APA.<sup>165</sup>

The August 2018 and July 2019 Updates to the TPG sought to avoid the APA requirements of substantive rulemaking in the same way as the May 2018

156. *See id.*

157. The “interpretive” exemption is not applicable to this analysis due to the interpretive nature of the Trial Practice Guide. *See id.*

158. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51, 357; *see also* *Cuozzo*, 136 S.Ct. at 2142.

159. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. at 51,350.

160. “There must (a) be an underlying statute or regulation that itself has the force of law, (b) that law must have some tangible meaning, though with some “‘active’ ambiguity (an ambiguous term, a general term, or a direct clash with another provision—not a passive silence, or empty or vague language like ‘fair and equitable’ or ‘in the public interest’), and (c) the agency’s ‘interpretive rule’ must only interpret that ambiguity, without adding new content beyond the ‘fair intentment’ of the words of the underlying law. Boundy, *supra* note 151, at 3 (footnote omitted).

161. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. at 51,349.

162. *See generally* Boundy, *supra* note 151.

163. 35 U.S.C. §§ 316(a), 326(a).

164. *See* 5 C.F.R. § 1320.3(c)(1), (4)(i) (noting that the scope of coverage is any “rule or regulation,” any “requirement contained in a rule of general applicability”); 44 U.S.C. § 3506(c)(2)(A) (60-day comment period for any change in information to be collected by the agency, not only for those that increase burden.)

165. Boundy, *supra* note 151.

change to the claim construction standard and go still further—lacking any notice of proposed rulemaking or inclusion in the Federal Register whatsoever. The August 2018 Update sought to avoid substantive treatment entirely, stating that “[t]he office publishes the TPG to provide practitioners with guidance on typical *procedures* and times for taking action in AIA trials.”<sup>166</sup> The same again for the July 2019 Update.

But both Updates include required rules having the force and effect of law, all of which exist well beyond mere optional procedures for PTAB and Director to follow—they outline requirements the parties must comply with and on which PTAB often rules—and explicitly includes substantive criteria a petitioner must comply with when filing a petition, and a patent owner must comply with in response.<sup>167</sup> Most pointedly, the section addressing the considerations in instituting a review includes the following regarding the substance of a petition filed to USPTO:

[P]arties may wish to address in their submissions whether any other such reasons exist in their case that may give rise to additional factors that may bear on the Board’s discretionary decision to institute or not institute, and whether and how such factors should be considered along with the *General Plastic* factors.<sup>168</sup>

Not satisfied with that optional language or the permissive nature of the August 2018 Update, the July 2019 Update went further—dramatically limiting prior practice, imposing new procedural and substantive standards, and implementing an entirely new amendment process.<sup>169</sup>

The data agrees. An early study of the implementation of these provisions demonstrates they are a *de facto* rule, finding PTAB required all petitioners to include new arguments, and that they *never* instituted more than two parallel petitions after the rule, and almost never instituted a second, a marked departure from prior practice.<sup>170</sup>

Optional couching language aside, by requiring that the petitioner address additional factors beyond those required by the statute, the Update addresses the substantive requirements of the petition and should have been categorized as a substantive rule required to comply with the APA notice and comment rulemaking procedures.<sup>171</sup> Instead, PTAB has labored under these requirements for years, and they have now been the basis and support for promulgating rules designed to enshrine

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166. Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (emphasis added).

167. *PTAB Trial Practice Guide Update*, supra note 6.

168. *Id.* at 11. This effectively codified the *General Plastics* case, giving substantive weight to bind the whole board. *Id.*

169. UTPSO, *PTAB Trial Practice Guide Update* (July 2019), <https://www.uspto.gov/sites/default/files/documents/trial-practice-guide-update3.pdf?MURL=https://perma.cc/P3DX-W8K2> (noticed in Office Patent Trial Practice Guide, July 2019 Update, 84 Fed. Reg. 33,925 (July 16, 2019)).

170. See Grewal, supra note 137 (looking to all invocations of the new petition ranking requirements and noting that as a rule all third and fourth petitions were denied and nearly all second petitions were denied, a radical departure from preexisting practice).

171. See *Nat’l Org. of Veterans’ Advocs. v. Sec’y of Veterans Aff.*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (holding that failure to allow notice and comment on a substantive agency rule is grounds for invalidation).

the practice post-hoc—spinning a policy-based rule from whole cloth, then retroactively justifying it by codifying it based on it being standing PTAB practice—*circulus in probando*.

