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**TESTING THE LIMITS OF PROCEDURAL RULEMAKING: HOW THE
FEDERAL CIRCUIT CAN USE *TAFAS V. DUDAS* TO CLARIFY THE
AUTHORITY OF THE PATENT OFFICE**

*Michael Neuerburg*¹

*In an effort to reduce the backlog of unexamined patent applications, the United States Patent and Trademark Office created a controversial new set of rules for patent applicants. In *Tafas v. Dudas*, a Federal District Court judge issued a permanent injunction against the rules, finding their enactment to be outside the Patent Office's authority. On appeal, the Court of Appeals for the Federal Circuit will have the opportunity to define better both the rulemaking authority of the Patent Office and the Circuit's approach to the distinction between substantive and procedural rules. This Recent Development proposes a more flexible approach toward classifying a rule as substantive or procedural than that used by the District Court in *Tafas* and discusses how this approach would affect the analysis of the Patent Office's rulemaking authority.*

I. INTRODUCTION

Attempting to speed up the patent examination process, the United States Patent and Trademark Office (“PTO”) created a set of rules called the “Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications,” or more simply, the “Final Rules.”² These rules were to be enacted on November 1, 2007, and would have placed additional and unprecedented obligations or limitations on many patent

¹ J.D. Candidate, University of North Carolina School of Law, 2010.

² Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications (“Final Rules”), 72 Fed. Reg. 46,716–46,843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

applicants.³ However, in the case of *Tafas v. Dudas*,⁴ the United States District Court for the Eastern District of Virginia issued a preliminary injunction against enactment of the Final Rules the day before they were to be enacted, followed by a decision and permanent injunction on April 1, 2008.⁵ The court held that the Final Rules were substantive and thus outside the PTO's authority, citing cases from the United States Court of Appeals for the Federal Circuit ("Federal Circuit") which hold that the PTO does not have substantive rulemaking power.⁶ The PTO has appealed, and *Tafas v. Dudas* is pending before the Federal Circuit.

The stated goal of the Final Rules is to reduce the backlog at the Patent Office by creating a more "focused and effective examination process" for patent applications.⁷ One important factor affecting the complexity of a patent application, and thus the time required to examine it, is the number of claims in the application.⁸ Applications with twenty-five or more claims

³ *Id.* at 46,836. Rule 75 requires an Examination Support Document for applications containing more than five independent claims or twenty-five total claims. *Id.* at 46,836. Rule 78 requires a petition and showing when filing a third or subsequent continuation application. *Id.* at 46,837. Rule 114 requires a petition and showing when filing a second or subsequent RCE. *Id.* at 46,841; see *infra* notes 8–14 and accompanying text for an explanation of some terms of art used in Patent Law.

⁴ 541 F. Supp. 2d 805 (E.D. Va. 2008).

⁵ *Id.* at 808 n.2.

⁶ *Id.* at 811; see *infra* Part II(A).

⁷ Final Rules, 72 Fed. Reg. 46,716, 46,717 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

⁸ ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE 19–21 (2nd ed. 2004). The claims in a patent define exactly what the invention is. Other products only infringe upon the patent if they contain each and every element of one or more of the patent claims. Claims typically contain technical language and are very precisely worded to have the proper legal effect. The process of obtaining a patent is known as patent prosecution. A central goal of patent prosecution is to find the best possible set of claims allowed by the examiner. Patents usually contain many claims describing the same invention so that similar products which would not infringe one claim because of a minor variation will be covered by another claim. Another reason for multiple overlapping claims is to protect the invention, even if some claims are later held to be invalid. There are two general types of claims: independent and dependent. Independent claims do not refer to other claims, while dependent

average an examination period that is four to six months longer than the examination period for applications with five or fewer total claims.⁹ According to the PTO, applications with more than twenty-five claims also have a significantly higher error rate than applications with fewer than twenty-five claims.¹⁰ Final Rule 75 (the “5/25 rule”) would require any application with more than five independent claims or more than twenty-five total claims to include extra documentation (called an examination support document, or “ESD”) with claim explanation and prior art search information.¹¹ The PTO argues that because applications with many claims are comparatively time-consuming and difficult to examine, it is fair and efficient to require such applications to include extra documentation designed to streamline the examination process.¹² The court rejected the 5/25 rule as substantive because the rule would create a significant new obligation for patent applicants, since applicants had previously never been required to perform a prior art search.¹³

claims incorporate all the elements of another claim and then add additional elements. Dependent claims typically take less effort to examine because the examiner will have already considered the elements incorporated by reference and need only consider the new elements. *Id.*

⁹ Posting of Dennis Crouch to Patently-O Blog, <http://www.patentlyo.com/patent/2008/09/evidence-base-1.html> (Sept. 14, 2008) (on file with the North Carolina Journal of Law & Technology).

¹⁰ Brief for the Appellants at 9, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. July 18, 2008) (citing JA181 (AR 05059) (FY05/FY06 data)).

¹¹ Final Rules, 72 Fed. Reg. 46,716, 46,843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1). *See infra* Part III(A).

¹² Brief for the Appellants, *supra* note 10, at 10.

¹³ Brief of Amicus Curiae American Intellectual Property Law Association in Support of Appellees at 20–22, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Oct. 3, 2008). Although there is no obligation on the applicant to perform a prior art search, many applicants perform at least a basic prior art search anyway. *Id.* However, because an ESD would become part of the patent application history, it could form an additional basis for challenges to the patent's validity by defendants in infringement actions. *Id.* The American Intellectual Property Law Association (“AIPLA”) argues that, to minimize this risk to the eventual patent, preparing an ESD would require more time and effort by counsel than would performing a simple prior art search. *Id.* For this reason, AIPLA believes that the cost of an ESD would be closer to the cost of a

Another important factor contributing to application examination time is the use of continuation applications and Requests for Continued Examination (“RCEs”). Both continuation applications and RCEs are methods by which an applicant may pay the Patent Office to extend the examination of an application family.¹⁴ There is no limit on how many continuation applications or RCEs an applicant may file.¹⁵ Final Rules 78 and 114 (collectively the “2+1 rule”) would require any applicant who wished to file more than two continuation applications or one RCE that the continuation application or RCE contained material that could not have been presented previously.¹⁶ The PTO justifies Rules 78 and 114 as discouraging unnecessary continuation applications and RCEs, thereby encouraging efficiency by applicants and reducing the backlog of unexamined patents.¹⁷ The District Court, on the other hand, considered the rules to infringe upon a patent applicant's right to an unlimited number of continuation applications and RCEs.¹⁸

validity/invalidity opinion (\$15,241 average cost) than to a novelty search (\$2,000 typical cost). *Id.*

¹⁴ DURHAM, *supra* note 8, at 34–35. A continuation application is an application that discloses the same invention as a prior application. *Id.* It explicitly refers to the prior application and is filed before the original application is abandoned. *Id.* By fulfilling those three conditions, the continuation application receives the benefit of the “parent” application's filing date. In many cases, this earlier filing date is crucial, because 35 U.S.C. § 102 would bar the continuation application otherwise. *Id.* Continuation applications can be filed off of other continuation applications; “children” and “grandchildren” all receive the benefit of the first application's filing date, provided that each application in the chain is filed properly. *Id.* The chain of continuation applications is referred to as an “application family.” *Id.* Unlike a continuation application, an RCE is not a new application, but simply extends the examination of an application. *Id.* Note that Rule 78 would limit both normal continuation applications and continuation in part applications to two total. *Id.*

¹⁵ *Tafas*, 541 F. Supp. 2d at 809.

¹⁶ Final Rules, 72 Fed. Reg. at 46,838–839, 46,841.

¹⁷ Brief of Amicus Curiae, *supra* note 13, at 20–22.

¹⁸ *Tafas*, 541 F. Supp. 2d at 814–815. The court found the right through a textual reading of 35 U.S.C. § 120 and 35 U.S.C. § 132, the statutes authorizing continuation applications and RCEs, respectively. *Id.*; *see also infra* Part III (B–C).

