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IN THE UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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TRANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),  
SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JON DUDAS, Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent & Trademark Office, and  
UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

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Appeal from the United States District Court For the Eastern District of Virginia  
in Consolidated Case Nos. 1:07-CV-846 and 1:07-CV-1008,  
Senior Judge James C. Cacheris

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## **STATEMENT OF RELATED CASES**

No other appeal in or from the present civil action has previously been before this or any other appellate court. Counsel knows of no case pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

## **STATEMENT OF JURISDICTION**

This case involves challenges to the validity of rules of practice in patent cases issued by the United States Patent and Trademark Office (USPTO or Office). The challenges arise under the Administrative Procedure Act, 5 U.S.C. §§ 701 et seq., and the Patent Act, 35 U.S.C. §§ 1 et seq. The plaintiffs invoked the jurisdiction of the district court under 28 U.S.C. §§ 1331 and 1338. On April 1, 2008, the district court entered a final order granting summary judgment to the plaintiffs and permanently enjoining defendants from implementing the revised rules. JA27-28. Defendants filed a timely notice of appeal on May 7, 2008. JA358-59. This Court has jurisdiction over the appeal under 28 U.S.C. § 1295(a).

## **STATEMENT OF ISSUES**

1. Whether the USPTO's revised rules of practice for patent cases are within the scope of the Office's statutory rulemaking authority.
2. Whether the revised rules conflict with the Patent Act.
3. Whether the USPTO must provide public notice and comment for rules that are not subject to notice and comment under the Administrative Procedure Act.

## **STATEMENT OF THE CASE**

In August 2007, the USPTO issued revisions to its existing rules of practice for patent cases. The revised rules require applicants who file more than two continuation or continuation-in-part applications or more than one request for continuing

examination to show that the amendment, argument, or evidence could not have been submitted previously. The rules also require an applicant to provide specified information regarding claims and prior art if the application contains more than five independent claims or twenty-five total claims. The revisions are intended to enable the Office “to conduct a better and more thorough and reliable examination of patent applications” by “reduc[ing] the large and growing backlog of unexamined applications while maintaining or improving the quality of issued patents.” JA52, 53 (72 Fed. Reg. 46716, 46717 (Aug. 21, 2007)).

The plaintiffs brought suit against the USPTO to challenge the validity of the revised rules. In April 2008, the district court entered summary judgment in favor of the plaintiffs, holding that the rules exceed the scope of the USPTO’s statutory rulemaking authority and conflict with other provisions of the Patent Act. 541 F. Supp. 2d 805 (E.D. Va. 2008). The USPTO now appeals.

## **STATEMENT OF FACTS**

### **I. The Present Rulemaking Proceedings**

The USPTO’s principal source of patent rulemaking authority is 35 U.S.C. § 2(b)(2). Section 2(b)(2) authorizes the USPTO to “establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the Office.” Id. § 2(b)(2)(A). Section 2(b)(2) further authorizes the Office to issue regulations that,

inter alia, “facilitate and expedite the processing of patent applications” and “govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office.” Id. § 2(b)(2)(C)-(D). In addition, the Patent Act contains other provisions that authorize more specific rulemaking exercises. Among other things, the Act provides specifically for the Office to issue regulations regarding requests for continued examinations (RCEs). Id. § 132(b).

Acting pursuant to its rulemaking authority, the USPTO has promulgated rules of practice for patent cases. 37 C.F.R. Part 1. In January 2006, the Office initiated two related rulemaking proceedings to revise its rules of practice. See JA29-42 (71 Fed. Reg. 48-61 (Jan. 3, 2006) (proposed rules)); JA42-50 (71 Fed. Reg. 61-69 (Jan. 3, 2006) (proposed rules)). The Office gave notice, solicited public comments, and conducted public meetings to discuss the proposed changes. After spending more than one year analyzing the public comments, the Office modified its original proposals and issued revised rules. See JA51-179 (72 Fed. Reg. 46717-46843 (Aug. 21, 2007) (final rules)).

This appeal involves challenges to four of the revised rules (collectively “the Final Rules”). Two of those rules, Final Rule 78 and Final Rule 114, are designed to assist the Office in addressing its growing backlog of unexamined new applications by discouraging unnecessarily repetitive use of continuation and continuation-in-part

applications and RCEs. Two other rules, Final Rule 75 and Final Rule 265, are intended to improve the Office's examination process by requiring applicants to provide examiners with specified information about claims and prior art when applications contain large, and hence particularly burdensome, numbers of claims.

**A. Final Rules 78 and 114: Continuation Applications and Requests for Continued Examination (RCEs)**

Continuation and continuation-in-part applications and RCEs enable applicants to extend the examination process in order to obtain consideration of new claims, arguments, or evidence. See generally 35 U.S.C. § 120 (continuation and continuation-in-part applications); *id.* § 132(b) (RCEs). When used properly, continuation applications and RCEs can assist applicants in prosecuting applications and obtaining protection for inventions that meet the Act's requirements for patentability. But when used unnecessarily, they can interfere with the efficient operation of the examination process, to the detriment of inventors and the public at large.

The excessive use of continuation and continuation-in-part applications and RCEs has contributed to one of the most serious problems now facing the USPTO – the “large and growing backlog of unexamined patent applications.” JA53 (72 Fed. Reg. 46717). In recent years, the backlog of unexamined applications has more than tripled, growing from 224,446 in 1998 to 701,147 in 2006. JA126 (*id.* at 46790). The

growing backlog has had a “crippling effect” on the Office’s ability to examine new applications. JA54 (id. at 46718). The average time that an application remains pending before first Office action has grown to 22.6 months, and up to 43.9 months in certain areas. JA92 (id. at 46756) (FY06 data). Such delays have a particularly acute effect on industries such as computer software and hardware technologies, where “product life cycles are short and new improvements can quickly make the technology obsolete.” Id.

Continuation and continuation-in-part applications and RCEs play a major role in this problem. As a percentage of all filings, continuation applications and RCEs increased from little more than a tenth (11.4%) in 1980 to nearly a third (29.4%) in 2006. JA54 (72 Fed. Reg. 46718). As the USPTO spends more time reviewing applications “that are a repetition of prior applications that have already been examined,” it is necessarily diverted from reviewing “new applications disclosing new technology and innovations.” Id.; see also JA102 (id. at 46766).

In addition, unlimited recourse to continuation applications and RCEs has led to misuse and abuse. Some applicants “rely on an unlimited number of continued examination filings to correct deficiencies in the claims and disclosure” that could have been avoided by greater diligence and care in the preparation of the initial applications. Id. at 46719 (giving examples). In other instances, “some applicants and

practitioners have used multiple continued examination filings as a strategy to delay the conclusion of examination” so that they can later add claims to their applications based on products or processes later discovered in the marketplace. Id.<sup>1</sup> Both scenarios constitute a “misuse of [the] continued examination practice” and a violation of an applicant’s and practitioner’s duty under 37 C.F.R. § 10.18(b)(2)(i) not to submit an application that causes unnecessary delay or needless increase in the cost of prosecution before the Office. JA55 (72 Fed. Reg. 46719).

Finally, when the patent application process can continue without end, “the public is left with an uncertainty as to what the set of patents resulting from the initial application will cover.” JA54 (72 Fed. Reg. 46718). Thus, the prior rules and their abuse “impose a burden on innovation both by retarding the Office’s ability to examine new applications and by undermining the function of claims to notify the public as to what technology is or is not available for use.” Id. The misuse of continued examination practices such as intentional delay “also prejudices the public by keeping applications in pending status while awaiting developments in similar or parallel technology and then later amending \* \* \* applications to cover these developments.” Id. at 46719.

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<sup>1</sup> The addition of such claims is improper when an applicant causes intentional delay “for the sole purpose of awaiting developments in similar or parallel technology.” JA97 (id. at 46761).

The USPTO issued Final Rules 78 and 114 to address these problems. Under Final Rule 78, “an applicant may \* \* \* file two continuation applications \* \* \* without any justification.” JA55 (72 Fed. Reg. 46719); JA174 (id. at 46838) (37 C.F.R. § 1.78(d)(i)(A)). If an applicant wishes to exceed that number, he must demonstrate “why the amendment, argument, or evidence sought to be entered could not have been previously submitted.” JA55 (72 Fed. Reg. 46719); see JA175 (id. at 46839) (37 C.F.R. § 1.78(d)(1)(vi)). Final Rule 78 “do[es] not set a *per se* limit on the number of continuing applications,” for an applicant may file more than two continuation applications by making the requisite showing. JA56 (id. at 46720). And even if such a showing 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. JA175 (72 Fed. Reg. 46839) (37 C.F.R. § 1.78(d)(1)); see JA65 (id. at 46729-30).

Similarly, under Final Rule 114, “an applicant may \* \* \* file \* \* \* [one] request for continued examination \* \* \* without any justification.” JA55 (72 Fed. Reg. 46719); JA177 (id. at 46841) (37 C.F.R. § 1.114(f)). If the applicant files more than that, he must show that the “amendment, argument, or evidence sought to be entered could not have been previously submitted.” Id. Final Rules 78 and 114 operate

independently, meaning that an applicant can file both two continuation applications and one RCE without having to make the required showing. JA66 (id. at 46730).