More importantly, the amendment requires responses and defines the substantive scope of motions to amend in these proceedings.<sup>172</sup> These specifically limit the substantive scope of what the PTAB can consider and the parties can argue (and, as an aside, add space and resource concerns); it is hard to see how such an area could be viewed as anything other than substantive.<sup>173</sup>

The 2018 and 2019 Updates are plainly substantive and include multi-factor tests that practitioners and parties must now spend dozens of pages and hours of attorney-time addressing. The USPTO should have—and now must—comply with notice-and-comment rulemaking procedures, as a regulation prescribed by the Director, or risk being struck down by the courts.<sup>174</sup> They should also be subject to stakeholder input as to their provenance and wisdom. As they stand now, the Updates amount to mere guidance that can be disregarded by filing parties, PTAB, or the Courts if it is unpersuasive; and if codification is sought now, it will be done so against the backdrop of blessing an unlawful interim practice based entirely on policy concerns absent from statutory authority.

Under the widely adopted interpretation of The Patent Act, the Director is limited to prescribing regulations for these proceedings, which require notice and comment protections.<sup>175</sup> Thus, any document released to the public by the Director and binding parties substantively—including those inserting new legal tests and erecting policy-based hurdles on stakeholder petitioners—should comply with notice and comment rulemaking procedures and the 2018 Update; the TPG ‘Updates’ are no exception. These concerns go double for the adjudication-issued rules of *General Plastic*, *NHK Spring*, *Fintiv*, and their progeny.<sup>176</sup>

It is critical to note that the concerns raised at the rulemaking stage—that the rule lacks statutory support, is against Congressional intent, is *ultra vires* from the USPTO’s mandate, and is driven by one-sided policy concerns—all apply with double the force to the original rules laid down as adjudicative decisions by PTAB. Those using the existence of these cases as support for codification are a dog chasing its own tail—a tautology of justification that demonstrates the lack of support for implementing the rules in the first place. And indeed, those practices launched an APA challenge filed jointly by Intel, Edward Lifesciences, Apple, Cisco, and Google, with an attempt at intervention from lobbying group U.S. Inventor.<sup>177</sup>

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172. PAT. TRIAL & APPEAL BD., *supra* note 6..

173. *Id.*

174. 35 U.S.C. §§ 316(a), 326(a).

175. *Aqua Prods. Inc. v. Matal*, 872 F.3d 1290, 1332 (Fed. Cir. 2017) (Moore, J., concurring); David Boundy, *The PTAB is Not an Article III Court, Part 1: A Primer on Federal Agency Rule Making*, 10:2 ABA LANDSLIDE 9 (2017); David Boundy, *The PTAB is Not an Article III Court, Part 3: Precedential and Informative Opinions*, 47 AIPLA QUARTERLY JOURNAL 1 (2019).

176. No. IPR2016-01357(PTAB Sept. 6, 2017) (later designated precedential); No. IPR2018-00752(PTAB Sep. 12, 2018) (same); No. IPR2020-00019(PTAB Mar. 20, 2020) (same).

177. See Amended Complaint at 1, *Apple Inc. et al v. Iancu*, No. 20-cv-6128-EJD (N.D. Cal. Nov. 9, 2020), ECF No. 54. For more coverage, see generally Dani Kass, *Edwards Lifesciences Bolsters Tech’s Attack on PTAB Denials*, LAW360 (Nov. 10, 2020, 4:19 PM),

While that challenge and attempted rulemaking are their own topic, are evolving, and are beyond the scope of this Article, they do reinforce that the USPTO's rulemaking procedures are subject to challenge and have raised concerns among the bar.

### 1. Paperwork Reduction Act of 1995

The Updates likewise run afoul of other Congressional safeguards. The Paperwork Reduction Act of 1995 (PRA) requires federal agencies to obtain Office of Management and Budget (OMB) approval before requesting most types of information from the public.<sup>178</sup> When OMB approves an agency request to collect information from the public, OMB (1) provides a valid OMB control number and expiration date for the agency to display on the instrument that will be used to collect the information and (2) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).<sup>179</sup> The statute requires the agency to follow the stated procedures for *any change* to the completion or submission requirements of any paperwork accepted by the agency.<sup>180</sup> Under the PRA, no persons are required to respond to a collection of information unless it displays a valid OMB control number.<sup>181</sup>