The District Court was correct in ruling that the 5/25 rule and the 2+1 rule are beyond the authority of the PTO to enact, and the Federal Circuit should affirm the ruling on appeal. As recently as August 19, 2008, the Federal Circuit reaffirmed that 35 U.S.C. § 2(b)(2), the broadest grant of authority to the PTO, “does not authorize the Patent Office to issue ‘substantive’ rules.”¹⁹ The 5/25 rule is substantive under the Court’s definition because requiring an EDS would be a significant new obligation to the applicant.²⁰

Rules 78 and 114 are also a policy change from the previous regime of unlimited continuation applications and RCEs. Whether the rules “affect individual rights or obligations”²¹ of applicants is a more difficult question. The District Court in *Tafas* found a right to unlimited continuation applications and RCEs through statutory interpretation, but it is not clear that the court’s interpretation of the Patent Act deserves more weight than the PTO’s interpretation.²² Circumstances beyond an applicant’s control may cause an applicant to use her continuations for something other than perfecting her claims,²³ thus the 2+1 rule could act to keep an applicant from fully claiming her invention.²⁴ Although this may be a rare occurrence, the inventor’s right to receive patent protection for her invention is central to the idea of patenting,²⁵ so

¹⁹ *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008) (citing *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996)).

²⁰ See *infra* Part III(A).

²¹ *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) (citing *Cubanski v. Heckler*, 781 F.2d 1421, 1426 (Fed. Cir. 1986)).

²² See, e.g., *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) (“We have long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer. . .”).

²³ The phrase “perfecting claims” refers to the patent applicant working toward her goal of crafting an allowable set of patent claims that fully protect her invention from infringement. See *DURHAM*, *supra* note 8, at 19–21.

²⁴ See *infra* Part III(B).

²⁵ Patent Act, 35 U.S.C. § 101 (2006) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”); see also U.S. CONST. art. 1, § 8, cl. 8.

that even rare occurrences should be strenuously avoided. Furthermore, the nature of certain types of invention research may require that the related patent applications be updated over time through continuations.²⁶ The District Court's analysis of Rules 78 and 114 is too limited; the analysis of Rule 114 is particularly problematic.²⁷

Part II considers the background for the District Court's decision in *Tafas*: First, the Federal Circuit's holding that the Patent Office lacks substantive rulemaking authority, and the Federal Circuit's definition of "substantive;" second, a discussion of when the Patent Office should be required to perform notice and comment rulemaking under the Administrative Procedure Act ("APA"); third, an explanation of why the Final Rules are not entitled to deference from the courts; and finally, proposed improvements to the process of characterizing a rule as substantive or procedural are set forth. Part III examines the Final Rules through the framework discussed in Part II(D): First, Rule 75, the 5/25 rule; second, Rule 78, allowing only two continuation applications as a matter of right; and third, Rule 114, allowing only one RCE as a matter of right.

II. BACKGROUND AND ANALYTICAL FRAMEWORK

This section discusses the underpinnings of the *Tafas* decision: why the Patent Office does not have substantive rulemaking authority; when notice and comment rulemaking is required of the Patent Office; what, if any deference is required toward the Final Rules, and a proposed structure for characterizing rules as substantive or procedural.

A. *The PTO does not have the authority to make substantive rules*

The District Court did not make new law when it ruled that the Patent Office does not have substantive rulemaking authority. The Patent Act's broadest grant of authority, 35 U.S.C. § 2(b)(2),²⁸ says that the PTO "may establish regulations, not inconsistent with law,

²⁶ See *infra* Part III(B).

²⁷ See *infra* Part III(B–C).

²⁸ 35 U.S.C. § 2(b)(2) (previously 35 U.S.C. § 6).

which shall govern the conduct of proceedings in the Office.”²⁹ In 1991, the Federal Circuit stated that “a substantive declaration with regard to the Commissioner’s interpretation of the patent statutes . . . does not fall within the usual interpretation of such statutory language.”³⁰ In 1996, the Federal Circuit stated the rule even more clearly:

As we have previously held, the broadest of the PTO’s rule making powers—35 U.S.C. § 6(a)—authorizes the Commissioner to promulgate regulations directed only to “the conduct of proceedings in the [PTO]”; it does not grant the Commissioner the authority to issue substantive rules. [Citing *Animal Legal Defense Fund*]. . . . Congress has not vested the Commissioner with any general substantive rule making power³¹

This holding from *Merck & Co. v. Kessler*³² has been frequently cited by the Federal Circuit, as recently as August 21, 2008, for the proposition that the Patent Office lacks substantive rulemaking authority.³³ Thus, not only has the holding that the PTO lacks substantive rulemaking authority been frequently and recently affirmed, but Congress has also had well over a decade to correct the Federal Circuit’s interpretation.³⁴

²⁹ 35 U.S.C. § 2(b)(2)(A).

³⁰ *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991).

³¹ *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549–1550 (Fed. Cir. 1996).

³² 80 F.3d 1543 (Fed. Cir. 1996).

³³ *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008); *see also* *Brand v. Miller*, 487 F.3d 862, 869 n.3 (Fed. Cir. 2007); *Eli Lilly & Co. v. Bd. of Regents*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003).

³⁴ *See* Brief of Plaintiffs-Appellees GlaxoSmithKline at 20, n. 6, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Sep. 24, 2008). For example, the Patent Reform Act of 2006, which never became law, contained the following provision:

RULEMAKING AUTHORITY—In addition to the authority conferred by other provisions of this title, the Director may promulgate such rules, regulations, and orders as the Director determines appropriate to carry out the provisions of this title or any other law applicable to the United States Patent and Trademark Office or that the Director determines necessary to govern the operation and organization of the Office.

S. 3818, 109th Cong. § 6(e) (2006).

The Federal Circuit's definition of "substantive," most recently cited in *Cooper Techs. Co. v. Dudas*,³⁵ is that "a rule is 'substantive' when it 'effects a change in existing law or policy' which 'affect[s] individual rights and obligations.'"³⁶ Both *Tafas* and *Cooper Techs.* used this definition of "substantive" when analyzing whether the rules in question are substantive or procedural.³⁷ To define procedural rules, the Federal Circuit in *Cooper Techs.* simply used the language of the Patent Act: rules which "govern the conduct of proceedings in the Office"³⁸ are procedural.³⁹ This definition is something of a tautology, and therefore less helpful in determining whether a rule is substantive or procedural.

In discussing whether the Final Rules are substantive or procedural, the PTO's appellant's brief emphasizes how the Final Rules relate to "proceedings in the Office," but the brief contains very little analysis of the practical impact of the rules on applicants.⁴⁰ The PTO argues that the Final Rules cannot be substantive because they do not alter the "substantive requirements for patentability," such as utility, novelty, and non-obviousness.⁴¹ Indeed, the PTO's appellate brief explicitly rejects the definition of "substantive" used by the courts in *Tafas* and *Cooper Techs.* as inappropriate to the analysis of whether a rule is substantive or procedural.⁴² However, the Court of Appeals for the District of Columbia ("D.C. Circuit") case, *American Hospital Association v.*

³⁵ 536 F.3d 1330 (Fed. Cir. 2008).

³⁶ *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) (citing a number of Supreme Court and circuit court cases).

³⁷ *Tafas v. Dudas*, 541 F. Supp. 2d 805, 814–817 (E.D. Va. 2008); *Cooper Techs.*, 536 F.3d at 1336.

³⁸ Patent Act, 35 U.S.C. § 2(b)(2)(A) (2006).

³⁹ *Cooper Techs.*, 536 F.3d at 1335 (citing 35 U.S.C. § 2(b)(2)(A)).

⁴⁰ Brief for the Appellants at 24–28, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. July 18, 2008).

⁴¹ *Id.* at 24.

