No. 2008-1352

United States Court of Appeals for the Federal Circuit

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

AND

SMITHKLINE BEECHAM CORPORATION (D/B/A GLAXOSMITHKLINE), SMITHKLINE BEECHAM PLC, AND GLAXO GROUP LIMITED (D/B/A GLAXOSMITHKLINE),

Plaintiffs-Appellees,

v.

JON DUDAS, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, AND UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

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 District Judge James C. Cacheris

BRIEF OF PLAINTIFFS-APPELLEES GLAXOSMITHKLINE

Sherry M. Knowles
Senior Vice President
Chief Intellectual Property Counsel
GLAXOSMITHKLINE
709 Swedeland Road
King of Prussia, PA 19406
(610) 270-4800

John M. Desmarais
Peter J. Armenio
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, NY 10022
(212) 446-4800

F. Christopher Mizzo
Jeffrey Bossert Clark
D. Sean Trainor
Scott Abeles
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005
(202) 879-5000

Counsel for Plaintiffs-Appellees SmithKline Beecham Corporation d/b/a GlaxoSmithKline, SmithKline Beecham plc, and Glaxo Group Limited d/b/a GlaxoSmithKline

September 24, 2008

CERTIFICATE OF INTEREST

Counsel for the Plaintiffs-Appellees, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, SmithKline Beecham plc, and Glaxo Group Limited d/b/a GlaxoSmithKline, certifies the following:

1. The full name of every party represented by me is:

   SmithKline Beecham Corporation d/b/a GlaxoSmithKline, SmithKline Beecham plc, and Glaxo Group Limited d/b/a GlaxoSmithKline.

2. The names of the real parties in interest represented by me are:

   The parties listed above are the real parties in interest.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

   SmithKline Beecham Corp., doing business as GlaxoSmithKline, is a corporation having its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19102, and is a wholly-owned subsidiary of GlaxoSmithKline plc, a publicly-traded company.

   SmithKline Beecham plc is a public limited company organized under the laws of England and Wales with its principal place of business at 980 Great West Road, Brentford, Middlesex, TW89GS, England, and is a wholly-owned subsidiary of GlaxoSmithKline plc, a publicly-traded company.

   Glaxo Group Limited, doing business as GlaxoSmithKline, is a company organized and existing under the laws of England and having an office and place of business at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 ONN, United Kingdom, and is a wholly-owned subsidiary of GlaxoSmithKline plc, a publicly-traded company.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

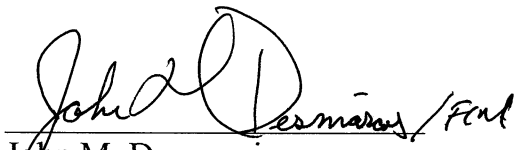
John M. Desmarais, Peter J. Armenio, Kirkland & Ellis LLP, Citigroup Center, 153 East 53rd Street, New York, New York 10022.

F. Christopher Mizzo, Jeffrey Bossert Clark, D. Sean Trainor, Scott M. Abeles, Elizabeth M. Locke, Jeffrey M. Gould, Ellen Lin, William Bestani, Kirkland & Ellis LLP, 655 Fifteenth Street, N.W., Washington, DC 20005.

Craig C. Reilly, 111 Oronoco Street, Alexandria, Virginia 22314.

Sherry M. Knowles, GlaxoSmithKline, 709 Swedeland Road, King of Prussia, Pennsylvania 19406

Dated: September 24, 2008



John M. Desmarais

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

STATEMENT OF RELATED CASES

Appellees SmithKline Beecham Corporation d/b/a GlaxoSmithKline, SmithKline Beecham plc, and Glaxo Group Limited d/b/a GlaxoSmithKline (collectively "GSK") agree that no other appeal in or from this 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.

JURISDICTIONAL STATEMENT

This case concerns rules that the United States Patent and Trademark Office ("PTO") issued in August 2007. *See* "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46,716 (Aug. 21, 2007) ("Final Rules") (JA51-179). GSK challenged these rules under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq.*, and the Patent Act, 35 U.S.C. §§ 1 *et seq.* The district court had jurisdiction to hear GSK's challenge under 28 U.S.C. §§ 1331 and 1338. On April 1, 2008, the district court granted GSK's motion for summary judgment and entered final judgment, invalidating the rules as *ultra vires* and permanently enjoining their implementation. *Tafas and GSK v. Dudas*, 541 F. Supp. 2d 805 (E.D. Va. 2008) ("*Tafas/GSK II*").

The PTO has appealed. This Court has jurisdiction over the PTO's appeal under 28 U.S.C. § 1295(a).

STATEMENT OF THE ISSUES

1. Whether the Final Rules exceed the PTO's limited statutory rulemaking authority.

2. Whether the Final Rules are contrary to existing patent law.

3. As an alternative ground to affirm the district court's invalidation of Final Rule 265, whether that Rule's preexamination search requirements are unconstitutionally vague.

4. As an alternative ground to affirm the district court's invalidation of Final Rules 75, 78, 114, and 265, whether those Rules are unlawfully retroactive.

5. Whether the PTO must provide notice and comment under the APA when promulgating procedural rules.

STATEMENT OF THE CASE

Article 1, Section 8 of the U.S. Constitution gives Congress the power to establish laws governing the United States patent system. Congress has considered vesting the PTO with substantive rulemaking power, but has chosen not to do so. Congress has to date given the PTO only limited rulemaking authority to govern the conduct of proceedings in the Office.

Instead, Congress created this Court and vested it with the power to interpret the patent laws. In carrying out that duty, this Court has dispelled any doubt regarding the PTO's limited rulemaking authority, holding that the PTO's broadest

powers do not include substantive rulemaking. *See Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996). This case arises out of the PTO's decision to spurn these limits; ignore the Constitution, Congress, and this Court; and promulgate the substantive Final Rules that violate well-established patent law and fundamentally alter patent practice.

The Final Rules do that by, among other things, limiting the number of continuing applications, requests for continued examination ("RCEs"), and claims that an applicant may file. In issuing these rules, the PTO makes an unprecedented and unlawful grab for power that threatens both incentives to innovate as well as the authority of this Court, the Supreme Court, and Congress. Indeed, by enacting the Final Rules, the PTO attempts to grant itself the authority to do exactly what this Court and its predecessor court have repeatedly told the PTO it lacks the power to do.

Accordingly, for all the reasons set forth herein, this Court should affirm the district court's judgment invalidating the Final Rules and permanently enjoining their implementation.

I. Course Of Proceedings.

In January 2006, the PTO issued two separate notices of proposed rule-making. JA29-41, JA42-50. During the notice and comment period, the public submitted more than 500 comments—almost all negative. Undeterred, the PTO

issued the Final Rules in August 2007, setting them to go into effect on November 1, 2007.

In October 2007, GSK filed suit and sought a preliminary injunction. On October 31, 2007, the district court preliminarily enjoined the PTO from implementing the Final Rules. *Tafas and GSK v. Dudas*, 511 F. Supp. 2d 652 (E.D. Va. 2007) ("*Tafas/GSK I*"). GSK then moved for summary judgment to vacate the Final Rules and permanently enjoin their implementation. *Amici curiae* filed twenty briefs in support of GSK's motion. The *amici curiae* broadly represented a wide array of industries and innovators, from information technology to biotechnology, from multi-national corporations to small inventors, and included such broad-based groups as the AIPLA, IPO, PhRMA, and BIO.

II. Disposition Below.

On April 1, 2008, the district court granted GSK's motion for summary judgment, holding that the Final Rules exceed the PTO's rulemaking authority and are contrary to the Patent Act and this Court's authoritative construction of that Act. *Tafas/GSK II* at 811-17. The district court concluded that 35 U.S.C. § 2(b)(2) does not vest the PTO with substantive rulemaking authority. *Id.* at 811-12. The district court further held that the Final Rules are substantive because they would drastically change existing patent law and alter applicants' rights under the Patent Act. *Id.* at 814.

Specifically, the district court found that Rules 75, 78, 114, and 265 impose arbitrary and mechanical limits on the number of continuing applications, RCEs, and claims that an applicant may file. Rules 78 and 114 (collectively, the "2+1 Rule") permit only 2 continuation applications or continuation-in-part applications, plus a single RCE in an application family.[1] Any further prosecution requires a successful "petition and showing," which "the USPTO intends to deny . . . in almost all circumstances." *Id.* at 814 (citing 72 Fed. Reg. at 46,769-77). Rules 75 and 265 (collectively, the "5/25 Rule") permit only five independent claims and/or twenty-five total claims in an application.[2] Any additional claims require that the applicant submit an examination support document ("ESD"), which must include the results of a hopelessly vague and boundless prior art search and provide a detailed explanation establishing, in the first instance, the patentability of all independent claims. The district court concluded that these rules improperly

[1] In establishing limits on applications, Rules 78(a) and (d) define "divisional," "continuation," and "continuing application"; preclude "voluntary divisional" applications under 35 U.S.C. § 121; and bar continuation-in-part applications stemming from a divisional. JA173-74. Rule 78(f) further precludes applicants from prosecuting similar patent applications; forces applicants to identify related applications; and will cause the rejection, without examination, of those applications that meet certain criteria as containing patentably indistinct claims. JA176.

[2] Rule 75(b) also clarifies how multiple dependent claims and other types of claims will be treated under the 5/25 Rule. JA172-73.

"shift[] the examination burden away from the USPTO and onto applicants." *Id.* at 816.

Because the PTO does not possess substantive rulemaking authority, and because the Final Rules are substantive, the district court declared the Final Rules to be null and void. JA27-28. The district court also opined that the PTO must follow notice and comment procedures under the APA when it promulgates rules pursuant to its limited authority. The PTO now appeals.

STATEMENT OF THE FACTS

GSK is the second largest pharmaceutical company in the world. JA1552 ¶ 6. GSK researches, develops, and markets life-saving medicines that treat some of the worst human diseases, including cancer, cardiovascular disease, HIV, and depression. JA1552 ¶ 7.

GSK's medical research requires very large, entirely at-risk investments to bring innovative drugs to market that support the health and life of American citizens. JA1552 ¶ 9; JA250-51 ¶ 32. In 2006, GSK invested $6.4 billion on medical research and development. JA1553 ¶ 12. GSK's discovery and development of just one new drug can take more than ten years and a billion dollars or more in up-front investments. JA258-59 ¶¶ 52, 54.