The 2018 and 2019 TPG Updates require significant information to be submitted by the public, but was neither approved by the OMB, nor is in compliance with the PRA.<sup>182</sup> The PRA protects the public from burdensome paperwork that involves any "collection of information" by or on behalf of the agency by requiring the agencies "to minimize the burden on the public to the extent practicable."<sup>183</sup> If an agency fails to obtain OMB approval for paperwork, any member of the public can assert a "public protection" provision at any time, and the agency can impose no penalty for the party's noncompliance with the agency's request for the paperwork.<sup>184</sup>

The PRA has been applied in a number of contexts.<sup>185</sup> The D.C. Circuit Court ruled in favor of a cellular licensee that previously had its application dismissed due to its failure to comply with applicable financial requirements.<sup>186</sup>

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<https://www.law360.com/articles/1327722/edwards-lifesciences-bolsters-tech-s-attack-on-ptab-denials> [<https://perma.cc/T8GY-8SR6>].

178. Paperwork Reduction Act, 44 U.S.C. §§ 3501–21 (1995).

179. *Id.*

180. *See* 5 C.F.R. § 1320.9 (2018).

181. 5 C.F.R. § 1320.8 (2018). *See also* 44 U.S.C. § 3512.

182. PAT. TRIAL & APPEAL BD., *supra* note 6.

183. *See Dole v. United Steelworkers of Am.*, 494 U.S. 26, 33 (1990); *see also* David E Bounty, *The PTAB is Not an Article III Court, Part I: A Primer on Federal Agency Rule Making*, 10:2 ABA LANDSLIDE 9, (2017).

184. 44 U.S.C. §§ 3507(a), 3512; 5 C.F.R. § 1320.6 (2018).

185. *See, e.g.*, Kevin P. Holewinski, *How Paperwork Act Might Affect EPA Penalties*, THE JONES DAY (May 8, 2001), <https://www.jonesday.com/files/Publication/122043ce-1314-4e9e-ad25-59e260dce7fb/Presentation/PublicationAttachment/0c5fac49-cf9b-449a-a3b0-82428e79f9f0/Holewinski-Paperwork%20Act.pdf> [<https://perma.cc/MN8S-AY93>].

186. *Saco River Cellular, Inc. v. FCC*, 133 F.3d 25, 32 (D.C. Cir. 1998).

Courts have widely applied the rules to dismiss alleged violations of the Clean Air Act and the Clean Water Act for noncompliance with the PRA.<sup>187</sup>

Here, the 2018 Update makes no mention of the compliance with the PRA, despite dealing directly with the filing requirements of Section II.A.3 (Word Count and Page Limits) and making changes and additions to the requirements the public must observe.<sup>188</sup> This noncompliance opens the USPTO to the potential inability to hold any petitioner responsible for the paperwork submission requirements in the sections covered by the Update.<sup>189</sup>

## 2. Executive Order 12,866

Nor do they comply with the “economically significant” requirements all agencies must observe. Executive Order 12,866 was signed on September 30, 1993, and requires agencies to allow the Office of Information and Regulatory Affairs to review all rules to ensure that rules advance the public interest.<sup>190</sup> EO 12,866 divides all rules into three tiers: (1) not significant (rules that have essentially no economic effect); (2) economically significant (“likely to result in . . . an annual effect on the economy of \$100 million or more”); and (3) significant (anything in between).<sup>191</sup> “The classification determines the level of scrutiny that the Office of Information and Regulatory Affairs gives the rule.”<sup>192</sup> For an economically significant rule, an agency must conduct a “Regulatory Impact Analysis.”<sup>193</sup>

It beggars belief that much of the USPTO’s agency action would not be economically significant regardless of the area it affects. The USPTO employs nearly 10,000 patent examiners, received 660,000 new patent filings last year, and issued over 330,000 patents.<sup>194</sup> The USPTO makes almost \$1 billion in revenue annually, has a \$3.5 billion annual budget, and of the roughly 4.3 million U.S. patents in force, just three recently resulted in a \$1.1-billion-dollar judgment by the courts.<sup>195</sup>

The 2018 and 2019 TPG Updates should be categorized as “economically significant.” The agency estimates the annual hours required for PTAB actions is 2.05 million hours, at an average of \$300 per hour, accounting for over \$600 million

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187. Holewinski, *supra* note 185 (citing *In re* Tower Cent. Inc., No. CAA-III-030, 1997 EPA ALJ LEXIS 140 (EPA 1994); *In re* Ketchikan Pulp Co., No. CWA-1089-12-22-309(g) (EPA 1995), 1995 EPA ALJ LEXIS 12, \*47).