The USPTO “will determine on a case-by-case basis” whether an applicant has made a sufficient showing “as to why the amendment, argument or evidence sought to be entered could not have been submitted earlier.” JA107 (72 Fed. Reg. 46771). Among the factors to be considered are: (1) whether the applicant should file an appeal or petition instead of continuing prosecution; (2) whether the applicant has acted with “reasonable diligence” in submitting the new evidence, amendment, or argument; and (3) the number of co-pending applications with substantially identical disclosures. Id. Examples of situations in which the Office expects to grant such petitions are: (a) when data necessary to overcome an obviousness rejection was diligently pursued and just became available, JA109 (id. at 46773); (b) when a final rejection contains a new ground of rejection that could not have been anticipated by the applicant, JA110 (id. at 46774); (c) when evidence demonstrating enablement or utility just became available from reasonably diligent testing, JA111-12 (id. at 46775-76); and (d) when the Board of Patent Appeals and Interferences suggests splitting an application subject to an interference, JA112 (id. at 46776). Even if an applicant fails to demonstrate why the additional evidence could not have been presented earlier, the

USPTO can suspend or waive these Rules “in an extraordinary situation” if “justice requires” it. 37 C.F.R. § 1.183; see JA105 (72 Fed. Reg. 46769).

**B. Final Rules 75 and 265: Submission of Examination Support Documents (ESDs) for Applications with Large Numbers of Claims**

Final Rules 75 and 265 address a related but distinct problem: the proliferation of applications containing large numbers of claims. In 1990, applications averaged about 14.4 claims each; by 2005, the average application contained about 21 claims. JA182 (Administrative Record (“AR”) 07099). This increase in the number of claims has contributed to the Office’s backlog of unexamined applications. JA57 (72 Fed. Reg. 46721). The increase has also affected the USPTO’s ability to correctly evaluate patent applications. As the number of claims increases, so does a patent examiner’s error rate. The error rate for applications with more than 25 claims is significantly higher than the error rate for applications containing fewer than 25 claims. JA181 (AR 05059) (FY05/FY06 data).

Final Rules 75 and 265 are designed to facilitate the Office’s examination of applications containing a large number of claims, by requiring applicants to provide information about the claims and prior art to assist the examiner in determining the patentability of the claims. See, *e.g.*, JA57 (72 Fed. Reg. 46721). Final Rule 75 permits an applicant to present up to five independent claims and twenty-five total claims for examination without providing any specific information about the

patentability of the claims. See JA57, 172 (72 Fed. Reg. 46721, 46836) (37 C.F.R. § 1.75(b)(1)). Should an applicant wish to present more than five independent claims or twenty-five total claims, Final Rule 75 requires the applicant to provide information about the claims in an examination support document (ESD). Id. Final Rule 75 places no limit of any kind on the number of claims that may be presented; an applicant remains free to present as many claims as he desires.

The requirements for an ESD are set forth in Final Rule 265. See JA178-79 (72 Fed. Reg. 46842-43) (37 C.F.R. § 1.265). Final Rule 265 requires an applicant to conduct a preexamination search and explain how the claimed invention is patentable over the search results. Final Rule 265 also gives an applicant the opportunity to correct deficiencies in the preexamination search upon notice from the Office.

Final Rules 75 and 265 do not alter the Office's obligation to search the prior art and examine the claims. See 37 C.F.R. § 1.104; JA135, 141 (72 Fed. Reg. 46799, 46805). Instead, with the ESD as a "launch pad," an examiner will have a better understanding of an invention and its background at the outset of the examination and thus will be able to perform a faster, more efficient, higher-quality examination. This assistance is vital in view of the limited time that examiners have to examine each application and the disproportionate burdens on examination resources that are imposed by applications with large numbers of claims.

## II. The Present Litigation

The plaintiffs filed separate suits to contest the validity of the Final Rules. The plaintiffs contended, *inter alia*, that the Final Rules are outside the scope of the USPTO's statutory rulemaking authority and that the rules conflict in various respects with other provisions of the Patent Act. On October 31, 2007, the district court granted a preliminary injunction against the implementation of the Final Rules. JA320-57 (511 F. Supp. 2d 652). On April 1, 2008, the district court entered summary judgment in favor of the plaintiffs and issued a permanent injunction against the Final Rules. JA1-28.<sup>2</sup>

The district court held that the Final Rules exceed the USPTO's authority under 35 U.S.C. § 2(b)(2). JA10-25. In so holding, the court did not attempt to determine whether the Final Rules “govern the conduct of proceedings in the Office” (§ 2(b)(2)(A)), “facilitate and expedite the processing of patent applications” (§ 2(b)(2)(C)), or “govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office” (§ 2(b)(2)(D)). Instead, the court held as a categorical matter that the Office has the statutory authority to issue “procedural” rules but lacks authority to issue “substantive” ones.

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<sup>2</sup> Although the district court addressed only four of the revised Rules, it erroneously enjoined the new rules in their entirety, including rules that were not challenged by the plaintiffs.

JA11, 13, 15. To determine whether the Final Rules are substantive or procedural, the court asked whether they “affect individual rights and obligations” or create “a change in existing law or policy which affects individual rights and obligations.” JA17. Applying that test, the court concluded that all of the Final Rules are substantive, because they “constitute a drastic departure from the terms of the Patent Act as they are presently understood” and thus “change existing law and alter the rights of applicants such as [the plaintiffs] under the Patent Act.” JA18.

That conclusion rests principally on the court’s determination that each of the Final Rules conflicts with provisions of the Act. The court first held that Rule 78 is inconsistent with 35 U.S.C. § 120, which permits continuation applications to claim the priority benefit of an earlier application. The court construed Section 120 to guarantee an applicant the right to file an unlimited number of continuation applications, and held that Rule 78 impairs that right by imposing what the court regarded as a “hard limit” on the number of continuation applications that may be filed. JA18-19.

For similar reasons, the court held that Final Rule 114 is inconsistent with 35 U.S.C. § 132(b), which directs the USPTO to issue regulations providing for continued examination of applications at the request of the applicant. The court construed Section 132(b) as giving applicants the right to request an unlimited number

of continued examinations and to do so with respect to each application in an application family. The court characterized Rule 114 as a “hard cap” that conflicts with Section 132(b) in two respects, by confining applicants to one RCE and by making that limit applicable to application families rather than to each individual application. JA20-22.

Finally, the court held that Final Rules 75 and 265 are inconsistent with multiple provisions of the Patent Act. The court held that Rule 75 conflicts with 35 U.S.C. § 112, ¶ 2, which provides for applications to include “one or more claims.” The court construed Section 112 to preclude the imposition of a fixed limit on the number of claims in an application, and characterized Rule 75 as imposing such a limit. JA22-23. The court further held that Rule 75 and Rule 265 are inconsistent with 35 U.S.C. §§ 102, 103, and 131. The court viewed Rules 75 and 265 as “shifting the examination burden away from the USPTO and onto applicants” in derogation of those provisions. JA24-25.

## **SUMMARY OF ARGUMENT**

**1.** The Final Rules are within the scope of the USPTO's rulemaking authority under the Patent Act. The Act's primary grant of rulemaking authority, Section 2(b)(2), authorizes the Office to issue rules that "govern the conduct of proceedings in the Office," "facilitate and expedite the processing of patent applications," and

"govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office." The USPTO correctly determined that the Final Rules fit within these grants of rulemaking authority. By setting filing and documentation requirements, the rules regulate the conduct of proceedings in the Office and the conduct of attorneys and other representatives, and by discouraging unnecessarily repetitive filings and providing examiners with needed information, they facilitate and expedite the processing of patent applications.

In holding that the Final Rules are ultra vires, the court made no effort to measure the Final Rules against the actual terms of Section 2(b)(2), nor did the court give the USPTO's interpretation of that provision the deference required by Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), and its progeny. Instead, the court held that the Office is confined to issuing procedural rules and that the Final Rules are impermissibly substantive. But the cases on which the district court relied do not engraft a rigid procedural/substantive distinction onto Section 2(b)(2). And even if they did, the Final Rules would still pass muster, for they regulate the procedures used in proceedings before the Office rather than the substantive criteria for the awarding of patents. The district court's conclusion that the rules are substantive rather than procedural rests on APA cases that do not involve that distinction at all, and the court's standards for measuring the "substantiveness" of rules

are at odds with the Supreme Court's jurisprudence under the Rules Enabling Act. The court compounded these errors by erroneously holding that Section 2(b)(2)(B), which provides for the USPTO to issue rules “in accordance with” 5 U.S.C. § 553, requires the Office to engage in notice-and-comment rulemaking even when Section 553 expressly provides that notice and comment are not required.

2. In the course of its ultra vires analysis, the district court held that the Final Rules are inconsistent with other provisions of the Patent Act. That holding is likewise incorrect. The court mischaracterized the effects of the Final Rules, misconstrued the statutory provisions, misunderstood the judicial precedents concerning those provisions, and failed to give the USPTO’s construction of the provisions the deference required by Chevron.