⁴² *Id.* at 35 ("[A]sking whether a rule changes the law or alters the rights of private parties makes no sense as a means of determining whether a rule is procedural. Procedural rules, like substantive rules, change the law; if they did not, there would be little point in promulgating them.").

Bowen,⁴³ cited in the PTO's brief does not state that an inquiry into the "substantive impact" of a procedure is inappropriate.⁴⁴ Rather, it acknowledges that "even unambiguously procedural measures affect parties to some degree," implying that rules with relatively minor substantive impact could still be considered procedural.⁴⁵

Other D.C. Circuit cases confirm this reading. For example, in *JEM Broadcasting Co. v. FCC*,⁴⁶ the court stated: "The issue [of whether a rule is substantive or procedural], therefore, 'is one of degree,' and our task is to identify which substantive effects are 'sufficiently grave so that notice and comment are needed to safeguard the policies underlying the APA.'" ⁴⁷ Thus, according to the D.C. Circuit, "substantive" and "procedural" are not exclusive, binary states but rather two ends of a spectrum. The question of how a rule "affects individual rights and obligations"⁴⁸ would seem to be helpful in determining where within that spectrum the rule lies.

The D.C. Circuit is not the only source suggesting that the substantive-versus-procedural divide is not as clear-cut as it may seem in light of *Merck*. In *In re Van Ornum*,⁴⁹ the U.S. Court of Customs and Patent Appeals ("C.C.P.A.")⁵⁰ held that a rule that was procedural with collateral substantive effects was within the PTO's rulemaking authority.⁵¹ The PTO rule at issue in *Van Ornum* stated that multiple patents for the same invention, which without a terminal disclaimer would have been denied for double

⁴³ 834 F.2d 1037 (D.C. Cir. 1987).

⁴⁴ *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037 (D.C. Cir. 1987).

⁴⁵ *Id.* at 1047.

⁴⁶ 22 F.3d 320 (D.C. Cir. 1994).

⁴⁷ *JEM Broad. Co. v. FCC*, 22 F.3d 320, 327 (D.C. Cir. 1994) (citing *Lamoille R.R. Co. v. ICC*, 711 F.2d 295, 328 (D.C. Cir. 1983)). Further discussion of the APA can be found *infra* § II(B).

⁴⁸ *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991).

⁴⁹ 686 F.2d 937 (C.C.P.A. 1982).

⁵⁰ The Court of Appeals for the Federal Circuit was created in 1982. Prior to that time, the C.C.P.A. was the appellate court responsible for patent matters. United States Court of Appeals for the Federal Circuit: About the Court, <http://www.cafc.uscourts.gov/about.html> (last visited Oct. 27, 2008) (on file with the North Carolina Journal of Law & Technology).

⁵¹ *In re Van Ornum*, 686 F.2d 937, 945 (C.C.P.A. 1982).

patenting, would become unenforceable if they were transferred separately to different owners.⁵² The court held that this rule amendment was valid and within the PTO's authority.⁵³ Although it is not explicit, this decision is consistent with the D.C. Circuit's view of procedural and substantive as two ends of a spectrum. The *Van Ornum* court noted, for example, that "the challenged rule has been in effect for more than a decade and this is the first attack on it which has come to our attention."⁵⁴ The implication is that the lack of challenges to the rule demonstrated that the effects of the rule were too slight for the rule to be considered substantive.

B. When notice and comment rulemaking is required for PTO rules

One apparent difficulty with the Federal Circuit's holding that the PTO lacks substantive rulemaking authority arises from the interaction of the Patent Act⁵⁵ and the Administrative Procedure Act ("APA").⁵⁶ Three rules combine to create an apparent contradiction. First, the Patent Act requires regulations enacted by the PTO to be made in accordance with the notice and comment provisions of the APA.⁵⁷ Second, those APA provisions do not require notice and comment for interpretive and procedural rules.⁵⁸ Third, the Federal Circuit has long held that the PTO may only promulgate interpretive and procedural rules.⁵⁹ From these three premises, it appears that the PTO is required to abide by the notice and comment provisions of the APA, but that any rule that the PTO has the power to enact is exempt from notice and comment under the APA. The PTO argued in *Tafas* that the proper resolution of this contradiction was to overturn the Federal Circuit decisions which held that the PTO may only promulgate interpretive and procedural rules, thus giving the PTO the power to

⁵² *Id.* at 945.

⁵³ *Id.* at 948.

⁵⁴ *Id.* at 946.

⁵⁵ Patent Act, 35 U.S.C. § 2(b)(2)(B) (2006).

⁵⁶ Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(A) (2006).

⁵⁷ Patent Act, 35 U.S.C. § 2(b)(2)(B) (2006).

⁵⁸ Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(A) (2006).

⁵⁹ *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549–1550 (Fed. Cir. 1996).

promulgate substantive rules.⁶⁰ The court in *Tafas* forcefully rejected this argument.⁶¹ Instead, to resolve the contradiction, the court ruled that the APA's notice and comment exceptions for procedural and interpretive rules⁶² do not apply to the PTO.⁶³ The *Tafas* court believed that the Patent Act⁶⁴ implies that the PTO must always engage in notice and comment rulemaking, even when promulgating procedural or interpretive rules.⁶⁵ In this, the District Court was incorrect.

In his *Administrative Law Treatise*, Richard J. Pierce, Jr. describes a "sensible approach" to characterizing rules as substantive or procedural under the APA:

If the characterization is fairly debatable, the court considers the purpose for which it is being asked to characterize the rule—whether the agency can promulgate the rule without any prior notice to the public and without receipt and consideration of comments from affected members of the public. With this purpose and implication of its choice of labels in mind, the court then looks at the rule to see whether its impact on substantive rights is so great that it should be adopted only after notice and comment.⁶⁶

Like the APA's provisions for notice and comment rulemaking,⁶⁷ the longstanding limitation on the Patent Office's rulemaking power⁶⁸ requires determining whether a rule is substantive. However, these two issues have quite different purposes. The PTO's rulemaking power is limited in order to ensure that the PTO does not exercise powers not delegated to it by Congress.⁶⁹ The

⁶⁰ *Tafas v. Dudas*, 541 F. Supp. 2d 805, 812–13 (E.D. Va. 2008).

⁶¹ *Id.* at 812 ("Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.") (quoting *Whitman v. Am. Trucking Assn'n*, 531 U.S. 457, 468 (2001)).

⁶² 5 U.S.C. § 553(b)(3)(A) (2006).

⁶³ *Tafas*, 541 F. Supp. 2d at 812.

⁶⁴ 35 U.S.C. § 2(b)(2)(B) (2006).

⁶⁵ *Tafas*, 541 F. Supp. 2d at 812.

⁶⁶ RICHARD J. PIERCE, JR., *ADMINISTRATIVE LAW TREATISE* § 6.5 (4th ed. 2002).

⁶⁷ Administrative Procedure Act, 5 U.S.C. § 553 (2006).

⁶⁸ *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–1550 (Fed. Cir. 1996); *see supra* note 33 (affirming decision).

⁶⁹ *Kessler*, 80 F.3d at 1549–50.

purpose of notice and comment rulemaking is to “give interested persons an opportunity to participate in the rule making,”⁷⁰ thus ensuring that the public is given notice and an opportunity to be heard before a binding rule is enacted. There is no reason that one test should be dispositive for both purposes. That is, the “tipping point” on the procedural/substantive spectrum, past which a rule is considered substantive rather than procedural, need not be the same for notice and comment rulemaking as it is for determining the PTO’s rulemaking authority. Professor Robert A. Anthony states that notice and comment rulemaking is required whenever a rule would have “practical binding effect upon private parties.”⁷¹ This standard is stricter than the “affecting individuals’ existing rights and obligations”⁷² standard used by the Federal Circuit in determining the PTO’s rulemaking power. Thus, it should be possible for rules with some substantive content to be within the PTO’s rulemaking authority, yet still be subject to notice and comment rulemaking.⁷³ Separating the tests for rulemaking authority and the notice and comment requirement would alleviate the need to reconcile the Patent Act with the APA. Furthermore, it avoids the harsh policy of the District Court’s solution, which would burden the Patent Office with the requirement of performing notice and comment rulemaking even for purely procedural rules.⁷⁴

⁷⁰ Administrative Procedure Act, 5 U.S.C. § 553(c) (2006).

