

# IS THE PTO AUTHORIZED TO PROMULGATE THE PROPOSED RULE CHANGE TO THE CONTINUATION PRACTICE?

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In January 2006, the United States Patent and Trademark Office (PTO) proposed a controversial rule<sup>1</sup> that could significantly affect how applicants use patent applications to protect their inventions. Specifically, 35 U.S.C. § 120 enables an applicant to file a continuation application that claims the priority date of a previously filed patent application.<sup>2</sup> Under the present PTO rules, an applicant can potentially file as many continuation applications as the applicant wants without providing any reasons for filing the continuation applications.<sup>3</sup> Under the proposed PTO rule, an applicant would be allowed to file one continuation application as a right. To file further continuation applications, the applicant would have to persuade the PTO that the content in the continuation application could not have been filed earlier.<sup>4</sup>

A number of organizations and individuals have criticized the proposed rule and some have questioned whether the PTO is authorized to promulgate the rule.<sup>5</sup> This Note investigates whether the PTO is autho-

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1. Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48 (Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1) [hereinafter Changes to Practice for Continuing Applications].

2. The term “continuation application” can refer to an application that is filed under 35 U.S.C. § 120, § 121, or § 132. The PTO has proposed rule changes that affect an applicant’s ability to file continuation applications under § 120 and § 132. Changes to Practice for Continuing Applications, 71 Fed. Reg. at 61. Although this Note focuses on the rule change that affects an applicant’s ability to file a continuation application under § 120, the Note is generally applicable to other types of continuation applications.

3. U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURES § 201.07 (8th ed. rev. 5, 2006) [hereinafter MPEP], *available at* <http://www.uspto.gov/web/offices/pac/mpep/mpep.htm>.

4. Changes to Practice for Continuing Applications, 71 Fed. Reg. at 48.

5. See Letter from Michael Kirk, Executive Dir., Am. Intellectual Prop. Law Ass’n (AIPLA), to Jon Dudas, Dir. U.S. Patent and Trademark Office (Apr. 24, 2006), *available at* [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp\\_continuation/aipla.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/aipla.pdf) (stating that in its view, the PTO is not authorized to promulgate the proposed rules); Letter from David E. Korn, Assistant Gen. Counsel, Pharm. Research & Mfrs. of Am. (PhRMA), to Jon Dudas, Dir. U.S. Patent and Trademark Office (May 2, 2006), *available at* [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp\\_continuation/phrma.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/phrma.pdf).

rized to promulgate the proposed rule and discusses the standard of review that the United States Court of Appeals for the Federal Circuit (CAFC) should use to review the proposed rule if it is promulgated and if its validity is challenged. The Note concludes that, if the proposed rule is promulgated and its validity is challenged, the CAFC should review and invalidate the rule under the “hard look” standard of review.

Part I discusses the PTO’s authority to promulgate rules. Part II discusses how the CAFC reviews PTO actions under the Administrative Procedure Act (APA). Part III describes how applicants use and abuse continuation applications. Part IV discusses the proposed rule and explains why the PTO has proposed the controversial rule. Finally, Part V analyzes whether the PTO is authorized to promulgate the proposed rule.

## **I. THE PTO’S AUTHORITY TO PROMULGATE RULES**

### **A. 35 U.S.C. § 2(b)(2) Authorizes the PTO to Promulgate Rules**

Under 35 U.S.C. § 2(b)(2) the PTO “may establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the [Patent and Trademark] Office [and] shall facilitate and expedite the processing of patent applications.”<sup>6</sup> Unfortunately, the statute does not provide clear limits on the PTO’s rulemaking authority because the phrase “not inconsistent with law” is the only phrase in the statute that imposes a limit on the PTO’s rulemaking authority. Hence, we must look to case law to determine the PTO’s rulemaking authority.

### **B. The PTO is Authorized to Promulgate Procedural, not Substantive Rules**

Established case law holds that the PTO is authorized to promulgate procedural rules, but it is not authorized to promulgate substantive rules. Specifically, in *In re Bogese*,<sup>7</sup> the CAFC stated that the “PTO has inherent authority to govern procedure before the PTO,”<sup>8</sup> which indicates that the

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uation/phrma\_con.pdf (stating that the proposed rules would “significantly limit, and in some cases altogether preclude, the ability of PhRMA’s members to obtain and enforce legitimate patent rights”).

6. Prior to the enactment of the Intellectual Property and Communications Omnibus Reform Act of 1999, S. 1948, 106th Cong. (1999) (enacted), the PTO’s rulemaking authority was stated in 35 U.S.C. § 6 (1999), which had essentially the same wording as 35 U.S.C. § 2(b)(2) (2000), namely, that the PTO “may . . . establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office.”

7. *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002).

8. *Id.* at 1368.

PTO has a broad authority to promulgate procedural rules. In *Merck & Co. v. Kessler*,<sup>9</sup> the CAFC stated that

[t]he broadest of the Patent and Trademark Office's (PTO) rule-making powers, 35 U.S.C. § 6(a), authorizes the Commissioner of Patent and Trademarks (Commissioner) 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. Congress has not vested the Commissioner with any general substantive rulemaking power.<sup>10</sup>

Similarly, in *Animal Legal Defense Fund v. Quigg*,<sup>11</sup> the same court stated that 35 U.S.C. § 2(b)(2)(A) authorizes the PTO to promulgate procedural rules, and that "[a] substantive declaration with regard to the Commissioner's interpretation of the patent statutes, whether it be sections 101, 102, 103, 112 or other sections, does not fall within the usual interpretation of such statutory language."<sup>12</sup>

Unfortunately, it is not always possible to categorize a rule as "only procedural" or "only substantive" because a rule may include aspects of both. Part V discusses different tests that courts use to determine whether a rule is procedural or substantive, and argues that under these tests, the proposed rule may be substantive.