The district court held that Rules 78 and 114 conflict with Section 120 and 132(b), respectively, because the rules place “hard limits” on the number of continuation applications and RCEs that an applicant may file, while the statutory provisions entitle applicants to make an unlimited number of such filings. But the rules do not in fact limit the number of continuation applications and RCEs that may be filed; they simply require an applicant to show the need for further filings once a threshold number of filings has been made. And even if the rules did impose fixed limits, they would not conflict with Sections 120 and 132(b). Section 120 was enacted

by Congress simply to provide a statutory basis for continuation practice, not to vest applicants with the right to file an endless stream of continuation applications. Likewise, Section 132(b), which directs the Office to issue regulations providing for continued examinations, does not entitle applicants to file an endless series of RCEs.

The district court held that Rule 75 conflicts with Section 112 ¶2 by limiting the number of claims that may be included in a single application. But Rule 75 places no limit whatsoever on the number of claims in an application, and Section 112 ¶ 2 does not address the permissibility of such a limit in any event. The court also held that Rule 75 and 265 conflict with the provisions of the Patent Act that assign the USPTO the burden of examination and the burden of establishing a prima facie case of unpatentability. But there is no conflict between those provisions and the rules, which merely require applicants to provide information about their claims and prior art so examiners can discharge their burdens more accurately and efficiently.

## ARGUMENT

### I. The Final Rules Are Within the Scope of the USPTO's Rulemaking Authority

#### A. Standard of Review

This Court reviews a district court's grant of summary judgment without deference to the lower court, applying the same standard as the district court. Star Fruits, S.N.C. v. United States, 393 F.3d 1277, 1281 (Fed. Cir. 2005); see also Florida Light & Power Co. v. Lorion, 470 U.S. 729, 744 (1985) (court of appeals and district court perform "identical task" in reviewing agency action under APA). The critical question is thus the standard that the district court ought to have employed in adjudicating the validity of the Final Rules.

The district court's decision rests on two principal statutory issues. The first is whether the Patent Act's grants of rulemaking authority, including but not limited to Section 2(b)(2), provide authority for the promulgation of the Final Rules. The second is whether the Final Rules are consistent with other provisions of the Patent Act. Well before the district court took up those issues, the USPTO had addressed the same issues in its rulemaking proceeding. In so doing, the Office offered a careful and considered administrative interpretation of the scope of its authority under Section 2(b)(2) and the meaning of the provisions of the Patent Act that are claimed to conflict with the Final Rules. See, e.g., JA143-52 (72 Fed. Reg. 46807-46816).

Where, as here, a court addresses the meaning of statutory provisions that are administered by a federal agency and have already been interpreted by the agency itself, the governing principles of judicial review are those prescribed by Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). Under Chevron, the first question is “whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” Id. at 842-43. But “if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute.” Id. at 843. See Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006), cert. denied, 127 S. Ct. 1246 (2007) (“First, we determine whether the statute speaks to the issue of the challenge, and if it is silent or ambiguous, we defer to the agency’s reasonable interpretation”).

Chevron deference is warranted when Congress, expressly or implicitly, “delegat[es] authority to the agency to elucidate a specific provision of the statute by regulation” and “Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute.” United States v. Mead, 533 U.S. 218, 227, 229 (2001). In determining whether Congress has so delegated, courts look to such factors as whether there is an “express congressional authorization[] to engage

in the process of rulemaking,” *id.* at 229; whether the grant of rulemaking authority “provides for a relatively formal administrative procedure” such as “notice-and-comment rulemaking,” *id.* at 230-31; and whether the agency’s interpretation seems like a “legislative type of activity” in that it “would naturally bind more than the parties to [a] ruling,” as opposed to an agency “ruling [that] stops short of third parties,” *id.* at 232-33. Although the presence of notice-and-comment rulemaking is one affirmative indicator, it is not an indispensable prerequisite for Chevron deference. See Barnhart v. Walton, 535 U.S. 212, 221-22 (2002).

All of of the principal indicia of congressional delegation under Chevron are found in the Patent Act in general and in the present rulemaking in particular. Section 2(b)(2) expressly authorizes the USPTO to engage in rulemaking to establish regulations that “govern the conduct of proceedings in the Office,” “facilitate and expedite the processing of patent applications,” and “govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office.” 35 U.S.C. § 2(b)(2)(A), (C), (D). In addition, Congress has expressly authorized the USPTO to “prescribe regulations to provide for the continued examination of applications for patent.” *Id.* § 132(b). Section 2(b)(2)(B) provides for the USPTO to conduct rulemaking proceedings in accordance with the notice-and-comment provisions of the APA, and the Final Rules in this case were issued pursuant

to notice and comment. Finally, the new Rules are in the nature of “legislative type of activity,” given that they “would naturally bind more than the parties to [a particular] ruling,” and do not “stop[] short of third parties.” Mead, 533 U.S. at 232-33.

This Court has consistently given Chevron deference to the USPTO’s exercise of its rulemaking authority under Section 2(b)(2). See, e.g., Bender v. Dudas, 490 F.3d 1361, 1368 (Fed. Cir. 2007), cert. denied, 128 S. Ct. 2080 (2008); Lacavera, 441 F.3d at 1383; Stevens v. Tamai, 366 F.3d 1325, 1333-34 (Fed Cir.), cert. denied, 543 U.S. 944 (2004); In re Sullivan, 362 F.3d 1324, 1328 (Fed. Cir. 2004); Ethicon v. Quigg, 849 F.2d 1422, 1425 (Fed. Cir. 1988). In Lacavera, for example, the Court was presented with an argument that “the USPTO exceeded the authority granted to it by 35 U.S.C. § 2(b)(2)” in promulgating certain regulations. 441 F.3d at 1383. The Court noted that “[u]nder 35 U.S.C. § 2(b)(2), the USPTO has broad authority to govern the conduct of proceedings before it,” and held that “[b]ecause the USPTO is specifically charged with administering this statute, we analyze a challenge to the statutory authority of its regulations under the Chevron framework.” Id. Similarly, Stevens v. Tamai noted that “the broadest of the Office’s rulemaking powers is the power to ‘establish regulations, not inconsistent with law, which-(A) shall govern the conduct of proceedings in the Office,’” and “[b]y this grant of power we understand

Congress to have ‘delegated plenary authority over USPTO practice’” to the Office, which explains “the substantial deference we accord such rules.” 366 F.3d 1325, 1333-34 (Fed. Cir. 2004) (emphasis added). See also In re Sullivan, 362 F.3d 1324, 1328 (Fed. Cir. 2004) (USPTO rulemaking under Section 2(b)(2) “was the product of notice-and-comment rulemaking, \* \* \* and we must accordingly give it ‘controlling weight unless [it is] arbitrary, capricious, or manifestly contrary to the statute.’”).

More generally, “it is settled law that the rule of deference applies even to an agency’s interpretation of its own statutory authority or jurisdiction.” Mississippi Power & Light Co. v. Mississippi ex rel. Moore, 487 U.S. 354, 381 (1998) (Scalia, J., concurring) (collecting cases). See, e.g., Maine Public Utilities Com’n v. FERC, 520 F.3d 464, 479 (D.C. Cir. 2008) (agency’s interpretation of scope of its jurisdiction is entitled to Chevron deference); EEOC v. Seafarers International Union, 394 F.3d 197, 201-202 (4th Cir. 2005) (rejecting argument that “Chevron deference should be abandoned when an agency has expansively interpreted a statutory provision defining the bounds of its power”). Accordingly, the USPTO is entitled to Chevron deference where, as here, it is engaged in interpreting the scope of its power under Section 2(b)(2) and its other sources of rulemaking authority.

Chevron deference is likewise called for when, in the course of a rulemaking proceeding, the USPTO is called on to determine whether its rules are consistent with

other provisions of the Patent Act. Agencies are entitled to Chevron deference when the consistency of their regulations with the requirements of the governing statute is called into question. See, e.g., Nuclear Information Resource Service v. NRC, 969 F.2d 1169, 1172-74 (D.C. Cir. 1992) (en banc) (applying Chevron to determine whether agency hearing procedures are consistent with statutory hearing requirements). In Eli Lilly & Co. v. Board of Regents, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003), cert. denied, 541 U.S. 968 (2004), this Court itself noted that “whether a procedural regulation promulgated by the PTO violates the statute” is a “straightforward Chevron question.”

This does not mean, of course, that the USPTO is entitled to Chevron deference whenever it opines on the meaning of the Patent Act. In Merck & Co., Inc. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), cert. denied, 519 U.S. 1101 (1997), this Court declined to give Chevron deference to a freestanding “determination” by the USPTO concerning the application of the Hatch-Waxman Act and the Uruguay Round Agreements Act to the term of issued patents. The Office’s “determination” was not issued as part of a rulemaking proceeding, and the Court concluded that the subject matter of the determination fell outside the scope of the agency’s authority to issue rules “govern[ing] the conduct of proceedings in the Office.” In those circumstances, the Court held that Chevron deference was not in order. 80 F.3d at 1546-50. But

where the Office is exercising its rulemaking authority, and where it finds itself called on to determine the scope of that authority and the consistency of its rules with other provisions of the Act, this Court's subsequent decisions in cases like Lacavera and Eli Lilly make clear that Chevron deference still obtains.