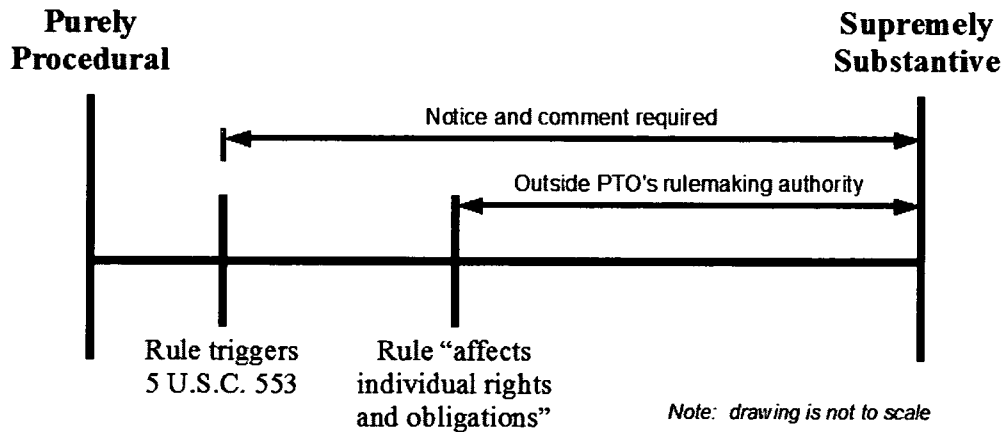
⁷¹ Robert A. Anthony, *A Taxonomy of Federal Agency Rules*, 52 ADMIN. L. REV. 1045, 1047 (2000).

⁷² *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979)).

⁷³ The rule in *Van Ornum* is one such rule. By placing a restriction upon transfer of patent rights in a special case, it was binding upon private parties, and thus subject to notice and comment rulemaking. A notice and comment hearing was held, but the rule was still found to be within the PTO’s authority to promulgate. *See In re Van Ornum*, 686 F.2d 937 (C.C.P.A. 1982).

⁷⁴ *See* Brief for the Appellants at 40, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. July 18, 2008).

Rule Ruling Ruler



C. The Final Rules are not entitled to Chevron deference

Because Congress generally delegates a substantial amount of authority to federal agencies, the rules and statutory interpretations made by those agencies tend to be given a high degree of deference.⁷⁵ One common level of deference, and the level which the PTO argues it should receive in *Tafas*, is *Chevron* deference.⁷⁶ Under *Chevron* deference, the reviewing court's first step is to determine "whether Congress has directly spoken to the precise question at issue."⁷⁷ If Congress has not, the second question for the reviewing court is whether the rule is "based on a permissible construction of the statute."⁷⁸ The PTO argues that it is entitled to *Chevron* deference regarding the Final Rules and in its interpretation of its own authority under 35 U.S.C. § 2(b)(2).⁷⁹

⁷⁵ *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984).

⁷⁶ Brief for the Appellants, *supra* note 10, at 18–23.

⁷⁷ *Chevron*, 467 U.S. at 842.

⁷⁸ *Id.* at 843.

⁷⁹ Brief for the Appellants, *supra* note 10, at 18–23.

The PTO's appellant's brief argues that the PTO should be afforded *Chevron* deference whenever the Office is exercising its rulemaking authority, based on the fact that the Federal Circuit has afforded PTO interpretations *Chevron* deference on many previous occasions.⁸⁰ However, two recent Federal Circuit cases make clear that, even if the PTO's rulemaking is *often* entitled to deference, it is not *always* entitled to deference. In *Brand v. Miller*,⁸¹ the Federal Circuit said, "[i]n most situations deference is due to agency positions on a legal question. But this is not a *Chevron* situation . . . because we have held in any event that the Board does not earn *Chevron* deference on questions of substantive patent law."⁸² The next year, in *Cooper Techs.*,⁸³ the court considered three questions before deciding that *Chevron* deference applied. First, the Federal Circuit determined whether the rule was within the PTO's rulemaking authority—that is, whether the rule in question was substantive, procedural, or interpretive.⁸⁴ The court found that the rule was interpretive, and thus within the general scope of the PTO's authority.⁸⁵ Second, the court considered whether the rule was promulgated lawfully, in accordance with the APA.⁸⁶ Concluding that it was, the court's third action was to verify that the statute interpreted by the rule in question was a statute that the PTO was responsible for administering.⁸⁷ Only after performing these three steps to ensure that the PTO had acted lawfully and within its authority in promulgating the rule did the

⁸⁰ Brief for the Appellants, *supra* note 10, at 23.

⁸¹ 487 F.3d 862 (Fed. Cir. 2007).

⁸² *Brand v. Miller*, 487 F.3d 862, 869 n.3 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 650 (2007).

⁸³ *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330 (Fed. Cir. 2008).

⁸⁴ *Id.* at 1335–36.

⁸⁵ *Id.* at 1336.

⁸⁶ *Id.* at 1336–37. The PTO had engaged in notice and comment rulemaking when promulgating the rule. *Id.* The court ruled that because the rule in question was interpretive, notice and comment rulemaking would not have been required. *Id.* Regardless, the rule was promulgated lawfully. *Id.* Presumably, if the court had found that notice and comment rulemaking should have been performed when it was not, the court would have struck down the rule. *Id.*

⁸⁷ *Id.* at 1337.

Federal Circuit begin the two-step *Chevron* analysis.⁸⁸ Thus, the district court in *Tafas* was correct in saying that the conclusion that the Final Rules were substantive “renders it unnecessary to decide whether the PTO’s interpretation of the Patent Act should be given *Chevron* deference.”⁸⁹

The PTO’s second argument for deference is that the PTO’s interpretation of its own authority is itself a question of statutory interpretation which deserves *Chevron* deference.⁹⁰ The PTO’s appellant’s brief quotes a concurring opinion by Justice Scalia saying: “it is settled law that the rule of deference applies even to an agency’s interpretation of its own statutory authority or jurisdiction.”⁹¹ If this rule applies, then the procedural versus substantive analysis performed by the district court in *Tafas* should have been replaced with the much more deferential question of whether the PTO’s interpretation that the Final Rules were within its rulemaking power was a permissible interpretation of 35 U.S.C. § 2(b)(2). Unfortunately for the PTO, Justice Scalia in his *Mississippi Power & Light Co. v. Mississippi*⁹² concurrence then goes on to say: “[t]o be sure, in defining agency jurisdiction Congress sometimes speaks in plain terms, in which case the agency has no discretion.”⁹³ Ever since *Animal Legal Defense Fund v. Quigg*,⁹⁴ it is clear that the Federal Circuit believes Congress spoke plainly in granting the PTO authority to “govern the conduct of proceedings in the Office”⁹⁵ and that the “usual

⁸⁸ But see RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 6.4 (4th ed. 2002) (The Federal Circuit may have been incorrect to give *Chevron* deference to an interpretive rule).

⁸⁹ *Tafas v. Dudas*, 541 F. Supp. 2d 805, 811 n.4 (E.D. Va. 2008); see also *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (holding that the “rule of controlling deference set forth in *Chevron* does not apply” when the rule was outside the PTO’s authority to promulgate).

⁹⁰ Brief for the Appellants, *supra* note 10, at 21.

⁹¹ *Mississippi Power & Light Co. v. Mississippi ex rel. Moore*, 487 U.S. 354, 381 (1988) (Scalia, J., concurring). But see Brief of Amicus Curiae William Mitchell College of Law Intellectual Property Institute in Support of Appellees at 15, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Oct. 3, 2008).