## II. COURTS REVIEW PTO DECISIONS UNDER THE APA

This Part describes the standard of review that courts use to review PTO decisions. Section II.A describes the Supreme Court's decision in *Dickinson v. Zurko* where the Court directed the CAFC to use the APA to review PTO decisions.<sup>13</sup> Section II.B describes the different APA standards of review that courts use to review agency decisions. Specifically, the Section explains how courts use different standards of review depending on whether the agency's action involves factual findings, statutory interpretations, or policy determinations.

9. *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996).

10. *Id.* at 1549-50. Since this case was decided prior to the Intellectual Property and Communications Omnibus Reform Act of 1999, the decision states that § 6(a) gives the PTO authority to promulgate rules. *Id.* at 1549. However, the relevant text of § 6(a) is essentially the same as 35 U.S.C. § 2(b)(2)(A) (2000). *See supra* note 6.

11. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991).

12. *Id.* at 930.

13. *Dickinson v. Zurko*, 527 U.S. 150 (1999).

### A. *Dinkinson v. Zurko*

The PTO denied Mary Zurko and her colleagues' patent application because the PTO averred that it was obvious in view of the prior art.<sup>14</sup> After the Board of Patent Appeals and Interferences (BPAI) affirmed the examiner's rejection, Zurko appealed to the CAFC, which reversed the BPAI's decision under the "clearly erroneous" standard of review.<sup>15</sup> The "clearly erroneous" standard is less deferential to the PTO than the "arbitrary or capricious" standard, which the PTO claimed was the proper standard of review under the APA. To resolve the standard of review controversy, the CAFC granted the PTO's petition for a rehearing *en banc*.<sup>16</sup> The court *en banc* unanimously affirmed the appellate panel's decision to use the less deferential "clearly erroneous" standard to review PTO decisions.<sup>17</sup>

On writ of certiorari, the Supreme Court, by a six to three vote, reversed the *en banc* decision and directed the CAFC to review the PTO's fact-findings using the APA's "arbitrary and capricious" standard.<sup>18</sup> After *Zurko*, the CAFC has reviewed PTO decisions under the APA's review standards. The following Section describes the different APA review standards ("arbitrary and capricious" being one of them) that courts use to review PTO decisions.

### B. Judicial Review Standards Under the APA

Like most administrative agencies, the PTO has both rulemaking and adjudicatory powers.<sup>19</sup> The PTO's rulemaking powers enable the PTO to add substance to the patent statutes.<sup>20</sup> The PTO's adjudicatory powers, on the other hand, enable the PTO to enforce statutes and regulations on a case-by-case basis.<sup>21</sup>

The PTO's rulemaking powers and adjudicatory power are closely related.<sup>22</sup> Courts view rulemaking during adjudicatory proceedings as a necessary corollary to an agency's rulemaking powers.<sup>23</sup> Specifically, in ad-

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14. *In re Zurko*, 111 F.3d 887, 888 (Fed. Cir. 1997).

15. *Id.* at 889.

16. *In re Zurko*, 142 F.3d 1447 (Fed. Cir. 1998), *aff'g en banc*, 111 F.3d 887 (Fed. Cir. 1997).

17. *Id.* at 1459.

18. *Zurko*, 527 U.S. at 165.

19. See 3 JACOB STEIN, GLEN MITCHELL & BASIL MEZINES, ADMINISTRATIVE LAW § 14.01 (Matthew Bender 2006).

20. See *id.*

21. *Id.*

22. *Id.*

23. *Id.*

dition to using its rulemaking powers to promulgate rules, the PTO uses its adjudicatory powers to issue both retroactive and prospective orders, which for all intents and purposes are equivalent to rules.<sup>24</sup> Hence, when the CAFC reviews a PTO adjudication, its holding controls the CAFC's review of PTO rulemaking.

Under the APA, an agency's action can be reviewed by a court if the agency action is a "final" action.<sup>25</sup> An agency action cannot be considered "final" until the decision making process has reached a stage where "(1) judicial review will not disrupt the orderly process of adjudication and (2) rights or obligations have been determined or legal consequences will flow from the agency action."<sup>26</sup> When the PTO promulgates a rule, it counts as a final action, and hence is reviewable by the judiciary.<sup>27</sup>

Sometimes the statute that authorizes an administrative agency to promulgate rules provides the standard of review that a court is supposed to use to review the agency action. However, if the statute does not specify a standard, the APA provides the applicable standard.<sup>28</sup> Indeed, one of the legislative intents behind the APA was to provide a consistent standard of review across all agencies.<sup>29</sup>

Even though the CAFC uses the APA standards to review PTO decisions, some scholars have pointed out that it has often failed to apply the appropriate standard.<sup>30</sup> Agency actions are usually classified into three categories: fact, law, and policy.<sup>31</sup> Each category has its own standard of review under the APA.<sup>32</sup> *Zurko* involved a fact issue, and hence the Supreme Court held that the CAFC should set aside PTO's fact findings if they are "arbitrary, capricious, [or] an abuse of discretion."<sup>33</sup> However, the

24. See, e.g., *In re Borgese*, 303 F.3d 1362, 1369 (Fed. Cir. 2002) (affirming the PTO's authority to deny the defendant's patent based on prosecution laches).

25. 5 STEIN ET AL., *supra* note 19, § 48.03.

26. *Id.*

27. *See id.*

28. See Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 10 (2006).

29. *See id.* at 10-11.

30. *See id.* at 22 (stating that the CAFC's decision in *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002) is squarely inconsistent with standard administrative law).

31. *Id.* at 15.

32. *Id.* at 16.