Companies like GSK rely on the robust patent protection provided by the current patent laws to recoup their significant investments. *Id.* ¶ 55. Because it

takes a long time to develop medical innovations, GSK has relied on the statutory framework and long history of judicial decisions that allow it to file any number of good-faith continuations, RCEs, and claims to obtain appropriate patent protection. JA1554-55 ¶¶ 17-19; JA1572-78 ¶¶ 27-28, 32-34, 38, 45-46. As of October 2007, GSK had over 1,900 patent applications pending, more than 100 in which it had already filed two or more continuing applications, and approximately 30 in which it had already filed two or more continuing applications and an RCE. JA1554-55 ¶¶ 18, 20. Additionally, GSK had numerous pending applications that contain more than five independent and/or twenty-five total claims. *See, e.g.*, JA2007-16. Thus, many of GSK's pending patent applications already exceed the Final Rules' limits.

The filing date of each patent application is critically important. An applicant's entitlement to a patent, *e.g.*, under 35 U.S.C. §§ 102 and 103, is judged from the earliest filing date to which the application is entitled ("the priority date"). The priority date is critical because, among other reasons, it sets the "stake in the ground" on prior art references against which the patent claims are analyzed. JA1568-69 ¶¶ 14-15; JA252-53 ¶ 37. If the priority date is lost, later-filed applications will only be entitled to their actual filing date and will be analyzed against additional prior art that became available between the time of the earliest-filed application and the later-filed applications. JA1569-70 ¶¶ 15, 18-19.

There have historically been, and still are, numerous valid reasons for filing continuation applications. *See* JA253-54 ¶¶ 38-39; *see also Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) ("*Symbol IV*") (identifying several reasons). For example, GSK files continuation applications to add new claims directed to subject matter that is disclosed but not claimed in an application for which examination has closed on the merits. JA253 ¶ 38. This often happens because GSK typically files patent applications on newly discovered classes of drug compounds (a "genus") well before commencing human clinical trials. JA1554-55 ¶¶ 18-19. GSK files applications with claims to "lead drug" candidates, understanding that it may need to prosecute claims to other drugs in the genus in continuation applications if the first drug fails in preclinical or clinical trials. *Id.* GSK, and others like it, have every incentive to pursue this process diligently, as the term of any resulting patent is measured from the earliest application's filing date. *See* 35 U.S.C. § 154.

It is critical that continuation patent applications obtain the benefit of the first application's "stake in the ground." Without it, an applicant's continued research efforts and investments, as well as the earliest-filed application, could be used against its own later-filed applications. Nonetheless, essentially overturning this Court's decision in *Symbol IV*, the PTO has indicated that most, if not all, currently valid reasons for filing continuations would be insufficient to carry the

applicant's burden under the Final Rules' petition and showing requirement. JA108-13 (72 Fed. Reg. 46,772-77). Thus, the Final Rules would strip applicants of their statutory right to claim priority in all but the rarest of circumstances.

It is also critical that applicants be able to file the number and types of claims they deem necessary to protect the full scope of their invention. The claims establish the metes and bounds of applicants' rights after applications issue as patents. The law has never permitted the PTO to limit the statutory right to claim an invention. JA255-56. Nor has the law ever allowed the PTO to require applicants to conduct hopelessly vague, boundless prior art searches or by requiring applicants to bear the burden of examination. *See Frazier v. Roessel Cine Photo Tech., Inc.*, 417 F.3d 1230, 1238 (Fed. Cir. 2005) ("no duty to conduct a prior art search"); *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.") As this Court's predecessor has made clear, the law allows an applicant "to determine the necessary number and scope of his claims." *In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970). The Final Rules are contrary to the Patent Act and this well-settled precedent.

SUMMARY OF THE ARGUMENT

Congress has not granted the PTO the authority to issue substantive rules. Nor has Congress empowered the PTO to issue rules that contradict the plain

language of the Patent Act. Nor does the PTO have the authority to issue rules that contradict this Court's or its predecessor's interpretation of the Patent Act; that power resides only in Congress, this Court, or the Supreme Court. By issuing the Final Rules, however, the PTO has done each of these things. Consequently, this Court should affirm the district court's decision invalidating these Final Rules.

The PTO stakes its appeal primarily on a claim to broad *Chevron* deference. The PTO contends that the district court should have deferred to the PTO's views—even in the face of contrary precedent from this Court—that the Final Rules: (i) fall within the PTO's delegated authority; and (ii) constitute a lawful use of that authority. The district court rightly rejected these views.

The PTO is not entitled to deference regarding the Final Rules because their promulgation exceeds the PTO's limited rulemaking authority. First, the scope of the PTO's rulemaking authority is a threshold legal question for which no deference is owed. *See Borlem S.A.-Empreedimentos Industriais v. United States*, 913 F.2d 933, 937 (Fed. Cir. 1990). As the Supreme Court has explained, "[a] ***precondition*** to deference under *Chevron* is a congressional delegation of administrative authority." *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990) (emphasis added). It is the role of the courts, not the PTO, to assess the scope of the PTO's delegated authority. Indeed, it would be ill-advised to defer to the PTO's self-interested views on the reach of its own power.

Second, the Final Rules are due no deference because they are substantive, and this Court conclusively held in *Merck* that the PTO lacks substantive rulemaking authority. *Merck*, 80 F.3d at 1549-50. Several recent decisions of this Court have reiterated *Merck*'s holding. *See, e.g.*, *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008). The Final Rules are substantive because they "constitute a drastic departure from the terms of the Patent Act" and "effect changes in GSK's . . . existing rights and obligations." *Tafas/GSK II* at 814. Thus, the Final Rules exceed the PTO's limited authority and are not entitled to any deference.

Third, the Final Rules cannot be given deference because they contradict the patent laws and precedent of this Court and its predecessor. *See* 35 U.S.C. § 2(b)(2) (stating that the PTO "may establish regulations, not inconsistent with law"). Final Rules 75, 78, 114, and 265 impose arbitrary and mechanical limits on the number of continuing applications, RCEs, and claims that applicants may file. These restrictions contradict Sections 112, 120, and 132 of the Patent Act, as well as the authoritative constructions of those sections, which establish that applicants have the right to file as many good-faith continuing applications, RCEs, and claims as they deem necessary. *See, e.g.*, *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968) (no limit to continuations); *Wakefield*, 422 F.2d at 900 (no limit to number of claims). Further, Rule 265 forces applicants to conduct boundless prior art

searches and shifts the burden of examination from the PTO to the applicant. This contradicts Sections 102, 103, and 131 of the Patent Act, as well as the authoritative constructions of those sections, which establish that the PTO, and not the applicant, bears the initial burden of examination. *See, e.g.*, *In re Warner*, 379 F.2d 1011, 1016 (C.C.P.A. 1967) (Section 102 "clearly places a burden of proof on the Patent Office."); *Oetiker*, 977 F.2d at 1445 (PTO must present *prima facie* case of unpatentability before burden may shift to applicant). It also contradicts this Court's determination that the Patent Act imposes no duty on applicants to search for prior art of which they were previously unaware. *See, e.g.*, *Frazier*, 417 F.3d at 1238 (no duty to search for prior art). Thus, the Final Rules violate Section 2(b)(2) because they are "inconsistent with law."

The Final Rules are also fatally flawed on two other independent grounds. First, the ESD's preexamination search requirement is unconstitutionally vague. It fails to provide fair notice as to how to comply and expressly requires applicants to search the entire world for prior art without regard to scope, time, or cost.[3] The search requirement also places applicants at substantial risk of inequitable conduct charges, in that every search is susceptible to criticism in some fashion. Second,

[3] Because Final Rule 265 fails to provide fair notice as to its boundaries, GSK would not know how to direct its employees how to comply with the ESD's requirements. *See* JA1561-63 ¶¶ 45-48.

the Final Rules apply retroactively to pending applications in an impermissible manner. They impose "new duties" on completed transactions (previously filed patent applications) and "impair rights a party possessed when he acted" (the right to fully protect an invention in exchange for relinquishing a trade secret). *See Landgraf v. USI Film Prods*., 511 U.S. 244, 280 (1994).

The PTO also criticizes the district court's decision that 35 U.S.C. § 2(b)(2)(B) requires the PTO to promulgate procedural rules under the notice and comment requirements of APA Section 553. But Section 2(b)(2)(B) expressly requires that the PTO issue procedural rules "in accordance with section 553 of title 5." To construe the statute as not requiring notice and comment would render that provision superfluous. Further, because procedural rules may produce significant harmful effects on private interests, it makes sense that they should be subject to public comment before implementation.

ARGUMENT

I. Standard Of Review.

This Court reviews the grant of summary judgment *de novo*, applying the "same standard as the district court." *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). In this APA-based rulemaking challenge, the district court was bound to "hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with

law." 5 U.S.C. § 706(2); *see also Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004).

II. The Final Rules Are *Ultra Vires* Because Congress Has Not Delegated Substantive Rulemaking Authority To The PTO.

A. The District Court Correctly Conducted An *Adams Fruit* Inquiry.

The PTO asserts that the district court got "the matter exactly backwards" by analyzing the scope of the PTO's authority before considering *Chevron*. PTO Br. 29. In its view, the district court should have first cloaked the agency with *Chevron* deference, then deferred to the PTO's view of the scope of its own powers, and then deferred again to the PTO's view that the Final Rules are consistent with the Patent Act.

A threshold question on appeal, however, is whether Congress has delegated relevant rulemaking authority to the PTO. The Supreme Court explained this threshold inquiry in *Adams Fruit*, concluding that "[a] ***precondition*** to deference under *Chevron* is a congressional delegation of administrative authority." 494 U.S. at 649 (emphasis added); *see also Gonzales v. Oregon*, 546 U.S. 243, 255-56, 258, 268 (2006) (applying *Adams Fruit* in finding that the DOJ lacked rulemaking authority to interpret certain terms in a controlled substances statute and, thus, *Chevron* did not apply); *Williams v. Taylor*, 529 U.S. 362, 387 n.13 (2000) (citing *Adams Fruit* and stating that *Chevron* deference depends on presence of a relevant delegation); *NLRB v. United Food & Commercial Workers, Local 23*, 484 U.S.

112, 123 (1987) (Deference given to regulations "promulgated pursuant to congressional authority.").

Courts must conduct this *Adams Fruit* inquiry without regard to the agency's own view of the scope of its authority. *See Borlem*, 913 F.2d at 937. If a court determines that Congress has not delegated the relevant authority, the challenged rules must be invalidated. *See, e.g.*, *Merck*, 80 F.3d at 1549-50 (invalidating PTO determination because it fell outside the PTO's limited authority to issue procedural rules). Only if the *Adams Fruit* threshold question—sometimes called *Chevron* step zero—has been answered in the affirmative may a court proceed to the two-step *Chevron* test. *See generally* Thomas W. Merrill & Kristin E. Hickman, *Chevron's Domain*, 89 Geo. L.J. 833, 836, 839 & n.25 (2001) (coining the term "*Chevron* step zero" and citing *Adams Fruit* as an instance of it).[4]

The PTO's preferred mode of analysis—deference first, evaluation of authority later—sidesteps the *Adams Fruit* inquiry and runs roughshod over the separation of powers. Moreover, it flies in the face of this Court's settled precedent, which adheres to *Adams Fruit*. *See, e.g.*, *Fabil Mfg. Co. v. United*

[4] The *Adams Fruit* threshold question also rebuts the government's alternative, half-hearted argument that *Skidmore* deference supports the Final Rules. *See* PTO Br. 23-24 n.3. Where *Adams Fruit* applies, the relevant questions of law have been committed to the judiciary for resolution and no deference lies whatsoever. *See Adams Fruit*, 494 U.S. at 649-50.