Finally, the Supreme Court's recent decision in National Cable & Telecommunications Ass'n v. Brand X Internet Services, 545 U.S. 967 (2005), establishes that an agency's interpretation of ambiguous statutory provisions is entitled to Chevron deference even if courts had previously arrived at a different construction without the benefit of the agency's views. In the Court's words, "[a] court's prior judicial construction of a statute trumps an agency construction otherwise entitled to Chevron deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." Id. at 982. Thus, if an interpretation of the Patent Act by the USPTO is otherwise entitled to Chevron deference, the fact that a court may have construed the provision differently in the past does not alter the deference that is due.<sup>3</sup>

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<sup>3</sup> Even in circumstances where the USPTO's construction of the Patent Act is not entitled to Chevron deference, it is still be entitled to deference under Skidmore v. Swift & Co., 323 U.S. 134 (1944). See generally Cathedral Candle Co. v. United States Intern. Trade Com'n, 400 F.3d 1352, 1355-56 (Fed. Cir. 2005) (discussing (continued...))

**B. The Final Rules Are Authorized by 35 U.S.C. § 2(b)(2) and Related Grants of Rulemaking Authority**

The first question addressed by the district court was whether the Final Rules come within the scope of the USPTO’s statutory rulemaking authority. When that question is placed within the framework of Chevron, the answer is straightforward. Each of the Final Rules fits comfortably within the terms of Section 2(b)(2) and the Patent Act’s other grants of rulemaking power, and the USPTO’s conclusion that the the Patent Act authorizes the Office to promulgate such rules is an eminently reasonable one that is entitled to prevail under Chevron.

As explained above, Rules 78 and 114 establish the number of continuation applications or RCEs that an applicant can file before any showing is required. Such rules are at the core of the Office’s authority under Section 2(b)(2)(A) “to establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the Office.” Rules 78 and 114 do not in any way address whether or how an applicant may satisfy the substantive requirements for patentability under 35 U.S.C. §§ 101, 102, 103, and 112, such as utility, novelty, or non-obviousness. Cf. Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 930 (Fed. Cir. 1991) (“A substantive declaration with regard to the Commissioner’s interpretation of the patent statutes,

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<sup>3</sup>(...continued)  
Skidmore standard).

whether it be section 101, 102, 103, 112 or other section, does not fall within the usual interpretation of [Section 2(b)(2)].”). Instead, the new Rules govern the conduct of proceedings in the Office by prescribing requirements for the filing of continuation applications and RCEs. The Rules regulate the timing and availability of procedural mechanisms, not the substantive criteria that will be applied in the proceedings.

Rules 78 and 114 also come within the Office’s statutory authority under Section 2(b)(2)(C) to establish regulations to “facilitate and expedite the processing of patent applications.” As the USPTO explained during the rulemaking, these Rules were intended to address the crippling backlog of unexamined applications, which results in part from the increased number of RCEs and continuation applications. The new Rules will have the salutary effect of encouraging due diligence in the presentation of such filings, reducing the number of unnecessary filings and permitting the Office to focus better on examining new patent applications. At the very least, the rules will curb the unforeseen growth in continuation applications, particularly the growth in third and subsequent continuations. JA180 (A05015) (data showing explosive growth in such filings between 1996 and 2006). Thus, the new Rules “facilitate and expedite the processing of patent applications.”

Rules 78 and 114 also draw support from Section 2(b)(2)(D), which authorizes USPTO to establish regulations to “govern the \* \* \* conduct of agents, attorneys, or

other persons representing applicants or other parties before the Office.” As noted earlier, the new Rules are directed, in part, at applicants and practitioners who have taken advantage of the availability of an unlimited number of filings either by submitting carelessly prepared applications that require subsequent corrective filings, or by engaging in deliberate delay so that they can later add claims to their applications based on products or processes later discovered in the marketplace. The USPTO considers both practices to be a “misuse of [the] continued examination practice” and a violation of an applicant’s and practitioner’s duty under 37 C.F.R. § 10.18(b)(2)(i) not to submit an application to cause unnecessary delay or needless increase in the cost of prosecution before the Office. JA55 (72 Fed. Reg. 46719). By curtailing the misuse and abuse of the patent application process by applicants and practitioners, Rules 78 and 114 “govern the \* \* \* conduct of agents, attorneys, or other persons representing applicants or other parties before the Office.”<sup>4</sup>

Finally, USPTO’s authority to promulgate Rule 114 is supported by the affirmative grant of rulemaking authority in 35 U.S.C. § 132(b), which directs the

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<sup>4</sup> 35 U.S.C. § 32 authorizes the Director to “suspend or exclude” any applicant, agent, or attorney who, *inter alia*, “does not comply with the regulations established under section 2 (b)(2)(D).” Final Rule 78 reinforces the existing obligation to refrain from making filings for the purpose of unnecessary delay, and by merely striking a priority claim, it has a less severe impact than already is permitted under Section 32 and the USPTO’s existing rules.

Office to “prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.” That is precisely what the Office has done in Rule 114, which provides that one RCE will be permitted as of right, and any subsequent RCEs will be entertained if they are accompanied by the requisite showing.

The Office likewise has statutory authority under Section 2(b)(2) to promulgate Final Rules 75 and 265, which require an applicant to file an ESD if his application contains more than five independent or twenty-five total claims. Rules 75 and 265 address only the form or manner in which a patent application can be presented. The Rules do not even present any limit on how many claims can be presented; it merely requires an ESD if the applicant exceeds the prescribed numbers. The Rules do not address or alter the substantive statutory criteria by which the application will be evaluated to determine whether a patent should issue. Accordingly, Rules 75 and 265 simply “govern the conduct of proceedings in the Office” and are therefore within the USPTO’s rulemaking authority under 35 U.S.C. § 2(b)(2)(A). And because Rules 75 and 265 are also aimed at reducing the Office’s extraordinary backlog of unexamined application and at reducing the number of examiner errors associated with a higher number of claims per application, those Rules also fall within the Office’s authority

to issue regulations to “facilitate and expedite the processing of patent applications.”  
35 U.S.C. § 2(b)(2)(C).

For these reasons, the USPTO’s conclusion that the Final Rules come within the scope of its rulemaking authority should easily prevail under Chevron. Indeed, the rules are so obviously within the terms of Section 2(b)(2) and other rulemaking provisions that the USPTO’s reading would be entitled to prevail even in the absence of Chevron deference.

**C. The District Court Erred in Rejecting the USPTO’s Interpretation of its Rulemaking Authority**

1. In holding that the USPTO’s statutory rulemaking authority does not encompass the Final Rules, the district court made a series of fundamental errors. The first error was the court’s complete failure to abide by principles of Chevron deference.

As noted above, the USPTO carefully considered the extent of its rulemaking authority and explained how and why that authority provides a predicate for the Final Rules. See, e.g., JA143-52 (72 Fed. Reg. 46807-46816). Yet the district court gave no deference to the Office’s views regarding the scope of its rulemaking authority. Instead, the court treated that issue as a matter to be resolved de novo, without regard to the USPTO’s own considered administrative construction of the applicable statutory provisions. In so doing, the court simply disregarded this Court’s directive

in Lacavera to “analyze a challenge to the statutory authority of [the USPTO’s] regulations under the Chevron framework.” 441 F.3d at 1383. This failure to abide by Chevron is categorical legal error, and it pervades the district court’s efforts to resolve the statutory issues in this case. Fortunately, this Court occupies the same position as the district court with respect to Chevron, and therefore may apply the Chevron framework in this appeal even without the district court having done so. See Brand X, 545 U.S. at 982-1003 (performing Chevron analysis of agency’s construction of statute after holding that court of appeals erred in declining to perform Chevron review).

The district court thought that its conclusion regarding the scope of the USPTO’s rulemaking authority “renders it unnecessary to decide whether the USPTO’s interpretation of the Patent Act should be given Chevron deference \* \* \* .” JA11 n.4. That gets the matter exactly backward. Chevron deference cannot be held in abeyance until after a court determines that an agency is acting within the scope of its statutory authority, for as explained above, the scope of the agency’s authority is itself a question to which Chevron principles apply.

The district court’s conclusions regarding the contours of the USPTO’s rulemaking authority under Section 2(b)(2) were based in part on the court’s reading of prior decisions by this Court, chief among them Merck. As discussed below,

Merck is fully consistent with the USPTO’s interpretation of its rulemaking authority in this case. But even if it were not, Chevron deference would remain in order under Brand X, for Merck does not “hold[] that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion.” Brand X, 545 U.S. at 982.