33. Under 5 U.S.C. § 706(2)(A) (2007), courts set aside agency fact findings that are determined in informal proceedings if they are "arbitrary, capricious, [or] an abuse of discretion . . ." On the other hand, for agency fact findings that are determined in formal proceedings, § 706 requires courts to set aside the fact findings if they are "unsupported by substantial evidence." *Id.* § 706(2)(E). Since all PTO adjudications are informal (except for 35 U.S.C. § 32 cases, which deal with disciplining patent agents and patent attor-

APA specifies a different standard of review when the agency decision involves a matter of law or a matter of policy.<sup>34</sup> The proposed PTO continuation rule is most likely a policy-based determination, but it may be viewed as a legal determination. Legal and policy-based determinations are reviewed using two different standards.

Unless Congress specifically provides otherwise,<sup>35</sup> an agency's legal determinations are reviewed under a set of standards that the Supreme Court put forward in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*<sup>36</sup> and later modified in *United States v. Mead Corp.*<sup>37</sup> *Chevron* outlined a two-step process for reviewing an agency decision when it involves statutory interpretation.<sup>38</sup> Specifically, if the statute is clear, courts are supposed to give effect to the Congressional intent instead of deferring to the agency's interpretation.<sup>39</sup> If the statute is unclear, *Chevron* requires courts to defer to the agency's interpretation if it is reasonable, which affords a high level of deference to the agency's interpretation.<sup>40</sup> In its 2001 decision in *Mead*, the Court weakened the *Chevron* deference by restricting it to situations where Congress has delegated authority to the agency to generally make rules. When Congress has not delegated authority, the Court stated that the sliding scale deference of *Skidmore v. Swift & Co.* must be used.<sup>41</sup> The *Mead* Court then stated that informal rulemaking would trigger the *Chevron* deference.<sup>42</sup> Note that the *Chevron* deference only applies if the agency has substantive rulemaking authority.<sup>43</sup> As discussed *infra* in Section V.B, notwithstanding the CAFC's assertions to the contrary, the PTO may have substantive rulemaking authority. If so, CAFC will be required to afford *Chevron* deference to the PTO's legal determinations.

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neys), the "arbitrary, capricious, [or] an abuse of discretion" standard is the appropriate standard for reviewing the PTO's fact findings.

34. Benjamin & Rai, *supra* note 28, at 15-16.

35. *Id.* at 25.

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

37. *United States v. Mead Corp.*, 533 U.S. 218 (2001).

38. *Chevron*, 467 U.S. at 842-43.

39. *Id.*

40. *See id.*

41. *Mead*, 533 U.S. at 228 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

42. *Id.* at 230-31.

43. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546 (Fed. Cir. 1996) (stating that only statutory interpretations by agencies with rulemaking powers deserve substantial deference).

Further, as discussed *infra* in Part V, the proposed rule will most likely fall in the policy category. An agency's policy decisions are reviewed under the same statute that describes the standard of review for an agency's fact-findings.<sup>44</sup> However, under settled principles of administrative law, courts apply a "hard look" review standard to an agency's policy decisions,<sup>45</sup> which is less deferential than the "arbitrary, capricious, [or] an abuse of discretion" standard which is used for the agency's fact-findings. Under the "hard look" standard, a court sets aside an agency action if it determines that the agency failed to take a "hard look" at the significant considerations contrary to its position.<sup>46</sup> In fact, of the three review standards, the "hard look" standard is the least deferential to the agency.<sup>47</sup>

### III. THE USE AND ABUSE OF CONTINUATION APPLICATIONS

#### A. 35 U.S.C. § 120 Entitles Applicants to File Continuation Applications<sup>48</sup>

The Manual of Patent Examining Procedure (MPEP) states that "[a] continuation application is a second application for the same invention claimed in a prior nonprovisional application and filed before the original prior application becomes abandoned or patented."<sup>49</sup> Further, "[t]he applicant in the continuation application must include at least one inventor named in the prior nonprovisional application."<sup>50</sup> Additionally, "[t]he disclosure<sup>51</sup> presented in the continuation must be the same as that of the original application; i.e., the continuation should not include anything

44. Benjamin & Rai, *supra* note 28, at 34-35.

45. See *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983) (stating that the hard look review standard applies to agency policy determinations, and that "an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider . . .").

46. *Id.*

47. Benjamin & Rai, *supra* note 28, at 36.

48. 35 U.S.C. § 120 states that "[a continuation] application for patent for an invention . . . shall have the same effect . . . as though filed on the date of the prior application."

49. MPEP, *supra* note 3, § 201.07.

50. *Id.*

51. The term "disclosure" refers to the description of the invention in a patent application which usually comprises text, figures, and claims. MPEP § 608 states that "[i]n return for a patent, the inventor gives as consideration a complete revelation or disclosure of the invention for which protection is sought."

which would constitute new matter if inserted in the original application.”<sup>52</sup> Moreover, the MPEP states that

[a]t any time before the patenting or abandonment of or termination of proceedings on his or her earlier nonprovisional application, an applicant may have recourse to filing a continuation in order to introduce into the application a new set of claims and to establish a right to further examination by the primary examiner.<sup>53</sup>

As long as the original disclosure supports the new set of claims, the claims can have a broader or narrower scope, or they can be directed to a different aspect or use of the invention.

## **B. Using Continuation Applications for Strategic Purposes**

An applicant can claim an invention using different sets of claims that sound very different from one another.<sup>54</sup> Further, due to practical reasons, the prior art search that is performed when an applicant prosecutes an application is far from complete, so even if the examiner allows a claim, it is not clear whether the claim will survive a validity challenge during litigation. Hence, a prudent patent prosecutor tries to claim an invention using different sets of claims, thereby increasing the probability that at least one set of claims will survive the extensive prior art search that is typically performed during litigation. Applicants can use continuations to implement this prosecution strategy.<sup>55</sup>

Further, applicants use continuation applications to ensure that they receive the broadest claim scope. Specifically, continuation applications are commonly used when the PTO allows narrow claims but rejects the broader claims of an application. In such situations, the applicant can ac-

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52. MPEP, *supra* note 3, § 201.07.