States, 237 F.3d 1335, 1341 (Fed. Cir. 2001) (rejecting, under *Adams Fruit*, Customs Service's claimed authority to set requisite burden of proof; "that task is for the judiciary or the Congress"); *see also Fed. Nat'l Mortgage Ass'n v. United States*, 379 F.3d 1303, 1307 (Fed. Cir. 2004) (agency pronouncement promulgated outside delegated authority "is not entitled to deference").

Under *Adams Fruit* and this Court's precedent, the district court correctly considered the PTO's authority to issue the Final Rules before turning to the Rules themselves. *See Tafas/GSK II* at 811 n.4 (court's conclusion on authority issue "renders it unnecessary to decide whether the USPTO's interpretation of the Patent Act should be given *Chevron* deference"). The PTO ignores *Adams Fruit*, neglecting even to mention it in its opening brief. That silence speaks volumes.

B. The District Court Rightly Declined To Defer To The PTO's Views When Conducting The *Adams Fruit* Inquiry.

This Court has made clear that no deference is due where an agency construes the bounds of its own authority. *See Borlem*, 913 F.2d at 937 (Courts "give deference to an agency acting within its scope of responsibility. . . . [However,] such deference should not apply when the issue is the legal scope of an agency's authority."); *see also Bolton v. MSPB*, 154 F.3d 1313, 1316 (Fed. Cir. 1998) ("Board's legal conclusion regarding the scope of its own jurisdiction" reviewed "without deference to the Board's determination.").

The PTO ignores this Court's precedent. Instead, the PTO cites Justice Scalia's concurrence in *Mississippi Power & Light Co. v. Mississippi ex rel. Moore*, 487 U.S. 354, 381 (1988) (Scalia, J., concurring). PTO Br. 21. That concurrence, however, did not form the basis for the holding in that case. Indeed, the majority opinion never even discussed the issue of whether deference should be given to an agency's view of its own authority, let alone cite to *Chevron*. While the Supreme Court "has not definitively ruled on this issue," *Northern Illinois Steel Supply Co. v. Secretary of Labor*, 294 F.3d 844, 846-47 (7th Cir. 2002), since *Mississippi Power*, the Supreme Court itself has not deferred to agencies' views of their own authority. *See, e.g.*, *Gonzales*, 546 U.S. at 258-69 (declining to defer to DOJ's view that it had authority to regulate assisted suicide); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159-62 (2000) (declining to defer to FDA's view that it had authority to regulate tobacco). Thus, the PTO's reliance on Justice Scalia's concurrence is unavailing. The law in this Court remains as set out in *Borlem* and *Bolton*.

Other circuits employ a rule of no deference as well. In *Northern Illinois Steel Supply Co.*, the Seventh Circuit acknowledged Justice Scalia's view, but instead followed the established law in that circuit, which requires "de novo" review of questions of agency authority. *Id.* at 847 (citing with approval this Court's holding in *Bolton*, 154 F.3d at 1316). Similarly, both the Eighth and D.C.

Circuits conduct *de novo* review of an agency's authority. *See, e.g.*, *Missouri v. Andrews*, 787 F.2d 270, 286 (8th Cir. 1986) ("The limits of an administrative agency's statutory authority remains an issue suitable for judicial resolution."); *N.Y. Shipping Ass'n, Inc. v. FMC*, 854 F.2d 1338, 1363 (D.C. Cir. 1988) (finding it "inappropriate" to defer to an agency's interpretation of the scope of its own authority).

Rather than address this Court's earlier decisions in *Borlem* and *Bolton*, and the decisions of the other circuits that are in accord, the PTO argues that this Court's later decision *Lacavera v. Dudas*, 441 F.3d 1380, 1383 (Fed. Cir. 2006), holds that *Chevron* deference applies to an agency's interpretation of its own authority. However, in *Lacavera*, the regulations at issue—those governing the recognition of attorneys to practice before the PTO—fit squarely within the PTO's authority to "govern the conduct of proceedings before it and to govern the recognition and conduct of attorneys." *Id.* (citing 35 U.S.C. § 2(b)(2) and *Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004)). As a result, this Court analyzed the PTO's regulations under the *Chevron* framework and deferred to them because "the PTO did not exceed its statutory authority in promulgating the regulations in question." *Lacavera*, 441 F.3d at 1383.

The *Lacavera* Court never dealt with the issue here—whether this Court should defer to the PTO's view as to the scope of its authority. This Court's

decisions both before and after *Lacavera* are unanimous—there is no deference on the issue of the "legal scope of an agency's authority." *Borlem*, 913 F.2d at 937; *see also Bolton*, 154 F.3d at 1316 (same); *Davis v. MSPB*, 278 F. App'x 1009 (Fed. Cir. 2008) (affording no deference to question of Board's jurisdiction); *Sweeney v. Dep't of Homeland Sec.*, 233 F. App'x 997, 1000 (Fed. Cir. 2007) (same).

C. The PTO Has No Authority To Issue Substantive Rules.

The district court properly concluded that the PTO lacks authority to issue substantive rules. *Tafas/GSK II* at 811-12. In arriving at its conclusion, the court relied on this Court's authoritative construction of the scope of the PTO's powers in *Merck*. As this Court has explained, "the broadest of the PTO's rulemaking powers . . . 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." *Merck*, 80 F.3d at 1549-50 (quoting former 35 U.S.C. § 6(a) and citing *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991) ("*ALDF*")) (capitalization in original). Because the PTO lacks "substantive rulemaking power," "the rule of controlling deference set forth in *Chevron* [did] not apply." *Id.* at 1550.[5]

[5] An unbroken line of cases, including one decided last month, attests to the vitality of *Merck*'s holding. *See, e.g.*, *Cooper Techs.*, 536 F.3d at 1336 ("We have also previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to (Continued…)

To hold otherwise would empower the PTO to reverse this Court's established precedent by imposing substantive rules under the guise of interpreting the Patent Act, as the PTO tried to do here with these Final Rules. But Congress endowed this Court, not the PTO, with exclusive and centralized authority to interpret the Patent Act.[6] *See* S. Rep. No. 97-275, at 1 (1981) (One of the reasons Congress established the Federal Circuit was to bring about uniformity in patent law.); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (same).

In finding that Congress did not delegate to the PTO the authority to promulgate substantive rules, *Merck* cited to an *en banc* Seventh Circuit decision, which held that "only statutory interpretations by agencies WITH RULEMAKING POWERS deserve substantial deference." *Merck*, 80 F.3d at 1549 (capitalization in original) (quoting *Atchison, Topeka & Santa Fe Ry. Co. v. Pena*, 44 F.3d 437,

---

issue 'substantive' rules.") (citing *Merck*, 80 F.3d at 1549-50); *Brand v. Miller*, 487 F.3d 862, 869 n.3 (Fed. Cir. 2007) (same); *Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003) (same).

[6] The PTO's lack of substantive rulemaking authority is further evidenced by the fact that Congress has considered giving the PTO such authority, but has never done so. *See Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ.*, 127 S. Ct. 1534, 1540-41 (2007) (highlighting congressional inaction as bearing on a dispute concerning agency authority). For example, since 2005, Congress has considered but declined to grant the PTO some form of substantive rulemaking authority. *See* H.R. 2795, 109th Cong. § 123 (2005); S. 3818, 109th Cong. § 6(e) (2006); *compare* JA1654 § 3(a)(5) (Senate Bill 1145 as introduced in 2007) *with* JA1715-18 (Section 3(a)(5) omitted); *see also* JA1567 ¶ 9.

441 (7th Cir. 1994) (*en banc*)). The concurring judges in *Atchison Topeka* made clear that the court applied *Adams Fruit* as a prerequisite to *Chevron* deference. *See* 44 F.3d at 445 (Easterbrook & Manion, J.J., Posner, C.J., concurring) ("The Federal Railway Administration has not been delegated either rulemaking or adjudicative power over the subject of hours of service. It therefore cannot demand obedience to its law-making choices after the fashion of *Chevron* . . . . *See Adams Fruit*.").

The PTO argues that *Merck*'s holding is irrelevant *dicta*. PTO Br. 32. It premises this notion on the misguided view that *Merck* did not concern rulemaking, but rather a "final determination." *Id.* at 32-33. In the PTO's view, *Merck*'s holding meant only that the PTO lacks a "roving commission to make freestanding pronouncements . . . regarding the" Patent Act. *Id.* at 33.[7]

But this Court has repeatedly used the PTO as an example of an agency that lacks substantive powers of any kind—not just with regard to "final determinations" or "freestanding pronouncements." *See Pesquera Mares Australes Ltda. v. United States*, 266 F.3d 1372, 1381 n.6 (Fed. Cir. 2001) (contrasting the Commerce Department's possession of substantive rulemaking authority with the

[7] The PTO's misreading of *Merck* is not entitled to deference. *See Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1085 (D.C. Cir. 2001) (Courts "owe no deference to an agency's reading of judicial orders or decisions.").

PTO's lack of such authority); *Small v. United States*, 158 F.3d 576, 581 n.1 (Fed. Cir. 1998) (contrasting the Air Force Secretary's possession of substantive rulemaking authority with the PTO's lack of such authority); *Hodge v. West*, 155 F.3d 1356, 1361 (Fed. Cir. 1998) (analogizing the lack of *Chevron* deference to the Court of Veterans Appeals to the PTO's lack of substantive rulemaking authority).

In advancing its *dicta*-based argument, the PTO ignores the positions it has previously advocated before this Court. Most obviously, as the *Merck* Court observed, the PTO invoked *Chevron* and argued that the "Final Determination is entitled to controlling weight." *Merck*, 80 F.3d at 1549 (internal quotations omitted). In fact, the government focused its entire petition for rehearing in *Merck* on the *Chevron* issue. *See generally* Fed. App. Pet. for Reh. and Sugg. of Reh. *En Banc*.[8] And the government used the terms "Final Determination" and "rule" interchangeably. *See, e.g.*, Br. of Fed. App. at 16 ("The fact that a pure question of law is involved in no way undermines this rule.").