2. The district court compounded its Chevron error by disregarding the language of Section 2(b)(2). The court duly recited the terms of the statute, but it did not go on to ask whether the Final Rules “govern the conduct of proceedings in the Office”; whether they “facilitate and expedite the processing of patent applications”; or whether they “govern the \* \* \* conduct of agents, attorneys, or other persons representing applicants or other parties before the Office.” Instead, the court held that Section 2(b)(2) precludes the Office from issuing “substantive” regulations, regardless of whether the regulations “govern the conduct of proceedings in the Office” or otherwise come within the actual terms of the statute. JA11-16.

That approach to the scope of the USPTO’s rulemaking authority is foreclosed by the CCPA’s decision in In re Van Ornum, 686 F.2d 937 (CCPA 1982). In Van Ornum, the CCPA addressed the USTPO’s rulemaking authority under former Section 6(a), the predecessor to Section 2(b)(2)(A). See 686 F.2d at 945. The regulation at issue in Van Ornum permitted an applicant to avoid a double-patenting rejection by

disclaiming a portion of the term of any resulting patent such that both patents would expire at the same time. Id. at 939. The challenged aspect of the regulation required common ownership between the two resulting patents. Id.

Van Ornum argued that the regulation was invalid because it was “substantive rather than procedural.” Id. at 945. The CCPA agreed with Van Ornum that the rule had incidental substantive effects, but held that it was nevertheless within the USPTO’s rulemaking authority:

[T]he rule is substantive in that it relates to a condition under which a patent will be granted which otherwise would have to be denied for double patenting. Much of the content of the PTO rules is “substantive” in this respect. The regulation clearly relates to application processing within the PTO in a manner consistent with statutory and case law, which is its principal business.

Id. at 945; see also id. at 949 (Baldwin, J., dissenting) (discussing breadth of majority’s holding).

As Van Ornum shows, the inquiry into the scope of the USPTO’s rulemaking authority cannot be pretermitted simply by asserting that a rule is “substantive,” or that it ultimately may have an effect on whether a patent will be granted or denied. As long as the regulation “relates to application processing within the PTO in a manner consistent with statutory and case law,” it lies at the core of the Office’s authority to issue rules “govern[ing] the conduct of proceedings in the Office.”

3. The district court predicated its substantive/procedural distinction primarily on this Court's decision in Merck, supra. But contrary to the court's belief, Merck does not replace the terms of Section 2(b)(2) with an open-ended inquiry into whether the Office's rules are "substantive" or "procedural," nor does it purport to overrule Van Ornum.

As noted above, Merck concerned the weight to be given to a "final determination" by the USPTO regarding the meaning of related patent term provisions in two different federal statutes. The Court held that Chevron deference was not due unless the Office had authority to promulgate rules regarding the subject matter of the final determination. 80 F.3d at 1549. The Court stated that former 35 U.S.C. § 6(a), the predecessor to current Section 2(b)(2)(A), "does NOT grant the Commissioner the authority to issue substantive rules." Id. at 1550 (citing Animal Legal Defense Fund, 932 F.2d at 930). Because Congress had not vested the USPTO with "any general substantive rulemaking power," the Office's final determination did not have the force of law and hence was not entitled to Chevron deference. Id.

Contrary to the district court's belief, Merck has little bearing on the issues of rulemaking authority in this case. In Merck, the USPTO was not engaged in rulemaking at all and did not purport to have any applicable rulemaking authority. The Office was not regulating any proceedings before it, and the final determination

did not have any bearing on the conduct of such proceedings. The Court therefore had no occasion to address the specific terms of the Office’s statutory rulemaking authority. The Court’s declaration that the USPTO does not have “any general substantive rulemaking power” and cannot “issue substantive rules” was not meant to demarcate the precise boundaries of Section 2(b)(2) or its predecessor, but instead conveyed only that the Office does not have a roving commission to make freestanding pronouncements (at least binding ones) regarding the meaning of substantive provisions of the patent statute.

That is not what is going on in this case. Here, the USPTO has engaged in an explicit exercise of rulemaking authority; the rules in question are directly grounded in the text of Section 2(b)(2); and the Office is not construing the terms of the Patent Act “in the air,” but instead is doing so as an integral part of the rulemaking exercise, in order to ensure that the rules remain within statutory bounds. The Final Rules do not even arguably involve the kind of freestanding pronouncement about substantive patent law that were at issue in Merck. Conversely, nothing in Merck suggests that the validity of the rules is to be determined by discarding the terms of Section 2(b)(2) in favor of an untethered inquiry into the “substantiveness” of the rules.

**4.** To determine whether the USPTO had exceeded the limits of procedural rulemaking, the district court asked whether the Final Rules “change existing law” and

“alter the rights of applicants.” JA18. The court derived that test from decisions addressing 5 U.S.C. § 553, the notice-and-comment provision of the APA. See Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979); Animal Legal Defense Fund, 932 F.2d at 927; American Hospital Ass’n v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987). In so doing, the court committed yet another error, for those cases were not discussing the distinction between procedural rules and substantive rules at all.

Section 553 establishes several distinct exceptions to the general requirement of notice-and-comment rulemaking. One exception applies when an agency issues “interpretative rules.” Id. § 553(b)(A). Another exception applies when the agency issues “rules of agency organization, procedure, or practice.” Id. In asking whether rules “effect a change in existing law or policy” or “affect individual rights or obligations,” the cases cited by the district court were not addressing the exception for rules of “procedure or practice,” but rather the separate exception for “interpretative” rules. See, e.g., Animal Legal Defense Fund, 932 F.2d at 927-31; American Hospital Ass’n, 834 F.2d at 1045-46. Far from treating those exceptions as interchangeable, courts have carefully distinguished between them and adopted different tests for each. Compare American Hospital Ass’n, 834 F.2d at 1045-46 (criteria for determining whether rule is interpretative) with id. at 1047 (criteria for determining whether rule is procedural).

To determine whether a rule is interpretative, it makes perfect sense to ask whether the rule “changes existing law” or “alters the rights” of private parties, since a rule that does so goes beyond merely interpreting the law. However, asking 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. And the mere fact that a rule alters a pre-existing “right” does not make the rule substantive. If the underlying right is procedural, a rule that alters it is likewise procedural; the rule is simply changing the contours of the procedural right.

For example, the district court held that 35 U.S.C. § 120 entitles applicants to file an unlimited number of continuation applications, and Rule 78 changes that putative entitlement by placing what the court regarded as a hard cap on the number of continuation applications that may be filed. For reasons discussed below, the district court’s interpretation of Section 120 is erroneous. But even if were correct, the putative “right” to make an unlimited number of filings is palpably a procedural right rather than a substantive one. Cf. Landgraf v. USI Film Products, 511 U.S. 244, 275 (1994) (“rules of procedure regulate secondary rather than primary conduct”). Accordingly, even if Rule 78 alters a right conferred by Section 120, it does not follow that Rule 78 is substantive.

5. The district court’s approach to determining whether the Final Rules are procedural or substantive is also at odds with the Supreme Court’s approach to the scope of judicial rulemaking authority under the Rules Enabling Act, 28 U.S.C. § 2072. The Rules Enabling Act vests the Supreme Court with “the power to prescribe general rules of practice and procedure” for cases in federal district courts and courts of appeals. *Id.* § 2072(a). At the same time, the Act provides that “[s]uch rules shall not abridge, enlarge or modify any substantive right.” *Id.* § 2072(b). Thus, the Rules Enabling Act explicitly embodies the kind of distinction between procedure and substance that the district court sought to apply in this case.

The Supreme Court has repeatedly rejected claims that particular rules “abridge \* \* \* substantive right[s].” See *Hanna v. Plumer*, 380 U.S. 460, 464 (1965); *Mississippi Pub. Corp. v. Murphree*, 326 U.S. 438, 445 (1946); *Sibbach v. Wilson*, 312 U.S. 1, 11 (1941). In doing so, the Supreme Court has rejected the approach employed by the district court here. As the Court explained in *Hanna*:

The test must be whether a rule really regulates procedure – the judicial process for enforcing rights and duties recognized by substantive law and for justly administering remedy and redress for disregard or infraction of them. \* \* \* Undoubtedly most alterations of the rules of practice and procedure may and often do affect the rights of litigants. [But] Congress’ prohibition of any alteration of substantive rights of litigants was obviously not addressed to such incidental effects as necessarily attend the adoption of the prescribed new rules of procedure upon the rights of litigants who, agreeably to rules of practice and procedure, have been brought before a court authorized to determine their rights.

380 U.S. at 464-65 (emphasis added and internal quotation marks omitted).

Here, the Final Rules clearly fall on the procedural side of the line drawn by Hanna. As noted above, the Rules govern only the process for patent applications, by specifying how many continuing applications and RCEs may be filed as of right and when an applicant must provide supporting information to assist an examiner in reviewing an application with a large number of claims. The Rules do not affect the substantive criteria for determining whether a patent application should be granted. Although the new Rules may have an incidental effect on whether the Office ultimately approves or rejects an application, the fact that the Rules “may \* \* \* affect the rights of litigants,” Hanna, 380 U.S. at 465, does not render them impermissibly substantive. See American Hospital Ass’n, 834 F.2d at 1047 (“even unambiguously procedural measures affect parties to some degree”). Thus, even if the district court were right that Section 2(b)(2) draws a categorical distinction between procedural and substantive rules, the court’s conclusion that the Final Rules are substantive cannot stand.