⁹² 487 U.S. 354 (1998).

⁹³ *Id.* at 382.

⁹⁴ 932 F.2d 920 (Fed. Cir. 1991).

⁹⁵ Patent Act, 35 U.S.C. § 2(b)(2)(A) (2006).

interpretation of such statutory language” would not include substantive rulemaking power.⁹⁶ In the PTO’s appellant’s brief, although the PTO argued that the Final Rules were procedural, it did not argue that the “conduct of proceedings in the Office”⁹⁷ language in the general statutory grant of authority should include substantive rules.⁹⁸ Finally, Congress has had many opportunities over the years to explicitly grant substantive rulemaking power to the Patent Office, and it has consistently declined to do so.⁹⁹ Instead, Congress has reserved for itself many of the powers it might have delegated to the PTO, such as the power to set many of the fees involved in patent prosecution.¹⁰⁰ Thus, because Congress plainly did not grant substantive rulemaking authority to the PTO, the PTO has no special discretion in regard to its own authority. Accordingly, its interpretation of the extent of that authority, including the question of whether the Final Rules are within its authority, should not receive deference.

D. A proposed clarification of rule characterization

The District Court’s first step in analyzing whether the Final Rules are substantive or procedural should have been to define the problem: either analyze the set of rules as a single package or break the rules up and analyze subsets separately. For some rules the choice is easy because the rules intertwine. Rules 75 and 265 are an example. Rule 75 requires submission of an ESD for applications containing more than 5 independent claims or 25 total

⁹⁶ *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991). For example, compare Congress’s grant of authority to the PTO, 35 U.S.C. § 2(b)(2) (“may establish regulations, not inconsistent with law, which—(A) shall govern the conduct of proceedings in the Office”), with the grant of authority to the Federal Communications Commission, 47 U.S.C. § 154(i) (“The Commission may perform any and all acts, make such rules and regulations, and issue such orders, not inconsistent with this chapter, as may be necessary in the execution of its functions.”).

⁹⁷ Patent Act, 35 U.S.C. § 2(b)(2)(A) (2006).

⁹⁸ Brief for the Appellants, *supra* note 10, at 2008–1352. In fact, Appellants conceded that “the Office has the statutory authority to issue ‘procedural’ rules but lacks authority to issue ‘substantive’ ones.” *Id.* at 11–12.

⁹⁹ See *supra*, note 34.

¹⁰⁰ Patent Act, 35 U.S.C. § 41 (2006).

claims.¹⁰¹ Rule 265 sets out the requirements for a proper ESD submission.¹⁰² Rule 75 without Rule 265 is meaningless, and Rule 265 without Rule 75 is pointless. Only together do the rules make sense, so they should be treated as one rule when determining whether they are substantive or procedural. When two rules have nothing to do with one another, they should be analyzed separately. Then if one rule is found to be unacceptable, the wheat is not thrown out with the chaff. When rules interact weakly, the court faces a more difficult choice. On one hand, an agency should not be allowed to do by halves what it cannot do as a whole. That is, an agency should not be allowed to promulgate two procedural rules which in aggregate are substantive. On the other hand, rejecting rules unnecessarily creates more work for both the court and the agency, as the agency must then ask the court to consider the innocent rule standing alone. Analyzing a set of rules in their aggregate does not mean that rules would only be considered together. It simply means that the effect of the interaction of the rules is considered in addition to the effect of the individual rules.

The District Court did not define the problem clearly. This is a moot point, however, as it found each rule, standing alone, to be substantive.¹⁰³ Even so, the court should have considered the Final Rules in the aggregate, rather than individually.¹⁰⁴ This is especially true because the District Court's injunction was issued against the rules in their entirety. Thus, the injunction acts against Rule 105,¹⁰⁵ which is arguably independent of the other Final Rules, even though the District Court did not examine Rule 105 in its decision.¹⁰⁶ Once the court has decided which rules shall be

¹⁰¹ Final Rules, 72 Fed. Reg. 46,716, 46,836–837 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

¹⁰² *Id.* at 46,842–43.

¹⁰³ *Tafas*, 541 F. Supp. 2d at 805.

¹⁰⁴ *Infra* Part III(C).

¹⁰⁵ Final Rules, 72 Fed. Reg. 46,841 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1). This change to 37 C.F.R. pt. 1.105 would allow the patent examiner to require a submission from the patent applicant which explained where in the patent's specifications there was written description support for the patent claims.

¹⁰⁶ *Tafas*, 541 F. Supp. 2d 805.

considered together and which separately, it may proceed to characterize each set of rules as substantive or procedural.

Under the Federal Circuit's definition, "a rule is 'substantive' when it 'effects a change in existing law or policy' which 'affect[s] individual rights and obligations.'"¹⁰⁷ When considering the effect of the rule upon the individual, care must be taken to consider each of the individual's options under the rule, and the impact of each option. "[E]ven a rule establishing a time limit for filing briefs can have a devastating effect on the substantive rights of a party who does not file by the time limit."¹⁰⁸ However, the impact of filing within the time limit may be much less substantial—the attorney responsible for the brief may simply have to devote more of her time to it. Although the impact of missing the filing date may be devastating, careful parties will file by the deadline and experience only a small impact. Thus, even if the impact of one option under the rule would be significant, the rule might still be procedural if the overall impact of the rule is less significant. Furthermore, the impact of the rule must be upon the party's rights and obligations—an impact on the party's schedule or pocketbook will not qualify.¹⁰⁹

III. ANALYSIS OF THE FINAL RULES

This section analyzes the Final Rules using the method presented in Part II(D). First, Rule 75, the 5/25 rule; second, Rule 78, which would allow only two continuation applications as a matter of right; and third, Rule 114, which would allow only one RCE as a matter of right.

¹⁰⁷ *Animal Legal Def. Fund*, *supra* note 21 (citing a number of Supreme Court and circuit court cases).

¹⁰⁸ RICHARD J. PIERCE, JR., *ADMINISTRATIVE LAW TREATISE* § 6.5 (4th ed. 2002).

¹⁰⁹ *See id.* Pierce summarizes two cases which support this assertion. In both cases, the D.C. Circuit found that rules were procedural even though the rules could have imposed new burdens upon individuals, because the burdens did not "alter the rights or interests of parties." *JEM Broad. Co. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994); *James V. Hurson Assocs., Inc. v. Glickman*, 229 F.3d 277 (D.C. Cir. 2000).

A. *Final Rule 75 is substantive and beyond the PTO's authority to enact*

Final Rule 75 (the “5/25 rule”) would require any application with more than five independent claims or more than twenty-five total claims to include extra documentation (called an examination support document or ESD) with claim explanation and prior art search information.¹¹⁰ There are three options available to the patent applicant under the 5/25 rule: (1) non-compliance with the rule, (2) submission of a compliant ESD when necessary, and (3) avoidance of the rule by reducing the number of claims below the 5/25 limit. The consequences for a missing or insufficient ESD are severe.¹¹¹ According to Final Rule 265, if the prior art search or ESD is insufficient, the applicant would be given a non—xtendable two month period in which to correct it.¹¹² If, within this time, the applicant either has not filed a sufficient ESD or has reduced her number of claims below the 5/25 limit, the application would be deemed forfeit by the PTO.¹¹³ This consequence is so severe that applicants will take great care to avoid it; thus non-compliance is not a reasonable option for applicants.

The court in *Tafas* described compliance with the 5/25 rule as “shifting the examination burden away from the PTO and onto applicants.”¹¹⁴ ESD compliance entails performing a search of U.S. patents and patent application publications, foreign patent documents, and non-patent literature.¹¹⁵ The ESD must contain a description of the search, a listing of the most pertinent references found, an identification of all of the limitations of each of the claims in each reference, “a detailed explanation of how each of the application’s independent claims is patentable over the cited references,”¹¹⁶ and a showing of the 35 USC § 112 support for

¹¹⁰ Final Rules, 72 Fed. Reg. 46,716, 46,836, 46,842, 46,843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

¹¹¹ Final Rules, 72 Fed. Reg. at 46,843.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Tafas v. Dudas*, 541 F. Supp. 2d 805, 816 (E.D. Va. 2008).