Still, the PTO brushes *Merck* aside and argues that Section (2)(b)(2) and other provisions of Title 35 authorize the PTO to promulgate the Final Rules. *See*

[8] This brief and the PTO's "Brief of Federal Appellants" filed in *Merck* are submitted as exhibits to GSK's Motion for Judicial Notice of PTO Briefs Filed in the *Merck* Appeal, filed on September 24, 2008.

PTO Br. 24-28.[9] While it is true that the PTO possesses ***some*** rulemaking authority relating to "procedures" in the PTO, the critical point is that it does not possess the ***relevant*** authority to pass ***these*** substantive Final Rules. "[I]t is fundamental 'that an agency may not bootstrap itself into an area in which it has no jurisdiction.'" *Adams Fruit*, 494 U.S. at 650 (quoting *Fed. Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973)). The cases upholding other PTO rules as reasonable exercises of procedural or interpretive authority under *Chevron* are inapposite. *See* PTO Br. 20. All of those cases came after *Merck*, relate to "procedural" rules, and do not address the issue of substantive rulemaking authority. For example, the PTO invokes statements from *Lacavera v. Dudas*, 441 F.3d 1380, and *Stevens v. Tamai*, 366 F.3d 1325, in an effort to show that its Section 2 powers are broad. *See* PTO Br. 20-21. But nothing in those cases

[9] The PTO has retreated from the argument, advanced in the district court, that Section 2(b)(2)'s reference to APA Section 553 somehow delegates substantive rulemaking power to the PTO. The district court soundly rebuffed that argument. *See Tafas/GSK II* at 812 ("[T]he structure of Section 2(b)(2) makes it clear that the USPTO must engage in notice and comment rulemaking when promulgating rules it is otherwise empowered to make-namely, procedural rules. The requirement of compliance with Section 553 cannot be read as creating substantive rulemaking authority by implication. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ('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.')."). *See* § VI, *infra*.

purports to overrule *Merck* and both are readily distinguishable because they upheld exercises of only ***procedural*** authority.

Likewise, the PTO's reliance on *National Cable & Telecommunications v. Brand X Internet Services*, 545 U.S. 967 (2005), is misplaced. The *Brand X* Court first addressed whether the action fell within the agency's authority before giving deference. *See* 545 U.S. at 980-82 (concluding that *Chevron* deference applied only after noting that "no one questions that the order is within the Commission's jurisdiction"). Thus, *Brand X* did not overrule *Adams Fruit* and does not support the PTO's argument here.

The PTO next argues that a substantive-procedural split is foreign to *Chevron*. *See* PTO Br. 30-31. But the PTO's argument reveals its fundamental misunderstanding of Congress' delegation powers and the scope of the PTO's authority. Congress can withhold rulemaking authority over a specific area, defined in any way it sees fit. *See, e.g.*, *Adams Fruit*, 494 U.S. at 650 (no delegation to Labor Department over private rights of action); *Atchison Topeka*, 44 F.3d at 441 (no delegation to Federal Railway Administration over hours of service). Here, Section 2(b)(2)'s language and history demonstrate that Congress declined to vest the PTO with substantive rulemaking authority.

Congress demonstrated its intent to confine the PTO's authority when it ratified *Merck*'s holding. Three years after *Merck*, Congress enacted the present

Section 2(b)(2) in terms identical to former Section 6(a). *See* American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4172, 113 Stat. 1501, 1501A-573 (1999) ("AIPA"). In so doing, Congress ratified *Merck* and reaffirmed the PTO's limited rulemaking authority to issue only procedural rules. *See Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change."). As a result, Congress further confirmed this Court, not the PTO, as the arbiter of substantive patent law.

The PTO nevertheless contends that *In re Van Ornum*, 686 F.2d 937 (C.C.P.A. 1982), "forecloses" consideration of the dichotomy between substantive and procedural rules. PTO Br. 30. *Van Ornum*, however, in no way addressed the issue presented here. In affirming the validity of the regulation at issue, the *Van Ornum* court concluded that the regulation "clearly relates to application processing within the PTO in a manner consistent with statutory and case law." 686 F.2d at 945. *Van Ornum* did not find that the PTO had "substantive" rulemaking powers, nor did it "foreclose" the dichotomy between substantive and procedural rules. That dichotomy, however, formed the foundation for the *Merck* decision, which Congress implicitly approved when it enacted Section 2(b)(2).

In short, there is no basis for abandoning, or otherwise declining to apply, *Merck*'s prohibition on substantive PTO rulemaking, as Congress ratified in Section 2(b)(2).

D. The Final Rules Are Substantive.

After holding that "Section 2(b)(2) does not permit the USPTO to promulgate substantive rules," and that any such rules are "null and void," the district court concluded that the Final Rules are substantive. *Tafas/GSK II* at 813. In reaching that conclusion, the district court carefully applied the Supreme Court's and this Court's settled view of what it means for rules to be substantive. *See id.* at 814. Under that authority, any rule that "'effects a change in existing law or policy' which 'affect[s] individual rights and obligations'" is substantive. *ALDF*, 932 F.2d at 927 (internal quotations omitted); *see also Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979) (Substantive rules are those that "affect[] individual rights and obligations.") (internal quotations omitted); *Am. Hosp. Ass'n. v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (Rules are substantive if they "grant rights, impose obligations, or produce other significant effects on private interests . . . or [] effect a change in existing law or policy.") (internal quotations omitted). The Final Rules are substantive because they "constitute a drastic departure from the terms of the Patent Act" and "effect changes in GSK's and

Tafas's existing rights and obligations." *Tafas/GSK II* at 814; *see also* §§ III.A.-III.C., *infra*.

The PTO first argues that the district court misconceived the test for whether the Final Rules are substantive or procedural. PTO Br. 33-35. That test, the PTO asserts, was improperly drawn from cases discussing the differences between substantive rules and ***interpretive*** rules, not the differences between substantive and ***procedural*** rules. *Id*. at 34.

The PTO's argument constructs a false dichotomy between interpretive and procedural rules. Under the APA, it makes no functional difference whether the agency characterizes its rule as procedural or interpretive, because neither may be substantive and neither may alter private rights. *See Cooper Techs.*, 536 F.3d at 1336 (recognizing that an interpretive rule, in contrast to a substantive rule, does not affect any change in existing law or policy, but "merely clarifies or explains existing law or regulations") (quoting *ALDF*, 932 F.2d at 927) (internal quotations omitted); *Schism v. United States*, 316 F.3d 1259, 1279, 1281 (Fed. Cir. 2002) (Rules governing "internal departmental affairs" are "housekeeping" matters that authorize only "what the APA terms 'rules of agency organization, procedure or practice' as opposed to 'substantive rules.'") (quoting *Chrysler*, 441 U.S. at 309-10) (emphasis omitted).

Moreover, courts have relied on the APA's distinction between substantive and procedural rules for guidance. *See, e.g.*, *Fressola v. Manbeck*, 36 U.S.P.Q. 2d 1211, 1212 (D.D.C. 1995). In *Fressola*, the court was confronted by the rule requiring that each claim be a single sentence. *Id.* In examining the "one-sentence rule," the court recognized that "courts examine the impact of the rule before characterizing it as 'substantive' or 'procedural,' placing agency rules in the former category only to the extent they 'depart from existing practice' or 'trench [] on substantive rights and interests.'" *Id.* at 1215 (citation omitted). The court concluded that the rule was procedural because, among other reasons, "the rule does not affect the substance of an applicant's claims—again, an applicant can convert any claim originally written with multiple sentences into a one-sentence claim—neither does it impact upon 'substantive rights and interests.'" *Id*. Hence, where statutes authorize an agency to promulgate only procedural rules, it is proper to look to the APA's test for what constitutes a substantive rule for guidance.

Moreover, the government's reliance on *American Hospital Association* forecloses any argument that the Final Rules are merely procedural. PTO Br. 34. As that court explained, a rule which "encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior" is not procedural. *Am. Hospital Ass'n*, 834 F.2d at 1047. The PTO designed the Final Rules precisely to address its "disapproval o[f] a given type of behavior"—the

PTO's perception that applicants file too many continuing applications, RCEs, and claims. The PTO has admitted that it crafted the Final Rules to "stop" continuing applications and limit claims. JA1346 at 51:5-22. This admission confirms that the Final Rules are substantive.

In contrast to the long line of cases looking to the APA's substantive-procedural distinction to resolve questions on the scope of agency authority, the PTO urges this Court to look instead to the Rules Enabling Act. *See* PTO Br. 36-39. GSK is aware of no case taking that approach, and the PTO cites none. Even if this Court were to consider the Rules Enabling Act, it would find ample authority for the proposition that the procedural authority granted therein cannot be allowed to alter substantive law.

The PTO relies on *Hanna v. Plumer*, 380 U.S. 460, 464-65 (1965), which concerned service of process under former Fed. R. Civ. P. 4(d)(1) and its predecessors, for the point that mere incidental effects do not make rules substantive. PTO Br. 35-36. The Final Rules, however, do not have merely "incidental" effects on patent law. *See Tafas/GSK II* at 814 (the Final Rules "change existing law and alter the rights of applicants such as GSK"). In any event, the district court's decision does not concern the Rules Enabling Act or call into question the rules the Supreme Court issued. The government's attempt to cast Rule 78 and Fed. R. Civ. P. 15(a) in the same light is baseless. Unlike Fed. R.

Civ. P. 15(a), Rule 78 limits rights provided by the Patent Act and sanctioned by this Court.

The PTO tries to salvage the Final Rules by redefining what it means for a rule to be "procedural." The PTO appears to contend that any rule, regardless of whether it affects statutory rights, is procedural if it does not affect "substantive requirements for patentability under 35 U.S.C. §§ 101, 102, 103 and 112, such as utility, novelty, or non-obviousness." PTO Br. 24. But the Patent Act provides many substantive rights beyond those in Sections 101, 102, 103 and 112. *ALDF*, 932 F.2d at 930 ("A substantive declaration with regard to the Commissioner's interpretation of the patent statutes, whether it be section 101, 102, 103, 112 ***or other section*** . . . .") (emphasis added); *see Merck*, 80 F.3d at 1549-50 (finding the PTO's rule-like determination concerning Section 156 of the Patent Act to be substantive).

The PTO's fallback argument that "even if Rule 78 alters a right conferred by Section 120, it does not follow that Rule 78 is substantive," PTO Br. 35, is unfounded. By this logic, the PTO would have authority to rewrite statutes by characterizing statutory rights as procedural.[10] But there can be no clearer example

[10] The PTO's reliance on *Landgraf*, 511 U.S. 244, *see* PTO Br. 35, is inapt because that case involved the retroactive effect of a statute, not whether rules that altered statutory rights exceeded an agency's limited procedural powers.

of a substantive rule than one that "alters rights conferred by" the Patent Act and alters rights that courts have repeatedly sanctioned over many years.