It should be added that the district court’s approach to classifying rules as “substantive” rather than “procedural” would transform many of the Federal Rules of Civil Procedure into invalid substantive rules. For example, Rule 15(c) provides, much like Section 120, that amendments to pleadings “relate[] back to the date of the

original pleading” if specified conditions are met. But Rule 15(a), like Rule 78 in this case, regulates when and how often a pleading may be amended as of right. Once the limits in Rule 15(a) are reached, the party cannot make a further amendment without leave of the court or consent by the opposing party. Under the district court’s reasoning, the limitations in Rule 15(a) would be substantive rather than procedural, for they deprive litigants of the entitlement to make unlimited amendments as of right that would otherwise be enjoyed under Rule 15(c). The fact that the district court’s test calls into question rules issued by the Supreme Court under the Rules Enabling Act is further evidence of how much the court erred.

**D. Section 2(b)(2)(B) Does Not Require Notice and Comment for All USPTO Rulemaking**

Section 2(b)(2)(B) provides that the USPTO's rules are to be promulgated “in accordance with section 553 of title 5.” As noted above, Section 553 dispenses with notice and comment not only for “interpretative rules,” but also for “rules of agency organization, procedure, or practice.” *Id.* § 553(b)(A). Nevertheless, in the course of analyzing the scope of the USPTO’s rulemaking authority, the district court held that Section 2(b)(2)(B) requires the Office to use notice-and-comment procedures in all rulemaking proceedings, even ones that indisputably involve rules of “procedure or practice.” JA12-13.

That conclusion is contrary to the terms of Section 2(b)(2)(B) and Section 553. Section 2(b)(2)(B) simply provides that USPTO’s regulations shall be made “in accordance with” Section 553, and Section 553 expressly provides that notice and comment is not required for interpretive or procedural rules. Those exceptions to the general notice-and-comment requirement are no less a part of Section 553 than is the requirement itself. Accordingly, the directive in Section 2(b)(2)(B) to issue rules “in accordance with” Section 553 can only be understood to incorporate all of the provisions of Section 553, including the exceptions.

In Animal Legal Defense Fund, this Court rejected the argument that every rule issued by the USPTO under former 35 U.S.C. § 6 (the predecessor to Section 2(b)(2)) must “be subject to public notice and comment under section 553,” because “[s]uch a result would vitiate the statutory exceptions in section 553(b) itself.” 932 F.2d at 931. And other courts have interpreted similar language to include the exceptions found in the APA. See, e.g., International Bhd. of Teamsters v. Peña, 17 F.3d 1478, 1486 (D.C. Cir. 1994) (language requiring regulations to “be issued in accordance with section 553 of Title 5” “do[es] no more than make § 553 applicable, its exceptions no less than its affirmative requirements”); Edelman v. Lynchburg College, 535 U.S. 106, 114 n.7 (2002). In contrast, when Congress intends for an agency to

use notice and comment procedures for all rules, it uses much more specific language. See, e.g., 6 U.S.C. § 441(c); 7 U.S.C. § 4906(f); 42 U.S.C. § 5403(a)(4)(B)(i).

The district court's conclusion is also at odds with 35 U.S.C. § 3(a)(2)(B), which requires the USPTO to consult with the Patent and Trademark Public Advisory Committees before changing or proposing to change regulations "which are subject to the requirement to provide notice and opportunity for public comment under section 553 \* \* \* ." If Section 2(b)(2)(B) required all of the USPTO's rules to issue pursuant to notice and comment, Section 3(a)(2)(B)'s limiting reference to rules "which are subject to the requirement to provide notice and opportunity for public comment under section 553" would be superfluous.

The district court's reading would also mean that every regulation issued by USPTO under Section 2(b)(2) would require an agency analysis under the Regulatory Flexibility Act. See 5 U.S.C. §§ 603, 604. That would mean, for example, that the Office must perform a Regulatory Flexibility Act analysis when it engages in a ministerial rulemaking to change its address and phone number. See 70 Fed. Reg. 10488 (March 4, 2005). There is no reason to read Section 2(b)(2)(B) to produce such absurd results.

## **II. The Final Rules Are Consistent with the Patent Act**

At the outset of its opinion, the district court declared it unnecessary to decide

“whether the Final Rules run contrary to the Act’s provisions.” JA11 n.4. Nevertheless, the court found itself comparing the Final Rules with the provisions of the Act in order to determine whether the rules were procedural or substantive. In so doing, the court repeatedly construed the terms and meaning of the statutory provisions in question. Thus, for example, the court construed 35 U.S.C. § 120 in order to assess the validity of Rule 78, and construed 35 U.S.C. § 112 to determine the validity of Rule 75. JA18-20, 22.

In so doing, the court once again disregarded its obligations under Chevron. As noted above, the USPTO responded at length during the rulemaking to comments that the Final Rules conflict with other provisions of the Patent Act. In so doing, it offered its own understanding of the meaning of those provisions and their relation to the Office’s rulemaking authority under Section 2(b)(2). See, e.g., JA144-52 (72 Fed. Reg. 46808-46816). Yet far from reviewing the USPTO’s interpretations under Chevron, the court simply engaged in a de novo analysis of the statutory provisions. As we show below, the district court’s parsing of the Patent Act’s provisions is erroneous even when taken on its own terms. But at a more basic level, the court’s statutory analysis is wholly compromised by its failure to abide by Chevron.

**A. Final Rule 78 Is Consistent with 35 U.S.C. § 120**

The district court held that Final Rule 78 deprives applicants of rights

supposedly guaranteed to them by 35 U.S.C. § 120. The district court viewed Rule 78 as placing a “hard limit” on the number of continuation applications that an applicant may submit. JA20. But Rule 78 does not place any limit on how many filings the applicant may make. The rule simply requires that an applicant’s third and any subsequent continuation applications be accompanied by a petition and showing that “the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application.” JA175 (72 Fed. Reg. 46839) (Rule 78(d)(1)(vi)). The rule embodies a presumption that filing an initial application and two continuation applications, along with one RCE, gives an applicant sufficient opportunity to prepare a diligently prosecuted application for appeal, a presumption that the applicant is free to rebut by explaining why due diligence has not obviated the need for further proceedings. As long as the applicant makes the required showing, Rule 78 has no effect on the subsequent prosecution of the application. And even if the applicant fails to make that showing, Rule 78 leaves him free to pursue the application, albeit without the priority benefit of earlier applications.

The primary object of Rule 78 is neither to prevent the filing of continuation applications nor to deprive them of the priority benefit of earlier applications. Because the rule, by its terms, affects only claims that an applicant could have submitted previously if he had chosen to do so, the applicant can avoid the effect of

the rule altogether by including available claims in his initial application or in either of the first two continuation applications, reserving third or subsequent continuation applications for any claims that could not have been submitted before. Timely submission of claims, rather than the denial of priority or the rejection of applications, is the ultimate object of the rule.

For its part, however, the district court regarded avoidable and even deliberate delay as a statutory entitlement under Section 120. The district court interpreted Section 120 as vesting applicants with the right to file “an unlimited number of continuation and continuation-in-part applications as a matter of right.” JA20. Thus, in the district court's view, Section 120 entitles applicants to delay a final determination of patentability indefinitely through the filing of repeated continuation applications, even if the claims presented in those applications could have been presented earlier and even if the failure to have done so is the product of deliberate delay.

That interpretation of Section 120 cannot be reconciled with this Court's decision in In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002). In Bogese, an applicant sought to delay the prosecution of his application indefinitely by filing an extended chain of continuation applications. The applicant contended that “he had complied with the requirements of 35 U.S.C. § 120, and therefore was entitled to the benefit of

the original \* \* \* priority date and to a patent.” Id. at 1365. The patent examiner and the Board of Patent Appeals and Interferences nevertheless rejected the applicant’s claims on the basis of excessive delay. This Court affirmed that rejection, holding that despite Section 120, the USPTO could – even without enacting a regulation – reject the claims on the basis of prosecution history laches. Id. at 1367-68; see also Symbol Technologies, Inc. v. Lemelson Medical, 277 F.3d 1361, 1365-68 (Fed. Cir.), cert. denied, 537 U.S. 825 (2002). In so holding, the Court relied on the USPTO’s general authority to regulate the prosecution of patent applications and protect against unwarranted delay:

The PTO is the administrative agency that is “responsible for the granting and issuing of patents . . . .” 35 U.S.C. § 2 (2000). Like other administrative agencies, the PTO may impose reasonable deadlines and requirements on parties that appear before it. The PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of an application.

Id. (emphasis added).