¹¹⁵ Final Rules, 72 Fed. Reg. at 46,842.

¹¹⁶ *Id.*

each limitation of each of the claims.¹¹⁷ Requiring an ESD even in some circumstances is a change in policy, because currently the elements of an ESD are not required for any application.¹¹⁸ The Patent Office cites the “inordinate amount of patent examining resources” consumed by patents with large numbers of claims as its reason for promulgating the 5/25 rule.¹¹⁹ Thus, the Patent Office hopes that the rule will reduce the average examination time for applications.¹²⁰ Because this reduction would be accomplished either by applicants presenting fewer claims or through the additional information provided to examiners in the ESD,¹²¹ the 5/25 rule will have a significant impact on patent applicants in general.

The submission of an ESD could be a significant obligation for the applicant. One recent patent which illustrates this is Patent No. 7,393,254, for a Marine Buoy.¹²² This invention is for a new design of marine buoys. The design permits large marine buoys, traditionally constructed out of heavy materials in order to withstand the extreme stresses of their deep-water environments, to be constructed out of lighter, cheaper materials without sacrificing durability.¹²³ The patent contains fifty-nine claims: nine independent claims and fifty dependent claims.¹²⁴ Like the claims in most patents, these claims describe the invention in different ways and with various degrees of specificity, so that even if some claims are invalidated, the invention can still be protected by the remaining claims.¹²⁵ If an ESD had been required for this

¹¹⁷ *Id.*

¹¹⁸ *Tafas*, 541 F. Supp. 2d at 816.

¹¹⁹ Final Rules, 72 Fed. Reg. at 46,721. Note that 35 U.S.C. § 41 requires patent applicants to pay an additional fee for each additional claim past a certain number, so the PTO is already receiving at least some compensation for the additional resources expended on applications with many claims. 35 U.S.C. § 41 (2006).

¹²⁰ *Id.* at 46,717; *see also Tafas*, 541 F. Supp. 2d at 809.

¹²¹ Final Rules, 72 Fed. Reg. at 46,842.

¹²² Marine Buoy, U.S. Patent No. 7,393,254 (filed Feb. 19, 2007) (issued July 1, 2008).

¹²³ *Id.* col. 2, l. 29–34.

¹²⁴ *Id.* col. 13–18.

¹²⁵ *See DURHAM, supra* note 8, at 19–21.

application, the prior art search alone would have been time-consuming.¹²⁶ Once the search had been performed and described, and the most pertinent references listed, the ESD would have to describe in detail how each of the nine independent claims was patentable over each of the cited references.¹²⁷ Finally, for each limitation of each of the fifty-nine claims in the patent, the ESD would include a showing that the limitation was supported by the patent specification.¹²⁸ Creation of such an ESD would be a technical and time-consuming exercise, far more involved than simply submitting an extra document, and therefore a significant burden to the applicant.¹²⁹ The District Court in *Tafas* determined that the requirements of an ESD burdened not just the applicant's schedule and pocketbook, but the applicant's rights and obligations as well.¹³⁰ In particular, the District Court quoted a 2005 Federal Circuit case: "[T]his court has repeatedly reaffirmed the proposition that 'as a general rule, there is no duty to conduct a prior art search. . . .'"¹³¹

The applicant's third option, reducing his claims below the 5/25 limit, is likewise unattractive. It is probably possible for some applicants to trim the fat from their applications and avoid

¹²⁶ Prior art searching typically involves searching databases of domestic and foreign patents, patent applications, and scientific literature. Because marine buoys are used globally, the prior art search should also be global. And, because marine buoys have been used for centuries and the invention could be built without modern materials, the prior art search should not be limited to recent inventions. Thus, the body of domestic and foreign patent and scientific literature to search would be huge. Although computers do help expedite such searches, only a skilled person would be able to determine how relevant the prior art of each previously invented marine buoy would be.

¹²⁷ Final Rules, 72 Fed. Reg. at 46,842.

¹²⁸ *Id.*

¹²⁹ See Brief of Amicus Curiae, *supra* note 13. Also note that among the PTO fees set by Congress are additional fees for each independent claim in excess of three, and each dependent claim in excess of 20. Patent Act, § 35 U.S.C. 41(a)(1)(B). Thus, to the extent that the ESD requirement can be considered an additional fee required of applicants with a large number of claims, the PTO may be encroaching on authority Congress has reserved for itself.

¹³⁰ *Tafas*, 541 F. Supp. 2d at 816.

¹³¹ *Id.* (citing *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1238 (Fed. Cir. 2005)).

the 5/25 rule without degrading their eventual patent. However, for complex inventions, it may not be possible to craft a set of claims which both fully protects the invention and stays under the 5/25 limit.¹³² Thus, for at least some inventors, reducing the number of claims to the 5/25 level would result in some loss of their rights to patent their inventions.¹³³

It is clear that each of the three options under the 5/25 rule would result in a substantive effect upon patent applicants. Compliance with the ESD requirement would represent a significant new burden upon the applicant. Avoidance of the ESD requirement would result in incomplete patent protection for some inventions because non-compliance would result in patent abandonment. The ESD thus “affect[s] individual rights and obligations” under the Federal Circuit’s standard,¹³⁴ and the 5/25 rule is therefore substantive.

The PTO’s final argument is that even if the ESD requirement would have substantive effects, the procedural aspects of the 5/25 rule are so strong that the rule should be considered nominally procedural. That is, the PTO contends that at most, the 5/25 rule should be considered procedural with substantive collateral effects, and thus within the PTO’s authority under *In Re Van Ornum*.¹³⁵ However, *Van Ornum* is easily distinguishable because the rule in *Van Ornum* restricted an extremely minor and obscure “right”¹³⁶ and created no new obligation, compared to the significant new ESD obligation created by the 5/25 rule.¹³⁷ The 5/25 rule falls much closer to the substantive end of the spectrum than the *Van Ornum* rule, and the 5/25 rule should therefore be considered outside the Patent Office’s authority.

¹³² See Brief of Monsanto Company as Amicus Curiae at 7–14, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Oct. 3, 2008).

¹³³ Patent Act, 35 U.S.C. § 101 (2006).

¹³⁴ *Supra* note 105 (alteration in original).

¹³⁵ Brief for the Appellants at 30–32, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. July 18, 2008).

¹³⁶ The right at issue in *Van Ornum* was the right to transfer overlapping patents, which would have been invalid on double patenting grounds but for a terminal disclaimer, to two separate people. *In re Van Ornum*, 686 F.2d 937, 945 (C.C.P.A. 1982).

¹³⁷ See *supra* Part III(A).

B. Final Rule 78 is beyond the PTO's authority to enact

As with the 5/25 rule, rules 78 and 114 (collectively the 2+1 rule) represent a notable change in PTO policy. Chains of continuation applications have been in use for over fifty years.¹³⁸ The practice of allowing multiple RCEs has existed for nearly a decade.¹³⁹ The 2+1 rule would change these existing policies by requiring the applicant to submit a petition showing that material presented in the continuation or RCE could not have been submitted previously for any continuation after the second, or any RCE after the first.¹⁴⁰ Thus, the current use of continuations and RCEs to continue prosecution after a rejection would generally not be permitted past the 2+1 limit.¹⁴¹

While the 2+1 rule clearly changes continuation policy, its impact on the rights and obligations of an applicant is less clear. The PTO argues that efficient prosecution will allow applicants to perfect their claims within the 2+1 limit, and that the ability to request further continuations or RCEs upon petition and showing will protect the patent rights of applicants in cases of unforeseen circumstances.¹⁴² The PTO's concern for the rights of the applicant in these cases is not entirely convincing: "[E]ven if such a showing [that the material could not have been submitted previously] is not made, an applicant is not barred from filing a third or subsequent continuation application; the only consequence is that the new filing does not receive the benefit of the initial application's filing date."¹⁴³ The loss of the filing date benefit, which the PTO dismisses so glibly, would often entirely prevent the invention from being patented, resulting in the loss of the

¹³⁸ See generally *In re Henriksen*, 399 F.2d 253 (1968).