Putting its myriad arguments aside, the PTO essentially concedes that the Final Rules are substantive. The PTO argues that the rules deserve *Chevron* deference because they are legislative in nature. PTO Br. 20 (stating that the Rules are "in the nature of 'legislative type of activity'"). Legislative rules, however, are substantive rules. *See ALDF*, 932 F.2d at 927 (equating the two); *Am. Hosp. Ass'n*, 834 F.2d at 1045 (same). Thus, the PTO's own argument for deference belies any contention that the Final Rules are merely procedural.

III. The Final Rules Are Contrary To The Patent Laws.

The PTO has also exceeded its authority in promulgating the Final Rules because they are contrary to established patent laws. *See* 35 U.S.C. § 2(b)(2) (stating that the PTO "may establish regulations, not inconsistent with law"); *Cal. Indus. Prods., Inc. v. United States*, 436 F.3d 1341, 1356 (Fed. Cir. 2006) ("[T]he regulation . . . is due no *Chevron* deference due to Congress' unambiguously expressed intent."). This is especially true here, where this Court and its predecessor have already interpreted these same patent statutes over many decades and found their meaning to be unambiguous. As the Supreme Court made clear in *Lechmere, Inc. v. NLRB*:

> Once [courts] have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an

> agency's later interpretation of the statute against our prior determination of the statute's meaning.

502 U.S. 527, 536-37 (1992) (quoting *Maislin Indus., Inc. v. Primary Steel, Inc.*, 497 U.S. 116, 131 (1990)). As discussed below, the PTO's Final Rules, instead of adhering to precedent, would turn *stare decisis* on its head.

A. Rule 78 Is Contrary To The Patent Laws.

1. Rule 78 Imposes A Hard Limit On The Number Of Continuing Applications Where 35 U.S.C. § 120 Allows For No Such Limit.

The district court correctly found that Rule 78 creates a hard mechanical limit on the number of continuing applications an applicant may file and that, as a result, the rule strips applicants of valuable rights to which they are entitled under 35 U.S.C. § 120. *Tafas/GSK II* at 814-15. Section 120 states that a continuation application "shall" (*i.e.*, must) be given the same filing date as the earlier application to which it refers if other formal requirements are satisfied.

The PTO is powerless to limit Section 120, a point this Court's predecessor made clear forty years ago:

> [T]here is no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications, provided [an] applicant meets all the other conditions of the statute.

Henriksen, 399 F.2d at 254; *see also Ex parte Hull*, 191 U.S.P.Q. 157, 159-60 (Pat. & Tr. Office Bd. App. 1975) (finding that the PTO lacks such power). The

C.C.P.A. reaffirmed that principle in *In re Hogan*, finding that the statutory language of Section 120 is "clear and unambiguous" and does not limit the number of continuations an applicant may file. 559 F.2d 595, 604 (C.C.P.A. 1977); *see also Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed. Cir. 1994) ("The plain and unambiguous meaning of section 120 is that any application fulfilling the requirements therein 'shall have the same effect' . . . ."). Imposing a limit on continuation applications, the Court recognized, is "a matter of policy for the Congress." *Hogan*, 559 F.2d at 604 n.13.

Despite this Court's precedent, the PTO concedes that Rule 78 limits continuing applications. *See* JA1346 at 51:5-11 (conceding that the goal is "stopping" continuing applications); JA1726 ("Why Limit Continuations?"); JA1727 ("Limits continuations and RCEs"); JA1745 ("Limits the number of continuations and RCEs"). The PTO attempts to minimize Rule 78's burden by suggesting it is a mere "presumption" rather than a limit. *See* PTO Br. 42. But the petition and showing requirement is a hard limit on continuing applications, as the PTO has made clear that it will deny a petition for a third, or any subsequent, continuing application in all but the rarest of circumstances. *Tafas/GSK II* at 814

(citing 72 Fed. Reg. 46,769-77).[11] The PTO has said that it will reject additional continuations when filed for the purpose of having the PTO consider "newly discovered prior art" (JA109-10), when filed to address an examiner's unusual or changed interpretation of the claims (JA110), or when the applicant becomes disabled for a lengthy time during the pendency of the application (JA113). Moreover, the PTO has said that it will refuse additional continuations even when filed for reasons expressly sanctioned by this Court, including the submission of claims to cover a competitor's product. JA91 (72 Fed. Reg. 46,775); *see Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) ("[T]here is nothing improper, illegal or inequitable . . . to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution."). Rule 78, therefore, substantively changes the law.

The PTO, again ignoring this Court's precedent, attempts to manufacture a textual conflict between the district court's reading of Section 120 and "the overall

[11] Moreover, the PTO's ethical rules, *e.g.*, 37 C.F.R. § 10.85, may bar GSK from even submitting a petition in the first instance, as the petition requires affirmation that "an amendment, argument, or evidence . . . could not have been submitted" previously. JA175 (72 Fed. Reg. 46,839). That requirement is tantamount to a physical impossibility standard because it requires GSK to aver that it could not possibly have presented an amendment or argument earlier—further evidence that Final Rule 78 imposes a hard limit. *See* JA1576 ¶¶ 40-42.

approach of the Patent Act," in particular, Sections 112, 134, and 251. *See* PTO Br. 48-49. But no such conflict exists—the PTO has applied these sections without any conflict for decades and does not cite to any cases to support its position. For example, the PTO contends that allowing applicants to file continuing applications "allows applicants to broaden their claims long after the two-year limit for seeking a broadening reissue patent under Section 251 has passed." PTO Br. 48-49. But that obscures the fundamental difference between a broadening reissue—broadening claims in an already issued patent—with the right to seek broad claims during open prosecution of a continuation application. This Court has repeatedly endorsed continuing applications as a method of obtaining broader claims. *See, e.g.*, *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1055 (Fed. Cir. 2002) ("[A] patentee may file a reissue application and attempt to enlarge the scope of the original claims to include the disclosed but previously unclaimed subject matter . . . [or] a separate application claiming the disclosed subject matter under . . . § 120."); *see also Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1317 (Fed. Cir. 2007) ("[C]ontinuing applications may present broader claims than were allowed in the parent.") (citing *Symbol IV* at 1385).

Again ignoring precedent from this Court's predecessor, the PTO also contends that Section 120's legislative history fails to support the district court's decision. PTO Br. 47-48. Citing the PTO Board's decision in *Ex Parte Henriksen*,

154 U.S.P.Q. 53 (Pat. Off. Bd. App. 1966), the PTO contends that "chains of continuing applications were virtually unknown" before Congress originally passed Section 120. PTO Br. 47-48. The C.C.P.A., however, expressly disagreed with the PTO's now-recycled position. *See Henriksen*, 399 F.2d at 258-60 (in reversing the PTO Board's decision, finding that pre-1953 case law, including Supreme Court case law, and treatises supported the conclusion that there was no limit to the number of continuations). Rather, the C.C.P.A. agreed with the PTO Board dissenters in *Henriksen* and the pre-1952 Act commentators that "there was no limit to the sequence of consecutive applications." *Id*. at 259-60. As the Supreme Court recognized, this was the law long before the 1952 Act. *See Godfrey v. Eames*, 68 U.S. 317, 325-26 (1863) (recognizing that if an applicant complies with the statutory conditions, it is entitled to a continuation).

In sum, for over a century, applicants have been permitted to file additional continuing applications with no arbitrary or mechanical limit. Here, the PTO's reliance on *Brand X* to contravene decades of case law and "interpret" anew Section 120 is inappropriate. First, *Brand X* applies only when an agency acts within the scope of its rulemaking authority. 545 U.S. at 982. As discussed at length above, here the PTO has not. Second, *Brand X* only applies to ambiguous statutes. *Id.* at 980-82. Notably, both this Court and its predecessor have found Section 120 to be "unambiguous." *See Transco Prods.*, 38 F.3d at 556; *Hogan*,

559 F.2d at 604. Therefore, *stare decisis* controls. *See Lechmere*, 502 U.S. at 536-37.

The PTO's reliance on *Woodbridge v. United States*, 263 U.S. 50 (1923), and *Webster Electric Co. v. Splitdorf Electrical Co.*, 264 U.S. 463 (1924), to show historical limitations on the number of continuations an applicant may file is also misplaced. *See* PTO Br. 48. Those cases concern the doctrine of prosecution laches, which prohibits unreasonably dilatory conduct by individual applicants on a case-by-case basis; they do not set arbitrary, mechanical limits on continuation filings. *See Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 277 F.3d 1361, 1364 (Fed. Cir. 2002) ("*Symbol II*") (identifying *Woodbridge* and *Webster Electric* as prosecution laches cases); *see also Symbol IV*, 422 F.3d at 1385 (same); *In re Bogese II*, 303 F.3d 1362, 1367 (Fed. Cir. 2002) (same).

2. The Doctrine Of Prosecution Laches Does Not Save Rule 78.

The PTO argues that an interpretation of Section 120 that precludes the PTO from imposing limits on an applicant's statutory right to continuations cannot be reconciled with the doctrine of prosecution laches and *Bogese II*. PTO Br. 43-46. The doctrine of prosecution laches and *Bogese II*, however, do not authorize Rule 78. *See Tafas/GSK II* at 814-15 ("The mechanical rule adopted here goes far beyond" prohibiting the use of dilatory tactics in the prosecution of applications.).

The *Symbol II*, *Bogese II*, and *Symbol IV* trilogy establishes that the PTO may reject applications based upon prosecution laches only in extreme and unreasonable situations and on a case-by-case basis, not in Rule 78's mechanical and arbitrary manner. *See Symbol IV*, 422 F.3d at 1385-86 (affirming the unenforceability of fourteen patents under the prosecution laches doctrine when "an 18- to 39-year time period had elapsed between the filing and issuance of the patents in suit"); *Bogese II*, 303 F.3d at 1369 (affirming a PTO rejection where "Bogese filed twelve continuation applications over an eight-year period and did not substantively advance prosecution of his application when required and given an opportunity to do so by the PTO"). These cases make clear that the PTO's power is limited to applying the equitable doctrine of prosecution laches only on a case-by-case basis.

In particular, in *Symbol IV*, this Court expressly warned that the doctrine of prosecution laches "should be ***used sparingly lest statutory provisions be unjustifiably vitiated***" and "should be ***applied only in egregious cases*** of misuse of the statutory patent system." 422 F.3d at 1385 (emphases added). While ignoring *Symbol IV*, the PTO relies on *Bogese II*'s statement that the "PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for prosecution of an application." PTO Br. 44 (citing *Bogese II*, 303 F.3d at 1367-68). That "inherent authority," however,

does not permit the PTO to exceed its limited procedural authority and deny statutory rights under the guise of setting "reasonable" requirements. As the *Bogese II* court explained, the PTO lacks the ability to impose "a mechanical rule based on a misconstruction of the statutory requirements." 303 F.3d at 1368 n.6.