188. See Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018).

189. 44 U.S.C. § 3501–20.

190. Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,737 (Sept. 30, 1993).

191. Boundy, *supra* note 151, at 14.

192. *Id.* at 15.

193. *Id.* See also WHITEHOUSE.GOV, AGENCY CHECKLIST: REGULATORY IMPACT ANALYSIS 1 (2019) [<https://perma.cc/97X4-NUGW>].

194. USPTO, FY 2019 USPTO PERFORMANCE AND ACCOUNTABILITY REPORT 194, 29, 34 (2019), <https://www.uspto.gov/sites/default/files/documents/USPTOFY19PAR.pdf> [<https://perma.cc/YHV2-GPZ6>].

195. *Id.* See also Susan Decker, Ian Lopez, & Matthew Bultman, *CalTech Wins a \$1.1-Billion Patent Verdict Against Apple and Broadcom*, L.A. TIMES (Jan. 30, 2020), <https://www.latimes.com/business/story/2020-01-29/caltech-wins-a-1-1-billion-jury-verdict-against-apple-and-broadcom> [<https://perma.cc/9NJ4-LPAV>].

in agency attorney billable time alone—not to mention the private attorney’s fees, and substantive rights these proceedings effect on a grand scale.<sup>196</sup>

Significantly limiting the number of filings and increasing the number of denials is clearly an economically significant rule, and the USPTO is required to conduct a regulatory analysis on the effects of the Update on the public’s interest (and for that matter, it is required to do similar studies for many of its other rules, such as the change to the claim construction standard). By avoiding the requirements of this Executive Order, the USPTO has understated the economic impact on the persons required to comply with the procedures of the PTAB. The purpose of this Executive Order is to encourage the agency to analyze the impact of the rules they are producing, and the avoidance of such an analysis is likely damaging to the affected public.

### 3. Executive Order 13,771

Examples abound, even under the former Administration’s executive orders. President Trump signed Executive Order 13,771 on January 30, 2017, which charges federal agencies with repealing two existing regulations for every new significant regulation, and in such a way that the total cost of regulations does not increase.<sup>197</sup> “The USPTO has assembled a Working Group on Regulatory Reform to consider, review, and recommend ways that USPTO regulations can be improved, revised, and streamlined.”<sup>198</sup>

The USPTO has previously avoided the Executive Order EO 13,771 requirement by citing *de minimis* costs.<sup>199</sup> As stated above, the annual cost of the agency attorney’s fees to the public alone is over \$600 million—merely the beginning of a fulsome economic analysis—which cannot reasonably be considered *de minimis* costs. The USPTO should therefore be required to comply with the executive order.

Further, the enactment of the 2018 and 2019 TPG Updates was also not accompanied by two deregulations, makes no mention of the EO 13,771 compliance, and is therefore in direct conflict with the requirements of President Trump’s Executive Order.<sup>200</sup> This Executive Order is much broader than EO 12,866, which only requires an economic analysis of economically significant actions. This Order applies to all regulations being enacted and cannot be avoided by citing *de minimis* costs (when the costs are significant) or by categorizing a substantive rule as procedural to circumvent the additional compliance of APA rulemaking. Like in *Aqua Products Inc. v. Matal*, the agency must “afford interested persons general

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196. See Patent Trial and Appeal Board (PTAB) Appeals, 85 Fed. Reg. 76 (Apr. 20, 2020); see also U.S. PAT. & TRADEMARK OFF., TRIAL STATISTICS, PATENT TRIAL AND APPEALS BOARD (Dec. 2018), [https://www.uspto.gov/sites/default/files/documents/trial\\_statistics\\_201812.pdf](https://www.uspto.gov/sites/default/files/documents/trial_statistics_201812.pdf) [<https://perma.cc/GH9C-F7N5>].

197. Exec. Order No. 13,771, 82 Fed. Reg. 9,339 (Jan. 30, 2017).

198. USPTO, *Working Group on Regulatory Reform*, (June 12, 2017), <https://www.uspto.gov/about-us/working-group-regulatory-reform> [<https://perma.cc/6URK-MXXX>].

199. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,356 (Oct. 11, 2018).