Bogese offers direct support for the validity of Rule 78, for it makes clear not only that the USPTO may “set reasonable deadlines and requirements for the prosecution of an application,” but also that subjecting continuation application practice to such deadlines and requirements is not foreclosed by Section 120. In particular, Bogese forecloses any argument that the conditions enumerated in Section

120 for making a priority claim are exclusive and that an applicant is entitled to file “an unlimited number of continuation and continuation-in-part applications as a matter of right” (JA20) as long as those conditions have been satisfied.<sup>5</sup>

This is an even easier case than Bogese, for at least three reasons. First, Rule 78 is supported not only by the Office's “inherent authority \* \* \* to set reasonable deadlines and requirements for the prosecution of applications,” 303 F.3d at 1368, but also (unlike in Bogese) by the agency’s express statutory rulemaking authority. Cf. id. at 1372 (Newman, J., dissenting) (“the PTO has the right to promulgate rules for the prosecution of patent applications, \* \* \* [but] there was here no agency rule-making, no public notice and comment period”). Second, while the doctrine of prosecution history laches leaves applicants without clear guidance about how much delay is “too much,” Rule 78 tells applicants explicitly when they must justify delay in presenting claims, evidence, and arguments and what justification must be provided. See JA109-112 (72 Fed. Reg. 46773-76). Finally, Rule 78 places a more limited burden on continuing application practice than does the doctrine of

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<sup>5</sup> At a more general level, subjecting continuation applications to administratively imposed filing conditions is not inherently inconsistent with Section 120. For example, the USPTO requires all submitted papers to meet specified form requirements, and applicants are required to provide an English language translation of a prior-filed application filed in a foreign language. See 37 C.F.R. §§ 1.52(a), 1.78(a)(5)(iv). No one would seriously contend that Section 120 therefore precludes the Office from subjecting continuation applications to such prerequisites.

prosecution history laches. In Bogese, the consequence of the applicant's dilatory practices was the final rejection of all of his pending claims. Here, in contrast, the applicant remains free to prosecute the claim and to argue that intervening art (if any) does not render the invention non-patentable under Sections 102 and 103.

The district court believed that its reading of Section 120 followed from Application of Henriksen, 399 F.2d 253 (C.C.P.A. 1968). But nothing in Henriksen suggests that Section 120 confers an affirmative right to file an unlimited series of continuation applications. Instead, Henriksen merely holds that Section 120 does not itself impose a fixed limit on the number of continuation applications that an applicant may file. See Bogese, 303 F.3d at 1368 n.6 (discussing Henriksen). As this Court made clear more recently in Bogese, the mere absence of fixed limits in Section 120 itself does not negate the USPTO's "inherent authority \* \* \* to set reasonable deadlines and requirements for the prosecution of applications." Id. at 1368.<sup>6</sup> And even if Henriksen could be read as interpreting Section 120 to authorize an unlimited number of continuations, the USPTO's subsequent administrative interpretation would still be entitled to deference under Brand X.

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<sup>6</sup> The other decision cited by the district court, Application of Hogan, 559 F.2d 595 (C.C.P.A. 1977), did not involve any question regarding the permissible number of continuation applications. Instead, it involved a failure on the part of the Board to consider the effect of Section 120 altogether. See id. at 603.

The district court's reading of Section 120 is also at odds with the legislative history of the provision. Prior to 1952, the practice of giving a continuation application the benefit of the initial application's filing date had been adopted and elaborated by the Office and the courts without any explicit statutory foundation. See Godfrey v. Eames, 68 U.S. 317, 325-26 (1863) ("if a party choose to withdraw his application for a patent, and pay the forfeit, intending at the time of such withdrawal to file a new petition, and he accordingly do so, the two petitions are to be considered as parts of the same transaction, and both as constituting one continuous application"). The legislative history of the 1952 Act makes clear that, with minor exceptions not relevant here, Congress meant Section 120 simply to codify the existing body of decisional law and practices regarding continuation applications. See, e.g., S. Rep. No. 82-1979 (1952), reprinted in 1952 U.S.C.A.A.N. 2394, 2400 ("Sections 120 and 121 express in the statute certain matters which exist in the law today but which had not been written into the statute"); JA145 (72 Fed. Reg. 46809) (collecting legislative history).

Nowhere in the body of law that Congress codified in Section 120 was there any precedent for filing "an unlimited number of continuation and continuation-in-part applications as a matter of right" (JA20). To the contrary, chains of continuing applications were virtually unknown in the years preceding 1952. See, e.g., Ex parte

Henriksen, 154 U.S.P.Q. 53, 58-59 & n.2 (Pat. Off. Bd. App. 1966) (finding only one case, dating to 1867, with a priority chain longer than three), rev'd on other grounds, 399 F.2d 253 (C.C.P.A. 1968). Moreover, the Supreme Court had condemned deliberate delay on the part of applicants as “an evasion of the statute [that] defeats its benevolent aim.” Woodbridge v. United States, 263 U.S. 50, 56 (1923); see also Webster Elec. Co. v. Splitdorft Elec. Co., 264 U.S. 463, 466 (1924). Thus, there is no basis for reading Section 120 to create a previously unknown “right” to engage in the filing of endless continuation applications, a right that would insulate precisely the kind of deliberate delay that the Supreme Court had long condemned.

At a more general level, the district court’s interpretation of Section 120 is at odds with the overall approach of the Patent Act to the application process. Congress contemplated that applicants would claim what they regard as their invention in their initial application (35 U.S.C. § 112 ¶ 2); that applicants dissatisfied with an examiner’s decisions would turn to the Board rather than returning to the examiner again and again (id. § 134(a)); and that within two years after the issuance of a patent, the public and competitors would know whether they can rely on the existing claims to define what they may and may not do (id. § 251). In contrast, allowing applicants to file unlimited numbers of continuation applications permits an applicant to delay indefinitely what should be the prompt disclosure of what he “regards as his

invention” under Section 112; it undermines the role of the Board under Section 134; and it allows applicants to broaden their claims long after the two-year limit for seeking a broadening reissue patent under Section 251 has passed. See JA55, 98-99 (72 Fed. Reg. 46719, 46762-63). The district court’s approach to Section 120 defeats Congress’s expectations and frustrates the statutory scheme in each of these respects.

As the foregoing discussion indicates, the district court’s conclusion that Section 120 places a straightjacket on the USPTO is seriously flawed even when taken on its own terms. But it becomes even less supportable when Chevron principles are brought to bear. Section 120 does not specifically and unambiguously address whether applicants have an affirmative right to file an unlimited number of continuation applications, or whether its enumerated conditions are exclusive or non-exclusive. Accordingly, the USPTO’s construction of the statute in these regards is entitled to prevail as long as it is reasonable, even if it is not “the reading the court would have reached if the question initially had arisen in a judicial proceeding.” Chevron, 467 U.S. at 643 n.11. The Office’s construction of Section 120 readily meets that deferential standard.

**B. Final Rule 114 Is Consistent with 35 U.S.C. § 132**

When an applicant wishes to file more than one request for continued examination (RCE) with respect to a single application family, Final Rule 114 requires

the applicant to show that the amendment, argument, or evidence sought to be submitted could not have been presented earlier. See JA177 (72 Fed. Reg. 46841) (Rule 114(f)-(g)). The district court concluded that Rule 114 deprives applicants of rights conferred on them by 35 U.S.C. § 132(b), which provides in relevant part that the Office “shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.” As the USPTO pointed out during the rulemaking process, however, Section 132(b) simply obligates the Office to issue implementing regulations for continued examinations. It does not specify the conditions and requirements for continued examinations, but instead leaves that task to the Office itself through the prescribed exercise of its rulemaking authority. See JA147 (72 Fed. Reg. 46811). Section 132(b) therefore does not preclude the Office from requiring an applicant to make a showing of due diligence when requesting more than one continued examination with respect to an application family. Id.

The district court interpreted the words, “at the request of the applicant,” to mean that Section 132(b) “commit[s] the invocation of the continued examination process to the discretion of the applicant, not the USPTO,” and hence entitles applicants to file “an unlimited number of RCEs.” JA21. But that is not the only, or even the most obvious, reading of the phrase. “At the request of the applicant” can just as easily be understood to describe how a continued examination is initiated, not

to prescribe how many continued examinations must be performed. Neither the quoted phrase nor anything else in Section 132(b) specifically addresses whether the USPTO may place reasonable conditions on an applicant who already has requested and received a continued examination. Accordingly, the USPTO’s conclusion that Section 132(b) does not preclude the Office from requiring an applicant to justify second or subsequent RCEs (JA147 (72 Fed. Reg. 46811)) is, at the very least, a reasonable one, which means that it must prevail under Chevron.<sup>7</sup>

The district court also faulted Rule 114 for providing applicants with one RCE for an application family, rather than providing a separate RCE for each application in the family. JA20-21. The court relied on the fact that Section 132(a) and 132(b) speak in terms of reexamination and continued examination of “applications.” JA20 (quoting references to “his application” and “the application” in 132(a) and “applications” in 132(b)). But “application” does nothing more than identify the subject matter of Section 132. Congress could not have drafted Section 132 without referring to the reexamination and continued examination of “applications,” regardless of whether it did or did not mean to require continued examination of every

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<sup>7</sup> The district court also sought to attach significance to Section 132(b)’s use of the word “shall.” JA21. But that word simply makes the issuance of implementing regulations mandatory rather than permissive; it says nothing about the content of the regulations.

application in an application family. Thus, the bare reference to “applications” does not support the district court’s reading of the statute, nor does it cast doubt on the reasonableness of the Office’s contrary reading under Chevron.<sup>8</sup> And in any event, Rule 75 itself leaves applicants free to seek continued examination with respect to every application in a family provided that the requisite showing is made for each RCE after the first.