53. *Id.*

54. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002) (“[T]he nature of language makes it impossible to capture the essence of a thing in a patent application.”); see also, Craig Allen Nard, *A Theory of Claim Interpretation*, 14 HARV. J.L. & TECH. 1 (2000) (discussing attempts by courts to deal with the inherent imprecision of claim drafting). The imprecision of claim drafting is further substantiated by the high rate of reversals of claim construction determinations. See, e.g., Christian A. Chu, *Empirical Analysis of the Federal Circuit’s Claim Construction Trends*, 16 BERKELEY TECH. L.J. 1075, 1090 (2001) (finding that the Federal Circuit overturned district court claim constructions in 30%-39% of the cases).

55. Although continuations help an applicant to implement this prosecution strategy, they are unnecessary to implement this strategy. Specifically, an applicant can implement this prosecution strategy by ensuring that the original application contains sets of claims that are sufficiently diverse from one another.

cept the narrow claims (which are likely to survive a comprehensive prior art search) and use the resulting patent to prevent competitors from infringing on the applicant's product. Concurrently, the applicant can file the broad claims that were denied in the parent application in a continuation application to obtain more protection for the invention. In other words, continuations can help an applicant to quickly obtain a narrow patent that the applicant can assert against competitors, without foregoing the opportunity to ultimately obtain a broad patent.

Additionally, continuation applications allow individual inventors and start-up companies with limited funding to use a step-by-step approach to protect their inventions, especially when they do not have the resources to file multiple, simultaneous patent applications to claim every aspect of their inventions at once.<sup>56</sup>

Continuation applications are also usually an important part of the patent prosecution strategy for pharmaceutical and biotech companies. This is because pharmaceutical and biotech companies often have to file patent applications early in the development stage to avoid the statutory bar under 35 U.S.C. § 102(b).<sup>57</sup> However, at the time of filing, these companies may not know which drug or biologic, if any, will ultimately succeed through the multi-year, multi-phase, drug development process. Hence, pharmaceutical and biotech companies may file relatively broad application disclosures initially, and then as the research and clinical trials progress, they may file continuation applications with narrower claim scopes that may cover a specific use of the drug or a specific delivery mechanism.<sup>58</sup>

Individual inventors, who are often not sure whether there is a market for their inventions, also frequently use the continuation process. The inventor can file an initial application and determine whether there is a market while the application is pending at the PTO. Once the inventor has ascertained that there is a market for his or her invention, he or she can then determine whether it is cost effective to pursue broader claims in continuation applications.<sup>59</sup>

A controversial use of a continuation application occurs when an applicant uses a continuation to "trap" a competitor who designs around the

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56. Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO's Proposed New Rules Undermine an Important Part of the U.S. Patent System with Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 556, 557 (2006).

57. *Id.*

58. *Id.*

59. *Id.*

original patent application. Even though using a continuation in this manner may seem hard to justify on policy grounds,<sup>60</sup> courts have held that such a use of a continuation application is legal.<sup>61</sup>

### C. Abuse of Continuation Applications

A number of articles have criticized continuation applications for increasing the number of “bad patents.”<sup>62</sup> Of these, the predominant article is the 2004 article by Mark A. Lemley and Kimberly A. Moore (hereinafter, L&M) entitled “Ending Abuse of Patent Continuations,”<sup>63</sup> in which the authors argue that continuation applications are more likely to result in “bad patents” and hence should be significantly restricted or abolished altogether.<sup>64</sup> Note that the PTO has used the L&M article to justify the proposed rule change.<sup>65</sup>

The L&M article categorizes the harmful effects of continuation applications into five categories: (1) continuations delay in the prosecution process and create uncertainty for the patentee’s competitors, (2) continuations “wear down” the examiner, causing him or her to grant “bad patents,” (3) continuations allow patentees to change their claims to cover their competitor’s products, (4) continuations cause the “submarine patent” problem, where a patentee uses continuations to keep his or her patent “submerged” in the PTO and “resurfaces” the patent when his or her competitor has already developed multi-million dollar businesses using products that infringe on the “submarine patent,” and (5) continuations cause the “evergreening” problem, where a pharmaceutical company uses continuations to blatantly game the Hatch-Waxman Act.<sup>66</sup>

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60. Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 78 (2004) (arguing that allowing a patentee to write claims that read on a competitor’s invention is hard to justify on policy grounds).

61. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988).

62. See Lemley & Moore, *supra* note 60, at 75; Bruce A. Kaser, *Patent Application Recycling: How Continuations Impact Patent Quality & What The USPTO Is Doing About It*, 88 J. PAT. & TRADEMARK OFF. SOC’Y 426 (2006).

63. Lemley & Moore, *supra* note 60.

64. *Id.* at 65.

65. See *Changes to Practice for Continuing Applications*, 71 Fed. Reg. 48, 49 (Jan. 3, 2006).

66. Lemley & Moore, *supra* note 60, at 71-83. Under the Hatch-Waxman Act, a name-brand pharmaceutical company can sue a generic for patent infringement and obtain an automatic thirty-month stay to prevent the generic from entering the market. *Id.* at 82. However, pharmaceutical companies have used continuation applications to obtain multiple patents covering obvious variants of the same drug and using them to obtain not one, but multiple sequential thirty-month stays. For a discussion of the effects of the

The L&M article acknowledges that a combination of legislation and court decisions have largely solved the “submarine patent” and “ever-greening” problems.<sup>67</sup> Further, some practitioners don’t think continuations “wear down the [patent] examiner.”<sup>68</sup> Hence, although continuations can be abused, the residual harmful effects may not be serious enough to justify restricting the continuation practice significantly.