¹³⁹ Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 Fed. Reg. 50,092, 50,095–96 (Aug. 16, 2000) (to be codified at 37 C.F.R. pt. 1) ("an applicant . . . is not limited in the number of times [an RCE may be submitted]").

¹⁴⁰ Final Rules, 72 Fed. Reg. 46,716, 46,838–39, 46,841 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

¹⁴¹ *Id.* at 46769–77; see also *Tafas*, 541 F. Supp. 2d at 814 ("[The 2+1 rule] effectively imposes a hard limit on additional applications.").

¹⁴² Brief for the Appellants at 7–9, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. July 18, 2008).

¹⁴³ *Id.* at 7.

inventor's rights in his invention.¹⁴⁴ Given the difficulty of satisfying the "new material" petition and showing requirement along with the significant consequence of failing the petition and showing requirement, the court in *Tafas* quite reasonably characterized the 2+1 rule as a "hard limit" on continuations.¹⁴⁵

GlaxoSmithKline ("GSK") in its plaintiff-appellee's brief, and Monsanto Company ("Monsanto") in its amicus brief both convincingly argue that for certain types of inventions, Rule 78 would prevent inventors from fully protecting their invention.¹⁴⁶ Monsanto contends that multiple continuation applications are necessary in order to fully protect "complicated inventions that develop over time."¹⁴⁷ For these types of inventions, the initial patent application contains broad claims, and continuation applications contain more specific claims.¹⁴⁸ Monsanto cites as an example its own catalyst technology;¹⁴⁹ GSK describes a similar situation involving new classes of drug compounds.¹⁵⁰ In these examples, Monsanto and GSK use continuations to claim particularly successful specific embodiments of their general inventions.¹⁵¹ Thus, they argue that Rule 78's two continuation

¹⁴⁴ The Patent Act bars an inventor from receiving a patent under certain conditions. For example, an inventor must apply for a patent within a year of describing the invention in a print publication to be eligible for a patent on the invention. 35 U.S.C. § 102(b) (2006). Similarly, if the inventor offers the invention for sale in the United States, any application filed more than one year after the offer of sale would be ineligible for the grant of a patent. *Id.* Continuation applications which receive the benefit of the earlier application's filing date do not run afoul of these bars, where an application which did not benefit from the earlier filing date would be barred. 35 U.S.C. § 120 (2006).

¹⁴⁵ *Tafas*, 541 F. Supp. 2d at 814 (E.D. Va. 2008).

¹⁴⁶ Brief of Plaintiffs-Appellees GlaxoSmithKline at 6–9, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Sept. 24, 2008); Brief of Monsanto Company as Amicus Curiae at 3–5, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Oct. 3, 2008).

¹⁴⁷ Brief of Monsanto Company as Amicus Curiae at 7, *Tafas*, No. 2008–1352 (Fed. Cir. Oct. 3, 2008).

¹⁴⁸ *Id.* at 8–11.

¹⁴⁹ *Id.* at 7–25.

¹⁵⁰ Brief of Plaintiffs-Appellees GlaxoSmithKline at 8, *Tafas*, No. 2008–1352 (Fed. Cir. Sept. 24, 2008).

¹⁵¹ Brief of Monsanto Company as Amicus Curiae at 8–10, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Oct. 3, 2008); Brief of Plaintiffs-Appellees

limit would reduce their ability to protect developments made after two continuations had already been filed.¹⁵² While Rule 78 standing alone would have some substantive effect upon applicants, the substantive effect of Rule 78 would be even greater if the 5/25 rule were enacted as well.¹⁵³ Both the rules would interact to cause an effect greater than the sum of their parts. Rule 78 limits the applicant's ability to perfect his claims through continued prosecution; it thus encourages the applicant to act with foresight and file all claims in the initial application.¹⁵⁴ This foresight might be difficult to exercise in practice, especially if the invention is continuing to develop. Denied the opportunity to repeatedly amend their claims until they hit the "bullseye" of ideal protection, applicants could instead choose a "shotgun" approach. That is, they could file a large number of claims initially, hoping that some claims would hit the bullseye even without additional time to aim or perfect them. The 5/25 rule would require an ESD from applicants wishing to file a large number of claims,¹⁵⁵ thus placing a burden upon applicants who might otherwise use this alternate method to fully claim their inventions. Describing this difficulty, Monsanto says, "[o]ne rule demands uncommon prescience, the other thwarts it."¹⁵⁶ Thus, Rule 78 standing alone would have a substantive effect on applicants standing alone, and an even greater effect when combined with the 5/25 rule.

GlaxoSmithKline at 8, *Tafas v. Dudas*, No. 2008-1352 (Fed. Cir. Sept. 24, 2008).

¹⁵² Brief of Monsanto Company as Amicus Curiae at 17-18, *Tafas*, No. 2008-1352 (Fed. Cir. Oct. 3, 2008); Brief of Plaintiffs-Appellees GlaxoSmithKline at 8-9, *Tafas*, No. 2008-1352 (Fed. Cir. Sept. 24, 2008).

¹⁵³ See, e.g. Brief of Monsanto Company as Amicus Curiae at 11-16, *Tafas*, No. 2008-1352 (Fed. Cir. Oct. 3, 2008).

¹⁵⁴ *Id.* at 16.

¹⁵⁵ Final Rules, 72 Fed. Reg. 46,716, 46,836 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

¹⁵⁶ Brief of Monsanto Company as Amicus Curiae at 16, *Tafas*, No. 2008-1352 (Fed. Cir. Oct. 3, 2008).

Although the District Court held that Rule 78 was substantive, it considered the practical effect of Rule 78 only in passing.¹⁵⁷ Instead, the court held that Rule 78 conflicted with the Patent Act,¹⁵⁸ which states that continuation applications “shall have” priority benefit from the initial application.¹⁵⁹ Furthermore, the Patent Act specifically allows for chains of multiple continuations.¹⁶⁰ The *Tafas* court, relying on the Patent Act and two C.C.P.A. decisions,¹⁶¹ held that the statutory language meant that any continuation application, not just the first two, was entitled to priority from the initial application.¹⁶²

In support of its contention that it has the authority to place a limit upon continuations, the PTO cites the case of *In re Bogese*.¹⁶³ The *Bogese* case involves a patent applicant who filed ten identical

¹⁵⁷ *Tafas v. Dudas*, 541 F. Supp. 2d 805, 815 (E.D. Va. 2008) (“[Final Rule 78] may also impact applicants’ rights under Sections 102 and 103 and result in the denial of otherwise meritorious patents.”).

¹⁵⁸ Patent Act, 35 U.S.C. § 120 (2006). Stating:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

Id.

¹⁵⁹ *Tafas*, 541 F. Supp. 2d at 814–15.

¹⁶⁰ Patent Act, 35 U.S.C. § 120 (2006) (“[Continuations can be filed] on the first application or on an application similarly entitled to the benefit of the filing date of the first application.”).

¹⁶¹ *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968); *In re Hogan*, 559 F.2d 595, 604 n.13 (C.C.P.A. 1977) (“a limit upon continuing applications is a matter of policy for the Congress”).

¹⁶² *Tafas*, 541 F. Supp. 2d at 814.