It is well known that "[t]he very purpose of reliance on § 120 is to reach back, to avoid the effect of intervening references." *Hogan*, 559 F.2d at 604. By mechanically limiting that statutory right of priority, Rule 78's hard limit contradicts Section 120 and frustrates its purpose.[12]

B. Rule 114 Is Contrary To The Patent Laws.

Rule 114's arbitrary and mechanical limit of one RCE per "application family" violates Section 132(b) of the Patent Act in at least two ways. *Tafas/GSK II* at 815-16. First, the mechanical limit of one RCE contradicts the express language of Section 132(b), which states that the PTO "shall" prescribe regulations to provide for continued examination "at the request of the applicant." Second, Rule 114 violates the Patent Act by imposing a limit based on an "application

[12] The PTO's argument that Rule 78's mechanical limit is similar to the ministerial filing requirements of 37 C.F.R. §§ 1.52(a) and 1.78(a)(5)(iv) is misguided. Unlike Rule 78's restriction, those rules merely require, among other things, that papers filed with the PTO be "flexible, strong, smooth, non-shiny, durable, and white," and that writing be "plainly and legibly written, " *see* 37 C.F.R. § 1.52(a), and that an applicant file a translation for provisional applications filed in a foreign language, *see id.* at § 1.78(a)(5)(iv).

family" rather than an "application," which is "a clear departure from the plain language of the statute." *Tafas/GSK II* at 815.

The PTO asserts that Congress' inclusion of the word "shall" in Section 2(b)(2) merely requires the PTO to issue regulations and that "at the request of the applicant" could "just as easily be understood to describe *how* a continued examination is initiated, not to prescribe *how many* continued examinations must be performed." PTO Br. 50-51 (emphases in original). This approach violates a fundamental tenet of statutory interpretation that a statute must be read as a whole. In using the word "shall" in conjunction with the phrase "at the request of the applicant," Congress made clear its intent that RCEs not be limited and that continued examination be at the ***applicant's*** discretion. *Tafas/GSK II* at 815.

Section 132(b) gives each applicant the right to request continued examination and the discretion to exercise that right, and it does not limit the number of continued examinations. *Id*. The PTO's current position is a complete reversal of its previous understanding. When it initially promulgated regulations to provide for RCEs under Section 132(b), the RCE provisions applied to "all applications" and the PTO recognized that "an applicant . . . is not limited in the number of times" it may file an RCE. *See* "Request for Continued Examination Practice and Changes to Provisional Application Practice," 65 Fed. Reg. 50,092, 50,095-96 (Aug. 16, 2000).

Although the PTO now asserts it has broad latitude under Section 132(b) to impose reasonable "conditions and requirements for continued examinations," PTO Br. 50-51, that section provides the PTO with no greater rulemaking authority than Section 2(b)(2), *Tafas/GSK II* at 815 n.7. Further, the PTO's attempt to limit RCEs is not a "reasonable condition," but a hard mechanical limit. As with continuing applications, the PTO has indicated that it would deny a petition for additional RCEs in all but the rarest of circumstances, essentially a physical impossibility standard. *Id*. at 815; JA1576 ¶ 41.

Rule 114 also violates the Patent Act by imposing a limit based on an "application family" rather than an "application." The phrase "application family" appears nowhere in the Patent Act, let alone Section 132(b).[13] Congress intended RCEs to apply to all ***applications***. Indeed, when it enacted Section 132(b), Congress expressly stated that Section 132(b) "shall apply to all applications" filed on or after June 8, 1995. AIPA, § 4405(b)(1), 113 Stat. at 1501A-560 to 1501A-561.

[13] The PTO tries to paint the district court's reference to Section 132(a), which relates to the "reexamination" of applications, as error. PTO Br. 52. But the district court did not rely on Section 132(a) as relating to RCEs, but as evidence that the PTO's newfound "application family" limitation lacks support in the Patent Act. *See Tafas/GSK II* at 815.

To salvage its "application family" limitation, the PTO argues that Congress' use of the term "applications" is extraneous and "does nothing more than identify the subject matter of [the statute]." PTO Br. 51-52. The PTO urges this Court to ignore the word "applications" because Congress could not have drafted the statute without the word. *Id*. That approach once again violates a fundamental tenet of statutory construction that each word be given effect. In fact, by arguing that this Court should ignore a word Congress used in Section 132(b), the PTO highlights that Rule 114 runs afoul of the express language of the statute.

C. Rules 75 And 265 Are Contrary To The Patent Laws.

Rules 75 and 265 violate the patent laws by imposing arbitrary and mechanical limits on the number of claims applicants may submit. They force applicants to conduct boundless prior art searches and, thus, violate the fair notice doctrine of rulemaking. They also improperly shift the burden of examination from the PTO to the applicant.

1. Rule 75 Is Contrary To 35 U.S.C. § 112, ¶ 2.

The district court rightly concluded that Rule 75's "mechanical" limits, which bar applicants from filing more than five independent and twenty-five total claims absent compliance with the ESD's onerous requirements, are inconsistent with the Patent Act. *Tafas/GSK II* at 816. On appeal, the PTO argues that Rule 75's strictures are not "mechanical." *See* PTO Br. 53. But Rule 75's burden is

irrefutably imposed on applicants—mechanically and automatically—the moment an application exceeds Rule 75's arbitrary limits.

Likewise, the consequences for failing to abide by Rule 75 flow just as mechanically and automatically: the PTO "will abandon an otherwise meritorious application" and strip applicants of their statutory right to adequate patent protection. *Tafas/GSK II* at 816. So while the PTO takes issue with the ***degree*** of Rule 75's burden, it can offer no serious refutation of its ***nature***—it arises automatically, without regard to content or context.[14]

As the district court found, Rule 75 is inconsistent with Section 112, ¶ 2's grant to applicants to pursue "one ***or more*** claims" in patent applications. (emphasis added). Again ignoring many years of settled precedent from this Court and its predecessor, the PTO suggests that Section 112 "merely sets a floor on the number of claims that an applicant must submit." PTO Br. 54. However, neither Section 112's text, nor judicial construction of it, compel the PTO's reading. Instead of setting a floor, Section 112 makes clear that there is no statutory ceiling to the number of claims an applicant may seek. *Tafas/GSK II* at 816 (citing cases); *Wakefield*, 422 F.2d at 900 (rejecting PTO's attempt to limit claims under Section

[14] In October 2007, shortly before the Final Rules were to have gone into effect, the PTO's Patent Application Information Retrieval ("PAIR") system automatically flagged several GSK applications as exceeding the 5/25 limit. *See* JA2007-16.

112, as "there is no statutory authority for rejecting claims as being 'unnecessary'" and an "applicant should be allowed to determine the necessary number and scope of his claims"); *see also In re Chandler*, 319 F.2d 211, 225 (C.C.P.A. 1963).[15]

Again, as with continuation practice, this was the law well before the 1952 Act. At least as far back as 1938, this Court and its predecessor recognized that an applicant has "the right to, and ordinarily for his own protection does, express the same invention in more than one claim." *In re Clark*, 97 F.2d 628, 631 (C.C.P.A. 1938). In so doing, that "[applicant] is acting within the rights granted and the duties required by the patent laws." *Id.*[16]

In re Rubinfield, 270 F.2d 391 (C.C.P.A. 1959), which considered a rule restricting ***design*** patents to a single claim, is of no import. *See* PTO Br. 54-55. Design patents differ fundamentally from utility patents. *See Datamize, LLC v.*

---

[15] Further, in rebuffing the PTO's attempts to limit the number of claims, courts have required that the PTO evaluate applications on a case-by-case basis rather than in the mechanical fashion of Rule 75. *See In re Flint*, 411 F.2d 1353, 1359 (C.C.P.A. 1969) (citing *In re Chandler*, 319 F.2d at 225). In that regard, it is worth noting that Rule 75(b) states that an applicant may only present claims that are not "unduly multiplied." JA172. To the extent the PTO uses that language to impose a mechanical limit on the number of claims that may be presented, that too would be inconsistent with well-settled precedent.

[16] Again, *Brand X* is unavailing because the PTO lacks substantive rulemaking authority and *Brand X* applies only to ambiguous statutes, not to statutes that have been found over decades of uniform statutory construction to be unambiguous.

Plumtree Software, Inc., 417 F.3d 1342, 1354-55 (Fed. Cir. 2005) (rejecting argument based on this fundamental distinction); 8 Donald S. Chisum, *Chisum on Patents* § 23.01 (2007) ("A design patent fundamentally differs from a utility patent."); *compare* 35 U.S.C. § 101 *with* 35 U.S.C. § 171. Unlike utility patents, design patents do not allow for more than a single claim because the patent specification's drawings, not the claim language, define the scope of protection. *See In re Mann*, 861 F.2d 1581, 1582 (Fed. Cir. 1988) ("Design patents have almost no scope. The claim at bar, as in all design cases, is limited to what is shown in the application drawings."); *see also Rubinfield*, 270 F.2d at 395-96 ("[N]o useful purpose could be served by the inclusion of more than one claim in a design application or patent."); *Tecumseh Prods. Co. v. Briggs & Stratton Corp.*, 295 F. Supp. 2d 902, 909 (E.D. Wis. 2003) ("Unlike a utility patent, which is defined by a series of numbered claims, a design patent has only one claim which is defined by the accompanying figures."). So while a rule limiting design patents to one claim, as in *Rubinfield*, cannot impact an applicant's ability to protect the full scope of its design—which is dictated by the content of the drawings, not the number of claims—a similar rule arising in the utility patent context restricts an applicant's ability to protect its invention. Utility patent protection extends only to that which is expressly claimed. *Datamize*, 417 F.3d at 1354. A rule that strips an

applicant's right to include claims in a utility application necessarily strips that applicant of "the rights granted . . . by the patent laws." *Clark*, 97 F.2d at 631.

2. Rules 75 And 265 Are Contrary To 35 U.S.C. §§ 102, 103 And 131.

Acknowledging that regulatory requirements that shift the burden of examination or proof to applicants are unlawful, the PTO contends that Rules 75 and 265 do not do so, as they seek only "additional information" to assist the examiner. PTO Br. 55-58 (comparing these rules to the disclosure requirements of PTO Rules 56 and 105, and Fed. R. Civ. P. 26(a)). "This argument fails," as the district court concluded, because "these rules go far beyond merely requiring additional information." *Tafas/GSK II* at 816. Indeed, these rules impose new substantive obligations on any applicant that seeks to file more than 5/25 claims, contrary to Sections 102, 103 and 131 of the Patent Act.