The court’s reference to subsection (a) of Section 132 also reflects a misunderstanding of the relationship between subsections (a) and (b). Subsection (a) provides for the “reexamination” of an application at the applicant’s request after the initial examination provided in section 131. In contrast, “continued examination” under subsection (b) occurs after the reexamination provided for in subsection (a) is complete. Rule 114 does not concern reexamination under subsection (a), and its impact on subsection (a) reexaminations is not at issue here. Thus, the district court’s reliance on subsection (a) (see JA20) was misplaced.

**C. Final Rules 75 and 265 Are Consistent with 35 U.S.C. §§ 102, 103, 112, and 131**

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<sup>8</sup> In a related vein, the court noted that Congress provided that Section 132(b) shall “apply to all applications filed on or after June 8, 1995.” JA21. The court found the reference to “all applications” to be significant. But the provision relied on by the court is nothing more than a conventional effective-date provision, and its reference to “all applications” simply means that the effective date applies across the board.

As noted above, Final Rule 75 provides that an application that contains more than five independent claims or more than twenty-five total claims must be accompanied by an Examination Support Document (ESD). Rule 265, in turn, sets forth the required contents of an ESD. The district court held that Rules 75 and 265 are inconsistent with multiple sections of the Patent Act. But each of the provisions is inapposite.

1. The district court first held that Rule 75 is inconsistent with 35 U.S.C. § 112, ¶ 2, which requires applications to include “one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” The court believed that the reference to “one or more claims” gives an applicant the unqualified right to include as many claims in an application as he wishes, and held that Rule 75 conflicts with Section 112 by limiting the number of claims that may be filed. JA22.

This reasoning is misconceived in two independent respects. First, Rule 75 does not place a “mechanical limit[],” JA22, or indeed any kind of limit, on the number of claims an applicant can include in an application. To the contrary, an applicant “is always free to file as many claims as necessary.” JA150 (72 Fed. Reg. 46814). Rule 75 merely requires that applications be accompanied by an ESD when the number of claims exceeds the benchmarks in the rule.

Second, even if Rule 75 did impose an absolute limit on the number of claims in an application, that would not conflict with the reference to “one or more claims” in Section 112, ¶ 2. That phrase merely sets a floor on the number of claims that an applicant must submit, *i.e.*, an applicant must present at least one claim for examination, but may present more than one if necessary to claim his invention. It does not give an applicant a statutory right to file an unlimited number of claims in an application.

Application of Rubinfeld, 270 F.2d 391 (C.C.P.A. 1959), cert. denied, 362 U.S. 902 (1960), disposes of the district court’s notion that Section 112 establishes a right to present an unlimited number of claims. Rubinfeld sustained the validity of a USPTO rule that provided that “[m]ore than one claim is not permitted” in a design application. Id. at 395. The CCPA was “unable to find any clear conflict” between the rule and Section 112. Id. The court pointed out that “[w]hile 35 U.S.C. § 112 states that ‘The specification shall conclude with one or more claims,’ that provision does not necessarily mean that every applicant shall, as a matter of right, be entitled to present a plurality of claims regardless of the nature of the invention involved.” Id. Rubinfeld offers direct support for Rule 75, for the CCPA explained that section 112, ¶ 2, applies with equal force to utility patents as to design patents. Id. The district court’s holding cannot be squared with Rubinfeld, and the court made no attempt to

do so.

Instead of taking counsel from Rubinfield, the district court relied on three cases involving undue multiplicity of claims. See Application of Wakefield, 422 F.2d 897 (C.C.P.A. 1970); Application of Chandler, 319 F.2d 211 (C.C.P.A. 1963); In re Clark, 97 F.2d 628 (C.C.P.A. 1938). Those cases, however, are inapposite, since Rule 75 does not empower an examiner to reject an application for an undue multiplicity of claims. Moreover, even taken on their own terms, they hold only that the USPTO must act reasonably in imposing limits on the number of claims that can be filed. See, e.g., Clark, 97 F.2d at 631 (applicants should be “given a reasonable latitude of expression”); Chandler, 319 F.2d at 225 (C.C.P.A. 1963). None of them suggests that Section 112 grants an applicant an unqualified right to present an unlimited number of claims. And even if they did, they would not foreclose the USPTO’s contrary reading in light of Brand X.

2. The district court also held that Rule 75 and Rule 265 conflict with 35 U.S.C. §§ 102, 103, and 131, which collectively have been understood to assign the USPTO the burden of examination and the burden of establishing a prima facie case of unpatentability. But nothing in Rules 75 and 265 relieves the Office of those burdens or shifts them to applicants. Requiring the submission of an ESD does not change the burden of examination or the burden of proof regarding patentability, but

simply requires the applicant to come forward, in certain situations, with relevant information bearing on his claims. See JA151 (72 Fed. Reg. 46815) (ESD requirement “is not an abdication of the examination function, or a shifting of the burden to applicant to make a prima facie case of entitlement to a patent,” but “simply requires the applicant to provide additional information”). The burden of establishing a prima facie case of unpatentability continues to be borne by the Office. Requiring an applicant to assist the examiner by providing information regarding relevant prior art does not shift the burden of proof, any more than the obligation of a defendant to make affirmative disclosures of relevant information under Rule 26(a) of the Federal Rules of Civil Procedure relieves the plaintiff of his burden of proof in civil litigation.

For this reason, the district court’s reliance on In re Warner, 379 F.2d 1011 (C.C.P.A. 1967), cert. denied, 389 U.S. 1057 (1968), and In re Oetiker, 977 F.2d 1443 (Fed. Cir. 1992), was misplaced. Those cases merely stand for the proposition that the USPTO, in making a substantive rejection, bears the initial burden of setting forth a factual basis for the rejection. Nothing in Rule 265 shifts that burden. Neither Warner nor Oetiker concerns the scope of the USPTO’s rulemaking authority to put documentation requirements on applications. And even if Warner and Oetiker did address that subject, PTO’s subsequent interpretation of its statutory authority would be entitled to prevail under Brand X.

The courts have consistently held that the Office may place duties on applicants to produce information in support of examination, even in the absence of governing rules, notwithstanding the Office’s procedural responsibility to make a prima facie case of unpatentability when rejecting a claim. For example, Rule 56 places an affirmative burden on applicants to present known information that is material to examination. The validity of Rule 56 is undisputed, notwithstanding the fact that its practical effect is to “relieve the PTO of the full impact of th[e] rule” assigning the Office the burden of showing unpatentability. In re Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager & Cowen, JJ., concurring).

In Star Fruits, this Court sustained the validity of Rule 105, which allows the USPTO to require an applicant to submit readily available information that is “reasonably necessary to properly examine the matter.” Id. at 1279 (quoting 37 C.F.R. § 1.105). The court rejected the theory that Rule 56 marks the limit of what applicants could be compelled to submit to the Office. Id. at 1283. Instead, the court concluded that Rule 105, though broader than Rule 56, was within the purview of the USPTO’s delegated rulemaking authority under Section 2(b)(2)(A), and that the Office properly abandoned Star Fruits’s application when Star Fruits declined to provide the requested information. Id. at 1282, 1285. Thus, Star Fruits establishes that the Office may, by rulemaking, require applicants to submit information on the

prior art.

As the examiner did in Star Fruits under Rule 105, the Director here has concluded that additional information is reasonably necessary to adequately treat the matter. Nothing in such a requirement abrogates the Director's responsibility under Section 131 to "cause an examination to be made." Moreover, even if the contours of an "examination" were affected by this rule, Section 131 does not define or prescribe what it means to "cause an examination to be made."

The district court's reliance on cases dealing with inequitable conduct, such as Frazier v. Roessel Cine Photo Tech., Inc., 417 F.3d 1230 (Fed. Cir. 2005), and Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348 (Fed. Cir. 2005), is misplaced. Those cases merely identify what an applicant must submit to avoid inequitable conduct. There is no obligation for applicants to search the prior art under existing USPTO rules only because neither Rule 56 nor this Court's inequitable conduct law imposes such a duty on applicants. Nevertheless, neither Rule 56 nor inequitable conduct jurisprudence limit what the USPTO can require an applicant to provide to aid examination. See Star Fruits, 393 F.3d at 1282-83. Similarly, the fact that the Patent Act does not itself impose a duty to search does not place Rule 265 beyond the USPTO's rulemaking authority.

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

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I hereby certify that on July 18, 2008, I filed and served the foregoing BRIEF FOR THE APPELLANTS by causing an original and twelve copies to be mailed to the Clerk of the Court by first-class mail and by causing two copies to be mailed by first-class mail to each of the following counsel:

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