200. See Office Patent Trial Practice Guide, August 2018 Update, 83 Fed. Reg. 39,989 (Aug. 13, 2018); Office Patent Trial Practice Guide, July 2019 Update, 84 Fed. Reg. 33,925 (July 16, 2019).

notice of proposed rulemaking and an opportunity to comment *before* a substantive rule is promulgated.”<sup>201</sup> It cannot, like in *Aqua Products*, fabricate new roadblocks, and then seek to “reverse-engineer” adjudicative rulings into regulations *post hoc*.<sup>202</sup>

Still further, if any potential regulations are appropriately put into the Federal Register via notice and comment as a Notice of Proposed Rulemaking, there is nothing so urgent or unusual about any of the subject matter at hand that would justify deviating from the 60-day review period (set by Executive Order)<sup>203</sup> that has been standard practice for almost 30 years.

#### PART IV: RECOMMENDATION

*“Do not issue many edicts, and if you do, try to make them good ones and above all, ones that are carried out and obeyed; for edicts that are not carried out are as good as nonexistent, and they let it be known that the prince who had the intelligence and authority to issue them did not have the courage to enforce them; laws that intimidate but are not enforced become like the log that was king of the frogs: at first it frightened them, but in time they came to despise it and climbed up on it.”*<sup>204</sup>

The USPTO—if it seeks for parties and courts to defer to and respect its pronouncements, and to avoid the risk of widespread dissent, review, and reversal—*must* seek stakeholder input and hold open a full comment period of 60 days<sup>205</sup> for all updates to the PTAB TPG. It must do so to allow the public, the Courts, and Congress an opportunity to have their say in PTAB trial proceedings. It should recognize and respect their pronouncement’s substantive effect. And it must provide evidence-supported rationales for promulgating rules, and only do so within the authority granted it by Congress.

To do otherwise is to invite challenge, noncompliance, and reversal. In *Aqua Products*, after the Court found substantive rules being masked as procedural, the Federal Circuit, sitting *en banc*, invalidated them.<sup>206</sup> Properly meeting APA requirements would avoid these Updates being struck down by the Federal courts. Additionally, the feedback received during public comment from practitioners and academics on the considerations and effects of the TPG Updates will make for a

201. *Aqua Prod., Inc. v. Matal*, 872 F.3d 1290, 1339 n.6 (Fed. Cir. 2017) (emphasis added) (“The APA’s mandate states that ‘an agency shall afford interested persons general notice of proposed rulemaking and an opportunity to comment before a substantive rule is promulgated.’ *Chrysler*, 441 U.S. at 313, 99 S.Ct. 1705; *Perez v. Mortg. Bankers Ass’n*, 135 S.Ct. 1199, 1211, (2015) (Scalia, J., concurring). The Patent Office’s attempt to reverse-engineer *Idle Free* into a regulation with the force and effect of law cannot stand because failure to provide the public notice before engaging in substantive rulemaking runs afoul of the APA. *See Chrysler*, 441 U.S. at 316, 99 S.Ct. 1705.”).

202. *Cf. Fricano v. United States*, 22 Cl. Ct. 796, 800 (1991) (“[P]ost hoc ergo propter hoc . . . is regarded as neither good logic nor good law.”).

203. Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,740 (Oct. 4, 1993) (stating that the public’s opportunity to comment “in most cases should include a comment period of not less than 60 days”).

204. MIGUEL DE CERVANTES, *DON QUIXOTE* 909 (Edith Grossman trans., HarperCollins Pubs. 2009) (1612).

205. *See Office Patent Trial Practice Guide supra* note 188 and accompanying text.

206. 872 F.3d at 1335.

better PTAB and can improve the overall function of the USPTO.<sup>207</sup> It has been shown in the previous Updates that the comments received can introduce considerations that are valuable and useful to consider when drafting the final rules.<sup>208</sup>

All Updates to the TPG published by the USPTO should be required to comply with the Paperwork Reduction Act of 1995 by notifying the public of the required information and estimating the amount of time that is to be committed.<sup>209</sup> (This goes for all rules affecting the PTAB generally; even more so for those rules that the USPTO did not design to publish in the TPG.) The Food and Drug Administration, for example, has created its own Paperwork Reduction Act Office to ensure that there is communication between the agency and the OMB.<sup>210</sup> The USPTO should create a similar group tasked with compliance of the PRA to avoid the future inability to enforce their own paperwork submittal standards.