Rule 265 demands that applicants: (i) conduct an incomprehensibly vague, world-wide search of prior art without regard to scope, time, or cost; and (ii) provide "a detailed explanation particularly pointing out how each of the independent claims is patentable over the cited references." JA178. These are not information-gathering exercises consistent with existing legal obligations; these are new, open-ended obligations imposed on applicants in a manner at odds with existing law. *See Frazier*, 417 F.3d at 1238 (The Patent Act imposes "no duty to conduct a prior art search" and "no duty to disclose art of which an applicant could

have been aware.") (internal quotations omitted) (citing *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1351 n.4 (Fed. Cir. 2005)).[17]

In addition, Rule 265 shifts the burden of examination to applicants by requiring applicants to establish the patentability of each independent claim before the PTO demonstrates a *prima facie* case of unpatentability. In so doing, Rule 265 runs afoul of several provisions of the Patent Act. Section 131 provides that the director "shall cause an examination to be made," and Sections 102 and 103 provide that an applicant "shall be entitled to a patent unless" the claimed invention lacks novelty or is obvious in view of the prior art. 35 U.S.C. §§ 102, 103, 131. As the district court explained, "[t]he Federal Circuit has read these provisions as placing the burden of examination and burden of proof to make a *prima facie* case of unpatentability on the USPTO." *Tafas/GSK II* at 817 (citing *Warner*, 379 F.2d at 1016). Only ***after*** the PTO makes a case for unpatentability

[17] The PTO contends that *Frazier* and *Bruno Independent Living Aids* do not apply here because they considered only what an applicant must submit to avoid inequitable conduct. PTO Br. 58. But the proposition for which the district court cited both cases, that the Patent Act imposes no duty on an applicant to search the prior art, *Tafas/GSK II* at 816, applies with equal force whether analyzing an inventor's initial application for patent or the prosecution history on a charge of inequitable conduct.

can the burden shift to an applicant to rebut that showing. *See Oetiker*, 977 F.2d at 1445.[18]

The PTO's reliance on Rules 56 and 105 provides it no help. Rules 56 and 105 do nothing more than permit the PTO to gather already known or readily available information. *See* 37 C.F.R. § 1.56(a) (applicant must disclose to the PTO all "known" information material to patentability); *Id.* at § 1.105 (identifying categories of information known and available to applicants that the PTO may request); *Star Fruits*, 393 F.3d at 1283 ("Under [§ 1.105] the Office can require the applicant to submit such information when it is known or readily available."). Nothing in either rule authorizes the PTO to impose burdensome prior art searches or to shift the examination burden to applicants in the first instance.[19]

Only Congress can change the law so that the PTO may require that patent applicants conduct prior art searches and patentability examinations. Notably, Congress has considered granting the PTO authority to require prior art searches and patentability examinations, but has not done so to date. *See* S. 1145, 110th

---

[18] The PTO's citation to *Brand X* is inapplicable. *See supra* note 16.

[19] The same logic renders the PTO's analogy between Rule 265 and Fed. R. Civ. P. 26(a) unavailing. PTO Br. 56. Like PTO Rules 56 and 105, Rule 26(a) merely requires a litigant to disclose readily available information. Nothing in Rule 26(a) requires a litigant to affirmatively conduct a world-wide search for additional information outside its possession or control.

Cong. § 123 (1st Sess. 2007); *Tafas/GSK II* at 812 ("The Court may rely on congressional inaction when it signals Congress's satisfaction with the status quo.") (*citing Zuni Pub. Sch. Dist. No. 89*, 127 S. Ct. at 1540-41).

IV. Rule 265 Is Impermissibly Vague And Fails To Provide Sufficient Notice As To How To Comply.

The Court should also independently affirm Final Rule 265's invalidity because it fails to provide fair notice of its requirements. *See Tafas/GSK I* at 667-68. It is axiomatic that "[t]raditional concepts of due process incorporated into administrative law preclude an agency from penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule." *Satellite Broad. Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987). Thus, a regulation that "'requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application,'" fails to provide fair notice and may not be enforced. *United States v. Lanier*, 520 U.S. 259, 266 (1997) (quoting *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926)); *see also Satellite Broad. Co.*, 824 F.2d at 2-4 (prohibiting enforcement of a vague regulation relating to application requirements); *Radio Athens, Inc. v.*

FCC, 401 F.2d 398, 404 (D.C. Cir. 1968) (overturning denial of application because rule failed to provide adequate notice of requirements).[20]

Under Rule 75, if a patent application exceeds the 5/25 claim limit, the applicant must file an ESD in compliance with Final Rule 265. JA172. Neither the Rule, nor the PTO's responses to comments in the Final Rules, provides any boundaries on the scope of the ESD's search requirements and, as a result, GSK cannot comply with this regulation. JA1578-79 ¶ 49; JA1561-63 ¶¶ 45-48. Rule 265 does not indicate whether the applicant must conduct electronic searches, manual searches, or both; in which countries the applicant must search; or in which libraries or databases the applicant must search. Read literally, the ESD demands that applicants search patents, published patent applications, and patent literature throughout the entire world, without regard to scope or cost. Even the PTO's own Patent Public Advisory Committee ("PPAC") recognized that "[t]here is no rule of reason applied to foreign patent searching and non-patent literature searching." JA1973. As is the situation here, where "different divisions of the enforcing

[20] GSK's vagueness challenge does not require that patent applications be protectable property because this is a pre-enforcement challenge demonstrating that the Final Rules would frustrate GSK's ability to obtain patents. In any event, the Supreme Court's decision in *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984), subsequent case law, and provisions of the Patent Act identifying property rights in applications, strongly indicate that patent applications are constitutionally protected property. JA1493-97.

agency disagree about their meaning," it is "unlikely that regulations provide adequate notice."[21] *Gen. Elec. Co., v. EPA*, 53 F.3d 1324, 1332 (D.C. Cir. 1995).

Even the PTO cannot identify what steps would be sufficient to meet the preexamination search requirements. Its own previously filed declaration failed to identify a search that would be sufficient. JA1100-01 ("a text search of appropriate databases ***may be*** all that is required."); JA1101 ("If the supplied search adequately covers the relevant field of the invention, then it ***more than likely*** will be acceptable."); JA1102-03 ("the ESD Guidelines teach that a text search of appropriate databases ***may be*** all that is required") (emphases added). The PTO has never articulated what would constitute a proper search, even though it has had ample opportunity to do so during its rulemaking and this litigation.

The PTO essentially concedes that the search requirements are vague by claiming that the PTO's Manual of Patent Examination Procedure (MPEP) and hundreds of pages of guidance documents fill the Final Rules' many gaps. *See, e.g.*, JA1096-97 ¶¶ 11, 13-14. But neither the MPEP nor the post-hoc guidance documents provide instructions, which, if followed, guarantee compliance. JA1579 ¶¶ 50-51. In response to comments on the boundless nature of the

[21] The lack of fair warning is especially egregious because every search is susceptible to some form of criticism, which in turn places applicants at substantial risk of inequitable conduct charges or PTO disciplinary proceedings.

preexamination search, the PTO merely indicated that "[i]f applicant follows the search guidelines set forth in the MPEP, then the preexamination search ***should*** be sufficient." JA136 (emphasis added). "Should be sufficient," however, is not fair warning. And even assuming that the MPEP or guidance documents clarified the search requirements, the PTO may not rely on them to cure vagueness because the PTO never subjected them to notice and comment. *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (setting aside guidance documents not subjected to notice and comment); *Radio Athens*, 401 F.2d at 404 (same).

V. The Final Rules Are Impermissibly Retroactive.

The Supreme Court has made clear that "[r]etroactivity is not favored in the law" and that "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Congress has not granted the PTO any retroactive rulemaking authority. To determine if a rule is impermissibly retroactive, this Court examines: (i) the "nature and extent of the change of the law"; (ii) "the degree of connection between the operation of the new rule and a relevant past event"; and (iii) "familiar considerations of fair notice, reasonable reliance, and settled expectations." *Princess Cruises, Inc. v. United States*, 397 F.3d 1358, 1364 (Fed. Cir. 2005) (internal quotations omitted) (quoting *Landgraf*,

511 U.S. at 270). The Final Rules fail this test. *See Tafas/GSK II* at 809-10 (finding that the Final Rules apply retroactively).

A. The Final Rules Drastically Change The Law.

By seeking to apply the Final Rules' restrictions to the backlog of more than 700,000 pending applications, the PTO would change the law by imposing "new duties" on completed transactions, and "impair rights a party possessed when he acted." *See Landgraf*, 511 U.S. at 280.

First, the Rules impermissibly impose "new duties" that do not exist under the current system. When GSK and other applicants filed their currently pending applications, they had the right to file as many continuing applications, RCEs, and claims as they deemed necessary. *Tafas/GSK II* at 815-16. The Final Rules, however, impose new mechanical limits that have "no basis in either the statute or regulations [and] change[] the law in a significant way."[22] *See Princess Cruises*, 397 F.3d at 1365. As the C.C.P.A. stated in *Henriksen*, when the PTO rejected a continuation application, the PTO action was akin to "a retroactive rule change which may have the effect of divesting applicants of valuable rights . . . ." 399 F.2d at 261-62.

[22] The limits on retroactivity apply with equal force to both substantive and procedural rules. *See Martin v. Hadix*, 527 U.S. 343, 359 (1999).

Second, the Final Rules "impair rights" applicants held prior to filing their applications. *See Landgraf*, 511 U.S. at 280. When an inventor conceives an invention, it has a choice to make in contemplating protection for that invention. It may protect the invention as a trade secret, *see Ruckelshaus*, 467 U.S. at 1002 (recognizing that a trade secret is a protectable property right), or seek patent protection by filing a patent application. For more than a hundred years, inventors have made this choice based on the settled expectation of an unambiguous *quid pro quo*—in exchange for relinquishing a trade secret, the inventor receives the right to seek patent protection for the full scope of its invention. *See Henriksen*, 399 F.2d at 261-62 (continuations are "valuable rights"); *Clark*, 97 F.2d at 631 (the ability to file any number of claims is "within the rights granted . . . by the patent laws"). The Final Rules alter that bargained-for exchange by stripping applicants of the right to fully protect their inventions, and by preventing applicants from reclaiming their disclosed trade secrets, which are lost forever.[23]

[23] GSK's argument does not turn on whether it has property rights in pending applications as the presumption against retroactivity is not limited to cases involving vested rights. *See Landgraf*, 511 U.S. at 275 n. 29.