¹⁶³ Brief for the Appellants at 7–9, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. July 18, 2008) (citing *In re Bogese*, 303 F.3d 1362, 1364 (Fed. Cir. 2002)); see also *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361, 1364 (Fed. Cir. 2002) (holding that the doctrine of prosecution laches is a permissible method by which the PTO can combat undue delay in prosecution).

continuation applications in succession, transparently intending to simply extend the prosecution of his patent rather than help the application progress toward acceptance.¹⁶⁴ When the examiner rejected the tenth continuation, he warned Bogese that “the next continuation of this series may be rejected by invoking the equitable doctrine of laches, absent any substantive amendment to advance prosecution.”¹⁶⁵ Despite the warning, Bogese filed an eleventh identical continuation application.¹⁶⁶ His application was then deemed forfeit by the PTO, and he entirely lost his rights to a patent on his invention.¹⁶⁷ The Federal Circuit upheld the use of the doctrine of laches to prevent undue delay, stating that “the PTO may impose reasonable deadlines and requirements on parties that appear before it.”¹⁶⁸ The PTO argues that *Bogese* should be considered an explicit grant of authority for Rule 78.¹⁶⁹ However, it is not clear that the Federal Circuit intended to grant the PTO the authority to create “one size fits all” deadlines like Rule 78.¹⁷⁰

In summary, both GSK’s appellee’s brief and Monsanto’s amicus brief convincingly present the case that, at least for certain types of inventions, Rule 78 will reduce the inventor’s ability to obtain full patent protection for his invention.¹⁷¹ This effect on “individual rights and obligations”¹⁷² meets the Federal Circuit’s definition for a substantive rule. Additionally, the *Tafas* court’s statutory analysis provides strong support for rejecting Rule 78 as

¹⁶⁴ *In re Bogese*, 303 F.3d 1362, 1364 (Fed. Cir. 2002).

¹⁶⁵ *Id.* (The doctrine of laches means that failure to assert one’s rights can result in a loss of those rights.)

¹⁶⁶ *Id.* at 1365.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 1368.

¹⁶⁹ Brief for the Appellants, *supra* note 10, at 43–46 (citing *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002)).

¹⁷⁰ See generally *Bogese*, 303 F.3d at 1362.

¹⁷¹ See Brief of Plaintiffs-Appellees GlaxoSmithKline, at 6–9, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Sep. 24, 2008); Brief of Monsanto Company as Amicus Curiae at 7–25, *Tafas v. Dudas*, No. 2008–1352 (Fed. Cir. Oct. 3, 2008); see also *supra* Part III(B).

¹⁷² *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991).

inconsistent with the Patent Act.¹⁷³ For these reasons, the Federal Circuit should uphold the injunction against Rule 78.

C. *Final Rule 114 is not substantive when considered independently of the other Final Rules*

The *Tafas* ruling on Rule 114, finding a statutory right to unlimited RCEs, is more problematic than the Rule 78 ruling. Unlike 35 U.S.C. § 120, which specifically allows for multiple continuations,¹⁷⁴ 35 U.S.C. § 132 is silent on the issue of whether multiple RCEs would be allowed. It simply states that “[if] the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined.”¹⁷⁵ Nor was the *Tafas* court able to cite cases supporting the practice of unlimited RCEs, perhaps because RCEs are a relatively recent innovation.¹⁷⁶ Although the *Tafas* court held that the language of § 132 was “best read as evidence that Congress intended to allow for an unlimited number of RCEs,”¹⁷⁷ it also adopted an alternate position. This alternate position was that the word “application” in § 132 meant that every initial or continuation *application* was entitled to at least one RCE as a matter of right, rather than the one RCE per application *family* allowed under Rule 114.¹⁷⁸ However, the recent *Cooper Techs.* court held that the phrase “original application” in the statute on *inter partes* examinations could permissibly mean either the initial application of an application family or any initial or continuation application.¹⁷⁹ Thus the *Tafas* court’s interpretation of “application” is probably only one of multiple permissible interpretations. Because courts tend to show deference to agency interpretations of statutes that the agency is charged with

¹⁷³ *Supra* notes 155–160, and accompanying text.

¹⁷⁴ *Supra* notes 158, 160, and accompanying text.

¹⁷⁵ Patent Act, 35 U.S.C. § 132 (2006).

¹⁷⁶ Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 Fed. Reg. 50,092 (Aug. 16, 2000) (to be codified at 37 C.F.R. pt. 1).

¹⁷⁷ *Tafas*, 541 F. Supp. 2d 805, 815 (E.D.Va. 2008).

¹⁷⁸ *Id.*

¹⁷⁹ *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1343 (Fed. Cir. 2008).

administering, the Federal Circuit may be persuaded by the PTO's interpretation of § 132.¹⁸⁰

While the statutory analysis of Rule 114 performed in *Tafas* may not persuade the Federal Circuit, the question of whether Rule 114 is substantive is much simpler. Standing alone, Rule 114 is not substantive, and would be within the PTO's power to enact.¹⁸¹ This is because the entire effect of an RCE could alternatively be achieved through the use of continuation applications. When enacting the rules for RCE practice, the Patent Office described RCEs as a simpler alternative method for an applicant to pay for further examination of his application: "Previously, an applicant had to file a continuing application . . . to obtain continued examination of an application for a fee."¹⁸² Thus, the only effect of a limit on RCEs, without a corresponding limit on continuation applications, would be to force applicants to use continuations rather than RCEs past the limit. The D.C. Circuit has stated that this type of rule is procedural: "the 'critical feature' of a rule that satisfies the so-called 'procedural exception' is that it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency."¹⁸³

However, Rule 114 was not promulgated alone, but as part of the Final Rules.¹⁸⁴ Rule 114's interaction with Rule 78 is clear enough that the District Court often discussed the rules together as the "2+1 rule."¹⁸⁵ Though the District Court analyzed the rules individually and found them substantive because the PTO

¹⁸⁰ See *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984).

¹⁸¹ See *supra* Part II(A).

¹⁸² Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 Fed. Reg. 50,092, 50,092 (Aug. 16, 2000) (to be codified at 37 C.F.R. pt. 1).

¹⁸³ *James V. Hurson Assoc., Inc. v. Glickman*, 229 F.3d 277, 280 (D.C. Cir. 2000) (internal citations omitted).

¹⁸⁴ Final Rules, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

¹⁸⁵ *Tafas v. Dudas*, 541 F. Supp. 2d 805, *passim* (E.D. Va. 2008).

promulgated the Final Rules as a package,¹⁸⁶ it would have been appropriate to rule on them as a package, then remand to the PTO if the agency wished to pursue rules individually. For this reason, the District Court was correct in issuing an injunction against the Final Rules in their entirety despite the faulty ruling on Rule 114.

IV. CONCLUSION

The district court in *Tafas v. Dudas* was correct in its ruling that the Final Rules promulgated by the PTO to promote efficiency and reduce the backlog at the Patent Office are substantive and thus outside the Patent Office's rulemaking authority. The Court of Appeals for the Federal Circuit should affirm the decision on appeal. However, the Federal Circuit has the opportunity to do more. It should clarify the circumstances under which the Patent Office is required to engage in notice and comment rulemaking. It can more clearly define the scope of the Patent Office's authority, the deference due to Patent Office rules and interpretations, and the proper method of analyzing Patent Office rulemaking. In formulating this clarification, the Federal Circuit can draw upon the D.C. Circuit's experience in administrative law and provide a more nuanced view of substantive and procedural rules.¹⁸⁷

¹⁸⁶ Final Rules, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1). Not only are the Final Rules unified by their goal of creating a "better focused and effective examination process to reduce the large and growing backlog of unexamined applications" but the PTO understands that the rules would affect one another. *Id.* at p.46717. For example, discussing the use of continuation applications to file additional claims without triggering the 5/25 rule's ESD requirement, the PTO said: "Thus, an applicant may present up to fifteen independent claims and seventy-five total claims to a single patentably distinct invention via an initial application and two continuation or continuation-in-part applications that are filed and prosecuted serially without providing either an examination support document or a justification." *Id.* at p. 46,721.

¹⁸⁷ See generally Stuart M. Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 270 (2006) (arguing that the Patent Office and the Federal Circuit would benefit by adopting principles of administrative law from the D.C. Circuit).