Further, the rules published by the USPTO should be required to comply with EO 12,866 and 13,771 due to the economically significant impact of the regulations that are set forth in the TPG. As noted previously, PTAB proceedings have been shown to affect the U.S. economy to the tune of tens of thousands of job-hours and over \$3 billion since 2014,<sup>211</sup> and non-merits discretionary denials as a result of these de facto rules have been shown to now comprise more than 10% of all denials.<sup>212</sup>

As stated above, the USPTO should create and staff a compliance department tasked with ensuring that the requirements of the relevant statutes and acts are satisfied. An officer of the department should review all public notices and avoid any future liability of the agency regarding noncompliance with federal rules. And the USPTO should ensure as much stakeholder input as possible prior to submission of any proposed rules, as the Office of Information and Regulatory Affairs, the Executive branch, and the Courts have long urged.<sup>213</sup>

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207. The matters the TPG update addresses impact the way the PTAB works, which impacts the public. The problems the public sees with the PTAB are likely different, or at least from a different perspective, as the Director and can offer relevant and useful considerations and recommendations. *Cf. supra* note 92.

208. *Id.*

209. See Paperwork Reduction Act, 44 U.S.C. 3501, 3505 (1995).

210. See, *Paperwork Reduction Act Office*, U.S. FOOD & DRUG ADMIN. (Jan. 15, 2018) <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofOperations/ucm409137.htm> [<https://perma.cc/FR5F-X8JX>].

211. See *Unified's Patent Quality Initiative (PQI) Releases Economic Report Showing the AIA Led to Over 13,000 Jobs and Grew the U.S. Economy by \$3 Billion Since 2014*, UNIFIED PATENTS (June 24, 2020), <https://www.unifiedpatents.com/insights/2020/6/23/the-perryman-group-releases-economic-report-an-assessment-of-the-impact-of-the-america-invents-act-and-the-patent-trial-and-appeal-board-on-the-us-economy> [<https://perma.cc/8DTQ-TLHE>].

212. See *PTAB/District Court Trial Date Denials Spiraling Upward: PTAB Discretionary Denials Third-Quarter Report*, UNIFIED PATENTS (Oct. 21, 2020), <https://www.unifiedpatents.com/insights/2020/10/21/ptabdistrict-court-trial-date-denials-spiraling-upward-ptab-discretionary-denials-third-quarter-report> [<https://perma.cc/KW67-SKC6>].

213. See, e.g., OFF. INFO. & REGUL. AFFS., *ICF Reg Map* (2020), <https://www.reginfo.gov/public/reginfo/Regmap/index.myjsp> [<https://perma.cc/ZPT6-TTGN>] (summarizing third-party guidelines to rulemaking endorsed on OIRA's Regulatory Dashboard website).

## PART V: CONCLUSION

It seems clear that the USPTO is required to hold any rule with substantive effect open to the public for notice and comment, just like other administrative agencies must. It should, at a minimum, be seeking stakeholder input before throwing up any such policy-based rules. Instead, as just one example, the USPTO has unilaterally updated the PTAB TPG—twice—without holding these revisions open to the public for comment or complying with other procedural safeguards. Those revisions are now routinely relied upon by the agency and the parties to justify substantive outcomes, such as the exercise of the director’s absolute discretion to deny petitions outright. They have been used to justify a recently withdrawn rules package<sup>214</sup> and are the basis of request for comment on whether such an *ex post* facto codification would be legitimate.<sup>215</sup> Perhaps more troublingly, they have issued other rules entirely through “precedential” adjudicative decisions, without any opportunity for public comment or criticism. These practices do not comport with at least the APA public notice-and-comment requirement, the PRA’s requirement of informing the public of the anticipated time and paperwork required to comply with the rules set forth, Executive Order 12,866’s regulatory impact analysis requirement, or Executive Order 13,771’s requirement of deregulating two regulations before enacting one. What is clear is that, moving forward, the USPTO should carefully assess whether it is complying with all relevant regulations.

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providing recommendations to agencies on standard practices comporting with APA and due process requirements).

214. See OIRA, *supra* note 138. The rule contents were never made public, but after a fair number of complaints from stakeholder groups, the rule was withdrawn in favor of the more generic request for comments.

215. See Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board, 85 FR 66,502, 66,502–06 (Oct. 20, 2020) (to be codified at 37 CFR 42).