The PTO provides similar criticisms of the current continuation practice. It states that the “exchange between examiners and applicants becomes less beneficial and suffers from diminishing returns as each of the second and subsequent continuing applications or requests for continued examination in a series is filed.”<sup>69</sup> The PTO avers that the present continuation rules can cause multiple patents to issue for the same invention, which “tends to defeat the public notice function of patent claims in the initial application.”<sup>70</sup> Note that these harmful effects are covered by the first category of harmful effects in the L&M article. The PTO also avers that the present continuation rules are causing an alarming increase in the PTO’s backlog. However, as explained in Part IV, based on the present data it seems unclear whether the residual harmful effects of the continuation practice are sufficient to justify the proposed rule, and it also seems unclear whether the proposed rule will significantly reduce the PTO’s backlog.

#### IV. THE PTO’S PROPOSED RULE CHANGE

In the past, the PTO has unsuccessfully attempted to limit the ability of applicants to file continuation applications. In *In re Henriksen*,<sup>71</sup> the PTO attempted to restrict the number of continuation applications in a chain of continuations to a maximum of three. Under the current proposed rule, an applicant will have a right to file a single continuation application, and if the applicant wants to file additional continuations, he or she will have to show by petition that the amendments, evidence or argument presented in the additional continuation application “could not have been previously submitted.”<sup>72</sup>

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Hatch-Waxman Act, see Jeff Thomas, Note, Schering-Plough and *In Re Tamoxifen: Lawful Reverse Payments In The Hatch-Waxman Context*, 22 BERKELEY TECH. L.J. 13 (2007).

67. See *id.* at 83-94.

68. Schreiner & Doody, *supra* note 56, at 562-63.

69. Changes to Practice for Continuing Applications, 71 Fed. Reg. at 48.

70. *Id.*

71. *In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968).

72. Changes to Practice for Continuing Applications, 71 Fed. Reg. at 48.

During the “comment” period, some organizations criticized the proposed rule while others submitted comments that supported it.<sup>73</sup> Branded drug manufacturers criticized the proposed rule, whereas software and electronics companies generally supported it.<sup>74</sup> This is not surprising. A blockbuster drug can be worth billions, and the present continuation rule helps pharmaceutical companies to fully exploit the commercial potential of the drug. Hence, branded drug manufacturers are likely to oppose the proposed rule because it may reduce the profitability of their blockbuster drugs. In contrast, software and electronics companies that have large patent portfolios usually do not have a lot of money riding on any individual patent. For such companies, it is usually a numbers game. If the PTO promulgates the proposed rule, it may reduce the PTO’s backlog and enable these companies to obtain patents sooner, thereby increasing the number of issued patents in their portfolio. Hence, companies that derive substantial licensing revenues from their large patent portfolios are likely to support the proposed rule. The PTO may also benefit from the proposed rule. If the PTO’s backlog decreases, software and electronics companies may file more patents, thereby increasing the PTO’s revenues.

The PTO’s ever-increasing backlog appears to be the primary motivation for proposing the rule, but the proposed rule may not have a substantial impact on the PTO’s backlog.

#### A. The PTO’s Backlog

The PTO received 317,000 nonprovisional applications in 2005, of which 62,870 were continuations.<sup>75</sup> Further, the PTO received 52,750 requests for continued examination (RCEs)<sup>76</sup> in 2005. Based on this data, the PTO avers that approximately 30% of the PTO’s resources are being devoted to examining continuations or RCEs. In 2005, the PTO issued over 289,000 first office actions. In other words, the PTO sent out fewer

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73. See Comments on Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, Notice of proposed rulemaking, [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp\\_continuation/continuation\\_comments.html](http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/continuation_comments.html) (last visited Mar. 19, 2007).

74. See PhRMA’s comments, [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp\\_continuation/phrma\\_con.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/phrma_con.pdf); IBM’s comments, [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp\\_continuation/ibm\\_con.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/ibm_con.pdf) (last visited Mar. 19, 2007).

75. Changes to Practice for Continuing Applications, 71 Fed. Reg. at 50.

76. *Id.* An RCE enables an applicant to request the PTO to continue examination of a patent application after it has been rejected. RCEs are authorized under 35 U.S.C. § 132.

(289,000) office actions than the number of nonprovisional applications that it received. Since the number of first office actions that the PTO sent out was less than the number of new applications that the PTO received, the PTO is concerned that it is facing an ever-increasing backlog. It appears that the primary reason the PTO wants to promulgate the proposed rule is to reduce this backlog.<sup>77</sup>

In some technical arts, the workload has reached a crisis point. For example, based on recent PTO statistics, technical art unit 3626 (which deals with inventions related to health care insurance) has a backlog of 106 months.<sup>78</sup> In other words, if the backlog continues at the present rate, a patent application that is filed today will not be reviewed by an examiner for nine years. The PTO avers that it cannot reduce the backlog by hiring more examiners, so it must promulgate rule changes.<sup>79</sup>

#### **B. It is Unclear Whether the Proposed Rule Will Significantly Reduce the PTO's Backlog**

If the applicant wants to file a second or subsequent continuation application under the proposed rule, he or she will have to show by petition that the amendments, evidence or argument presented in the continuation application "could not have been previously submitted."<sup>80</sup>

The PTO has provided some examples that illustrate when a second or subsequent continuation application would be allowed. For instance, the applicant would be allowed to file a continuation if data necessary to support a showing of unexpected results becomes available to overcome a final rejection under 35 U.S.C. § 103, and the data is the result of a lengthy experimentation that was started after applicant received the first rejection.<sup>81</sup> On the other hand, a continuation application will not be allowed if the applicant argues that an amendment after final rejection should have been entered in the prior application.<sup>82</sup> However, these examples are very specific, and it is unclear how many continuations the PTO will deny under the proposed rule.