B. The Final Rules Apply To Past Events And Upset Expectations Of Fairness.

There is no disputing the strong connection between the Final Rules and past events. After all, the PTO crafted the Final Rules to reduce its backlog of pending applications. In addition, traditional notions of fairness—reasonable reliance, settled expectations, and fair notice—show that the Final Rules are impermissibly retroactive. *See Princess Cruises*, 397 F.3d at 1365-66 (the imposition of an "evidentiary presumption that cannot possibly be met strongly implicates fairness considerations"). Because the Final Rules undermine completed transactions, impose new duties as to those transactions, and impair preexisting rights to fully protect inventions, the Final Rules unfairly renege on bargains made and imperil pending applications. In fact, the PTO's own PPAC agreed: "It would be manifestly unfair to applicants who have drafted their applications in reliance on present practice only to have the practice changed, to their detriment." JA1982.

VI. Section 2(b)(2)(B) Requires The PTO To Engage In Notice And Comment Rulemaking When Promulgating Procedural Rules.

The PTO's argument that Section 2(b)(2)(B) incorporates the exceptions to the notice and comment requirements of APA Section 553(b) (for procedural and interpretive rules), PTO Br. 39, misreads both Sections 2(b)(2)(B) and 553. Section 553 expressly provides that the notice and comment exception for procedural and interpretive rules does not apply if a statute requires notice or

hearing. *See* 5 U.S.C. § 553(b). Here, Section 2(b)(2)(B) requires that any rule issued by the PTO "shall be made in accordance with section 553 of title 5," not "may." Further, Congress joined each of the provisions of Section 2(b)(2) with "and," not "or." As the district court correctly concluded, "[t]his use of the conjunctive means that under Section 2(b)(2) the USPTO may establish regulations, not inconsistent with law, that govern the proceedings in the Office, ***and*** those rules must be made in accordance with 5 U.S.C. § 553." *Tafas/GSK II* at 812 (emphasis added).

The case law interpreting the PTO's rulemaking authority and the chronology of relevant congressional pronouncements make clear Congress' rationale for creating this requirement. As explained above, Congress ratified *Merck*'s holding by enacting Section 2(b)(2)(A) to be identical to former Section 6(a). Thus, Congress confirmed that the PTO can only make "procedural" rules. Against this backdrop of limited procedural rulemaking authority, Congress then added Section 2(b)(2)(B), which invokes by reference the notice and comment requirements of Section 553. *See* AIPA, § 4172, 113 Stat. at 1501A-573. Thus, the only tenable reading of Section 2(b)(2)(B) is that Congress added it to require the PTO to engage in notice and comment for its procedural rulemaking. That reading makes sense because procedural rules may impose undue costs or burdens and, as such, should be subject to public comment.

Reading Section 2(b)(2) as the PTO urges would render Section 2(b)(2)(B)'s reference to Section 553 superfluous. The status quo before the American Inventors Protection Act of 1999 did not require that the PTO's procedural rules be issued under notice-and-comment procedures. *Contra United States v. Menasche*, 348 U.S. 528, 538-539 (1955) (Courts must "give effect, if possible, to every clause and word of a statute.") (internal quotations omitted).

The PTO's citations of authority to support its interpretation are likewise misguided. *ALDF*, for example, involved former Section 6(a), which did not include the mandatory language of Section 2(b)(2)(B).[24] The PTO's argument that other courts have interpreted language similar to Section 2(b)(2)(B) to include the exceptions found in Section 553(b) is incorrect. *See Int'l Bhd. of Teamsters v. Pena*, 17 F.3d 1478, 1486 (D.C. Cir. 1994) (dealing with exceptions in Section 553(a), not 553(b)); *see also Edelman v. Lynchburg College*, 535 U.S. 106, 114 n.7 (2002) (involving general reference to issuing rules in conformity with the APA, and not requiring that procedural rules be made in accordance with Section 553).

[24] Without the benefit or opportunity to consider GSK's opposing viewpoint, this Court's decision in *Cooper Technologies* appears to have applied the PTO's flawed argument that the PTO is not required to issue procedural rules through notice and comment, citing *ALDF*. 536 F.3d at 1336-37. Notice and comment was not at issue in *Cooper Technologies* because the procedural regulations at issue had been subjected to notice and comment. In fact, the parties never briefed the issue.

The PTO also contends that requiring notice and comment for procedural rulemakings contradicts 35 U.S.C. § 3(a)(2)(B), because that would require the PTO to issue all rules pursuant to notice and comment. PTO Br. 40. But the PTO need not issue all rules by notice and comment. Under APA Section 553(a), there are limited exceptions where notice and comment obligations do not apply.[25] Consequently, there is no conflict.

The PTO's argument that Congress would have used "more specific language" if it intended to require notice-and-comment procedures for procedural rules is unavailing. PTO Br. 39-40. Congress did use specific language in Section 2(b)(2)(B).

Lastly, the PTO's "absurd results" argument—that it would be required to engage in a Regulatory Flexibility Act analysis for any ministerial rulemaking, including a change of address and telephone number—is meritless. *See* PTO Br. 40. Even assuming that such a ministerial change falls under Section 553(b) rather than Section 553(a),[26] the PTO fails to explain why it would conduct such an

[25] Section 553(a) specifically exempts from an agency's notice and comment obligations matters "relating to agency management or personnel or to public property, loans, grants, benefits, or contracts." 5 U.S.C. § 553(a)(2).

[26] A Regulatory Flexibility Act analysis is only required for rules published under Section 553(b). *See* 5 U.S.C. § 601(2).

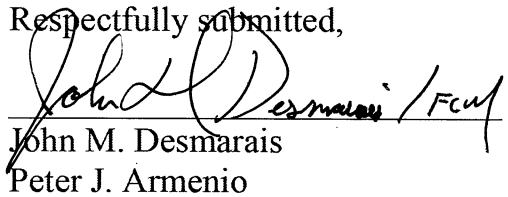
analysis when it is allowed to certify that such an analysis is unnecessary. *See* 5 U.S.C. § 605(b); *see also* 72 Fed. Reg. 9196, 9205 (Feb. 28, 2007) (PTO avoided analysis by certifying under Section 605(b)).

CONCLUSION

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

Dated: September 24, 2008

Respectfully submitted,



John M. Desmarais
Peter J. Armenio
KIRKLAND & ELLIS LLP
Citigroup Center
153 East 53rd Street
New York, NY 10022
(212) 446-4800

F. Christopher Mizzo
Jeffrey Bossert Clark
D. Sean Trainor
Scott Abeles
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005
(202) 879-5000

Of Counsel:
Sherry M. Knowles
Senior Vice President
Chief Intellectual Property Counsel
GLAXOSMITHKLINE
709 Swedeland Road
King of Prussia, PA 19406
(610) 270-4800

Attorneys for Plaintiffs-Appellees SmithKline Beecham Corporation d/b/a GlaxoSmithKline, SmithKline Beecham plc, and Glaxo Group Limited d/b/a GlaxoSmithKline

CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2008, I caused two copies of the BRIEF OF PLAINTIFFS-APPELLEES GLAXOSMITHKLINE to be served on the following counsel of record via Federal Express overnight delivery:

Scott R. McIntosh
Joshua Waldman
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Room 7232
Washington, D.C. 20530
Counsel for All Defendants

Steven J. Moore
James Nealon
Kelley, Drye &Warren LLP
400 Atlantic Street
Stamford, CT 06901-3229
Counsel for Triantafyllos Tafas

David W. Ogden
Randolph D. Moss
Brian M. Boynton
Wilmer Cutler Pickering Hale & Dorr LLP
1875 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
(202) 663-6000
Counsel for Amicus:
Pharmaceutical Research and Manufacturers of America

Randall Karl Miller
Arnold & Porter LLP
1600 Tysons Blvd.
Suite 900
McLean, VA 22102
(703) 720-7000
Email: randall_miller@aporter.com
Counsel for Amicus:
Biotechnology Industry Organization

Thomas J. O'Brien
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 739-5186
Fax: (202) 739-3001
Email: to'brien@morganlewis.com
Counsel for Amicus:
American Intellectual Property Law Association

Blair Elizabeth Taylor
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-7566
(202) 662-5669
Fax: (202) 778-5669
Email: btaylor@cov.com
Counsel for Intellectual Property Owners Association

Scott Jeffrey Pivnick
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Blvd.
Suite 1400
McLean, VA 22102
(703) 770-7864
Email: scott.pivnick@pillsburylaw.com
Counsel for Amicus:
Elan Pharmaceuticals, Inc.

Charles Gorenstein
Birch Stewart Kolasch & Birch LLP
8110 Gatehouse Road
P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000
Email: cg@bskb.com
Counsel for Amicus:
William Mitchell College of Law
Intellectual Property Institute of William Mitchell College of Law

Kevin Michael Henry
Sidley Austin Brown & Wood LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
Email: khenry@sidley.com
Counsel for Amicus:
Washington Legal Foundation

Matthew Christian Schruers
Computer & Communications Industry Association
900 17th Street, N.W.
Suite 1100
Washington, D.C. 20006
(202) 783-0070
Fax: (202) 783-0534
Email: MSchruers@ccianet.org
Counsel for Amicus:
Public Patent Foundation
Computer and Communications Industry Association
AARP
Consumer Federation of America
Essential Action
Foundation for Taxpayer and Consumer Rights
Initiative for Medicines, Access and Knowledge
Knowledge Ecology International
Prescription Access Litigation
Public Knowledge
Research on Innovation
Software Freedom Law Center

Jennifer Sue Martinez
Stanford Law School
559 Nathan Abbott Way
Stanford, CA 94305
(650) 725-2749
Counsel for Amicus:
Intellectual Property and Administrative Law and Public Health Professors

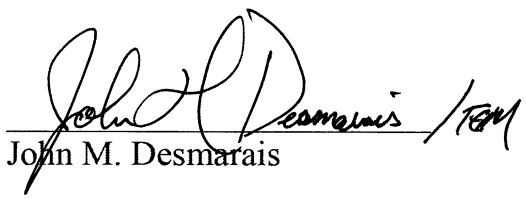
Robert Christian Bertin
Swidler Berlin LLP
3000 K Street, N.W.
Suite 300
Washington, D.C. 20007-5116
(202) 373-6672
Email: r.bertin@bingham.com
Counsel for Amicus:
Bar Association of the District of Columbia

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 13,912 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Dated: September 24, 2008



John M. Desmarais

DECLARATION OF AUTHORITY TO SIGN FOR ATTORNEY OF RECORD

Pursuant to Federal Circuit Rule 47.3(d), and under penalty of perjury pursuant to 28 U.S.C. § 1746, I, F. Christopher Mizzo, an attorney at Kirkland & Ellis LLP, do hereby certify that I have authority to sign the attached **Brief of Plaintiffs-Appellees GlaxoSmithKline, Certificate of Interest and Statement of Compliance** in Appeal No. 2008-1352, on behalf of John M. Desmarais, an attorney of record for Plaintiffs-Appellees, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, SmithKline Beecham plc, and Glaxo Group Limited d/b/a GlaxoSmithKline.

September 24, 2008

F. Christopher Mizzo