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77. See John Doll, Complete slide set presented at the Chicago Town Hall Meeting, Feb. 1, 2006, at 28, [http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/chicagoslides\\_back.ppt](http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/chicagoslides_back.ppt).

78. See Application Backlog by Technology, U.S. Patent and Trademark Office, <http://www.uspto.gov/web/patents/opstats/appbacklog.htm>. (last visited Mar. 15, 2007).

79. Doll, *supra*, note 77, at 28.

80. Changes to Practice for Continuing Applications, 71 Fed. Reg. at 48.

81. See Doll, *supra* note 77, at 80.

82. *Id.* at 83.

Note that, since the PTO examines applications based on the effective priority date, continuations are examined by the PTO before new applications.<sup>83</sup> Hence, a heavy workload of continuations prevents the PTO from examining new patent applications. Restricting the number of continuations can move some of the workload to the appeals process, freeing up resources at the PTO to review new applications.<sup>84</sup> Although the PTO has taken steps to make the appeals process more efficient,<sup>85</sup> the proposed rule may overwhelm the appeals process because the applicants whose continuation is denied may appeal the decision.

Furthermore, although the PTO is spending approximately thirty percent of its resources on continuations and RCEs, only six percent of its resources are being spent on second or subsequent continuations.<sup>86</sup> In view of these facts, it is unclear if the proposed rule will substantially reduce the PTO's backlog.

## V. IS THE PTO AUTHORIZED TO PROMULGATE THE PROPOSED RULE?

This Part analyzes whether the PTO is authorized to promulgate the proposed rule. Section V.A describes two CAFC decisions—*Henriksen*<sup>87</sup> and *Bogese*<sup>88</sup>—that define the PTO's authority to limit an applicant's ability to file continuation applications. Under these two decisions, it is unclear whether the PTO is authorized to promulgate the proposed rule. Section V.B discusses the test that courts use to determine whether a rule is procedural or substantive, and argues that the PTO's proposed rule is substantive. This Section revisits *Bogese* and it argues that the PTO's decision in *Bogese* was substantive. Finally, Section V.C argues that the CAFC should invalidate the proposed rule under the "hard look" standard of review.

### A. *Henriksen and Bogese*

#### 1. In re *Henriksen*

In *Henriksen*, the United States Court of Customs and Patent Appeals (CCPA)—the precursor to the CAFC—held that the PTO does not have

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83. MPEP, *supra* note 3, § 708 (stating that applications with the oldest effective filing date are given priority over newer applications).

84. See Changes to Practice for Continuing Applications, 71 Fed. Reg. at 49.

85. See *id.* at 51.

86. *Id.* at 57.

87. *In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968).

88. *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002).

the authority to impose an arbitrary limit on the number of applications that are allowed in a chain of continuation applications.<sup>89</sup> The applicant in *Henriksen* filed a chain of continuation applications, wherein each application claimed priority to an earlier filed application.<sup>90</sup> The BPAI upheld the examiner's decision to reject Henriksen's last continuation application in a chain of four continuation applications on the grounds that 35 U.S.C. § 120 limited an applicant to a series of at most three applications that claimed priority to the previous application. In reversing the BPAI's decision, the CCPA held that § 120 does not place a limit on the number of continuation applications that an applicant can file. The court came to this decision by carefully examining the legislative history of the Patent Act of 1952, which enacted § 120.<sup>91</sup> Although the court did not find congressional intent to limit the number of continuations to three, the court also did not find congressional intent to allow an applicant to file as many continuations applications as he or she desired. The court concluded that it is for the Congress to decide, with the usual opportunity for public hearing and debate, whether to impose a limit on the number of applications that are allowed in a chain of continuation applications.<sup>92</sup>

## 2. In re *Bogese*

In *Bogese*, the CAFC affirmed the BPAI's decision to deny a patent application based on a theory of prosecution laches.<sup>93</sup> The applicant, *Bogese*, filed a chain of eleven file wrapper continuation applications between 1989 and 1994.<sup>94</sup> In none of the eleven continuation applications, did *Bogese* amend the claims, or offer any argument addressing the rejection of those claims.<sup>95</sup> The PTO warned the applicant that the record showed a plurality of continuations with no substantive amendments to advance prosecution. The PTO claimed this, in effect, was tantamount to using the PTO to submarine the patent application, thereby obtaining inequitable benefits from the patent system.<sup>96</sup> Subsequently, when *Bogese*

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89. *Henriksen*, 399 F.2d at 253.

90. *Id.* at 255.

91. *Id.* at 256-58.

92. *Id.* at 262.

93. *Bogese*, 303 F.3d at 1362.

94. Under the PTO rules in effect at the time, applicants could file a "file wrapper continuation" application, which had the effect of abandoning the pending application and physically transferring the file history of the abandoned application into a new application for further prosecution. The new application contained the same claims and specification that existed in the abandoned application.

95. *See Bogese*, 303 F.3d at 1364-65.

96. *See id.* at 1364.

filed a continuation application without advancing prosecution, the PTO denied his patent application based on the theory of prosecution laches.

In *Bogese*, the CAFC followed the Supreme Court's decision in *Zurko* and applied the standard of review specified in the APA to the PTO's action. The CAFC held that under the APA, legal actions of the Board that were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" would be set aside.

In coming to this conclusion, the CAFC considered two issues: (1) whether the PTO was authorized to reject a patent application where the applicant failed to advance prosecution of his application for an unreasonably long period; and (2) if the PTO is so authorized, whether it acted arbitrarily in rejecting the applicant's patent application.

The CAFC relied on its decision in *Symbol Technologies, Inc. v. Lemelson Medical* where the court upheld the equitable doctrine of laches in an infringement context.<sup>97</sup> However, the *Bogese* court noted that the PTO's authority to sanction undue delay is even broader than the authority of a district court to hold a patent unenforceable for laches.<sup>98</sup> The *Bogese* court argued that, if a district court could bar enforcement of a patent based on prosecution laches, it necessarily followed that the PTO had the authority to reject patent applications for patents that would be unenforceable under the CAFC's holding in *Symbol Technologies*.<sup>99</sup>

The court further noted that like other administrative agencies, the PTO may impose reasonable deadlines and requirements on parties that appear before it. The court stated that the PTO had inherent authority to govern procedure before the PTO, and that authority allowed it to set reasonable deadlines and requirements for the prosecution of applications.<sup>100</sup>

The court distinguished *Bogese* from *Henriksen* by stating that nowhere did *Henriksen* suggest or imply that the PTO must allow dilatory tactics in the prosecution of applications, or that the PTO lacks inherent power to prohibit unreasonable delay in prosecution.<sup>101</sup>

The CAFC distinguished *Bogese* from cases that held it was permissible to maintain pendency of an application while competitors' products appear on the market in an effort to later draft and obtain the allowance of claims that read on the competitors' products. The court noted that an applicant's attempt to obtain new claims directed to inventions that he or she

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97. *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361 (Fed. Cir. 2002).

98. *See Bogese*, 303 F.3d at 1367.

99. *Id.* at 1369.

100. *Id.* at 1368.

101. *Id.*

believed were fully disclosed and supported in an earlier application was easily distinguishable from a failure to further the prosecution of an application toward the issuance of any claims.<sup>102</sup>

In her dissent, Judge Newman argued that the PTO is not authorized to reject a continuation application based on prosecution laches because, among other things, the PTO's decision did not involve an agency rule-making, public notice, or comment period.<sup>103</sup> However, this objection does not apply to the PTO's proposed rule because the PTO is promulgating the proposed rule using the notice-and-comment rulemaking procedure.

### 3. *The Proposed PTO Rule Falls in the Grey Area Between Henriksen and Bogese*

In *Henriksen*, the court held that the PTO cannot set an arbitrary upper limit on the number of continuation applications an applicant can file. However, the proposed rule does not set an upper limit. Under the proposed rule, an applicant can file as many continuation applications as the applicant desires as long as the applicant can persuade the PTO that the amendments, evidence, or argument presented in the continuation application could not have been previously submitted. Hence, the CCPA's decision in *Henriksen* most likely does not prevent the PTO from promulgating the proposed rule.

In *Bogese*, the CAFC held that § 120 did not give an applicant a right to file as many continuations as the applicant desires. The court held that PTO has authority to deny a continuation application under prosecution laches if the PTO determines that the applicant is unreasonably and inexplicably delaying prosecution. However, under the proposed rule, the PTO may deny an applicant's continuation application even if the applicant has not unreasonably or inexplicably delayed prosecution. Hence, the PTO is most likely not authorized under *Bogese* to promulgate the proposed rule.

*Henriksen* and *Bogese* do not conclusively determine whether the PTO is authorized to promulgate the proposed rules, so the next Section begins the process of determining what standard the PTO's rulemaking should be judged under.

## **B. The Proposed Rule is Most Likely Substantive, but the PTO May Be Authorized to Promulgate It**

The distinction between substantive and procedural rules is an important one in administrative law because it determines the process that an

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102. *Id.* at 1369.

103. *See id.* at 1370.

agency must follow to promulgate rules.<sup>104</sup> An agency can promulgate procedural rules without using the notice-and-comment process, but the agency is required to use the process to promulgate substantive rules.<sup>105</sup> Although the APA distinguishes the procedural requirements for substantive rules and procedural rules, the Act does not define the differences between the categories themselves.<sup>106</sup>

When an agency promulgates a substantive rule, it creates new law.<sup>107</sup> A substantive rule affects an individual's rights and obligations.<sup>108</sup> In contrast, a procedural rule controls the process that is to be used in dealing with the agency.<sup>109</sup>

The type of rulemaking process employed and the practical effects of the rule are indicative but inconclusive factors in determining the type of agency action taken.<sup>110</sup> Hence, the proposed rule is not substantive simply because the PTO is using a notice-and-comment process. Further, even if the practical effects of the proposed rule may be substantive in nature, that does not invariably make the proposed rule substantive.<sup>111</sup>

Courts determine whether a rule is substantive or not by using the substantial impact test (described *infra*) and by determining whether the rule affects an individual's rights. The following Section argues that under these tests, the proposed rule is substantive.

### 1. *The Proposed Rule May be Substantive*

Courts have held that if a rule creates new rights or obligations, thereby transforming procedure into substance, the rule has a substantial impact, and is substantive.<sup>112</sup> If a rule has substantial impact on an individual, and the individual can demonstrate that the agency did not promulgate the rule using APA's notice-and-comment procedure, the court will invalidate the rule.<sup>113</sup> The proposed rule could have a substantial impact on an applicant by preventing the applicant from filing a continuation application to protect his or her invention. Hence, under the substantial impact test, the proposed rule may be substantive.

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104. 3 STEIN ET AL., *supra* note 19, § 15.05.

105. *Id.*

106. *Id.* § 15.04.

107. *Id.* § 15.05.

108. *Id.* § 15.04.

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

In *Chrysler Corp. v. Brown* the Supreme Court stated that a substantive rule is one that affects individual rights and obligations.<sup>114</sup> In *Bogese*, the CAFC stated that an applicant does not have a *right* to file as many continuations as the applicant desires. Hence, it can be argued that the proposed rule does not affect the applicant's rights. However, since the proposed rule requires the applicant to file a petition to persuade the PTO that the continuation application could not have been submitted earlier, it most likely affects the obligations of the applicant. It may, therefore, be substantive under *Chrysler*.

## 2. *Bogese Revisited*

In *Bogese*, the CAFC affirmed the BPAI's decision to deny a patent application based on prosecution laches. The majority in *Bogese* relied on its decision in *Symbol Technologies*, where the court applied prosecution laches in an infringement context. As Judge Newman noted in her dissent in *Symbol Technologies*, "[t]he Patent Act and implementing regulations authorize the filing of continuing applications provided that certain requirements are met."<sup>115</sup> Specifically, § 120 does not specify that a continuation application will be denied if the applicant unreasonably or inexplicably delays prosecution. In other words, before *Bogese*, the patentee may not have been obligated to prevent unreasonable and inexplicable delays during prosecution of a continuation application.

By denying *Bogese*'s continuation application based on prosecution laches, it is possible that the PTO created a substantive rule that affects the obligations of an applicant who desires to file continuation applications. Further, by affirming the PTO's decision in *Bogese*, the CAFC may have implicitly authorized the PTO to promulgate substantive rules. Hence, although the proposed rule may be substantive, the PTO may be authorized to promulgate it.

### C. The CAFC Should Review the Proposed Rule Under the "Hard Look" Standard

As noted earlier, courts usually classify agency actions into three categories: fact, law, and policy. Courts use the appropriate standard of review under the APA. Clearly, agency rulemaking does not belong in the "fact" category. Agency rulemaking can either belong to the "law" or "policy" categories. If the agency engages in statutory interpretation the rulemaking falls into the "law" category.<sup>116</sup> In promulgating the proposed rule, the

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114. *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979).

115. *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361, 1368 (Fed. Cir. 2002).

116. See Benjamin & Rai, *supra* note 28, at 25.

PTO is not engaging in statutory interpretation.<sup>117</sup> Instead, the PTO's primary rationale for promulgating the rule is to reduce the PTO's backlog. Hence, if the PTO promulgates the proposed rule, it should be categorized under the "policy" category.<sup>118</sup>

Under settled principles of administrative law, courts use a "hard look" review standard to review agency actions that fall under the "policy" category.<sup>119</sup> Of the different standards of review, the "hard look" standard is the least deferential to the agency. Under this standard of review, a court will invalidate a rule "[i]f an agency fails to offer an adequate explanation for its rejection of such countervailing considerations, or promulgates a [rule] that fails to take into account relevant factors."<sup>120</sup> Further, the Supreme Court has held that a court should invalidate a rule "if the agency has relied on factors which Congress [did] not [intend] it to consider."<sup>121</sup>

It is unclear whether the PTO has adequately explained why it rejected countervailing considerations or whether the PTO has failed to take into account relevant factors. The PTO acknowledges that applicants use continuations for strategic purposes, such as for drafting claims that "encompass products or processes discovered in the marketplace."<sup>122</sup> However, the PTO argues that such considerations should be rejected because "the practice of maintaining [continuing applications] for the purpose of adding claims after such discoveries is not calculated to advance prosecution before the [PTO]."<sup>123</sup> Further, the PTO has cited the L&M article in support of the proposed rule. Since the L&M article discusses the benefits and drawbacks of restricting the continuation practice, and since the PTO has provided its rationale for rejecting certain strategic uses of continuations, the PTO may have adequately explained why it has rejected countervailing considerations.

However, in proposing the new rule, the PTO may have relied on factors which Congress had not intended the PTO to consider. In *In re Fisher*, the CAFC specifically stated that the PTO should not disallow patenting of a particular subject matter even if it would cause resource and mana-

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117. Although the statutory interpretations of 35 U.S.C. §§ 2(b)(2) and 120 are important to determine whether the PTO is authorized to promulgate the proposed rule, the PTO did not arrive at the proposed rule by engaging in a statutory interpretation of those statutes.

118. See Benjamin & Rai, *supra* note 28, at 32.

119. *Id.* at 35.

120. *Id.*

121. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983).

122. Changes to Practice for Continuing Applications, 71 Fed. Reg. 48, 49 (Jan. 3, 2006).

123. *Id.*

gerial problems for the PTO.<sup>124</sup> In other words, Congress may not have intended the PTO to promulgate a rule that restricts an applicant's rights and obligations if the main motivation for the rule is to reduce the PTO's backlog. Hence, the PTO may not be able to satisfy the "hard look" standard if its main rationale for promulgating the rule is to reduce its backlog.

To summarize, if the PTO promulgates the proposed rule, and if the rule is challenged, the CAFC should invalidate the rule under the "hard look" standard because the PTO has relied on factors that Congress may not have intended it to consider.

## VI. CONCLUSION

Continuations enable applicants to successfully protect their inventions because they give the applicant flexibility when prosecuting a patent. Continuations allow an applicant to decide when and how to protect various aspects of their inventions. However, since the current rules for filing continuations are very liberal, some applicants abuse the continuation rules.

Partly in response to its growing backlog, the PTO proposed a controversial rule change to the continuation practice that restricts the ability of an applicant to use continuations for strategic purposes. The proposed rule was roundly criticized by a number of organizations during the "comment" period of the notice-and-comment procedure for promulgating rules. Specifically, a number of organizations raised serious questions about the PTO's authority to propose such a rule.

This Note investigated the extent of the PTO's rulemaking authority and discussed the appropriate standard of review that the CAFC should use in reviewing the PTO's authority to promulgate the proposed rule. The Note concluded that, if the rule is promulgated and if its validity is challenged, the CAFC should invalidate the rule under the "hard look" standard of review.

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124. *In re Fisher*, 421 F.3d 1365, 1378 (Fed. Cir. 2005) (stating that the PTO should not disallow patenting of a particular subject matter simply because it would cause resource and managerial problems for the PTO, because such issues are public policy considerations which are more appropriately directed to Congress as the legislative branch of government).

