No. 2008-1352

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

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

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

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

REPLY BRIEF FOR THE APPELLANTS

JAMES A. TOUPIN
General Counsel

SYDNEY O. JOHNSON, JR.
Acting Solicitor

JANET A. GONGOLA
WILLIAM G. JENKS
NATHAN K. KELLEY
WILLIAM LaMARCA
JENNIFER M. McDOWELL
STEPHEN WALSH
Attorneys for the Director of
the U.S. Patent & Trademark Office
P.O. Box 15667
Arlington, VA 22215
(571) 272-9035

CARL J. NICHOLS
Acting Assistant Attorney General

CHUCK ROSENBERG
United States Attorney

SCOTT R. McINTOSH
(202) 514-4052
JOSHUA WALDMAN
(202) 514-0236
Attorneys, Appellate Staff
Department of Justice
950 Pennsylvania Avenue N.W.
Civil Division, Room 7232
Washington, D.C. 20530-0001

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A. Chevron Deference Applies to USPTO's Interpretations of the Applicable Statutory Provisions

The pending challenges to the Final Rules turn in large measure on the meaning of various provisions of the Patent Act. It is the settled law in this Circuit that USPTO's interpretation of the Patent Act, made in the exercise of its rulemaking authority under Section 2(b)(2), is entitled to Chevron deference. USPTO Br. 20 (collecting cases). This Court – citing the Office's opening brief in this very case – recently reaffirmed that point in Cooper Tech. v. Dudas, 536 F.3d 1330, 1337 (Fed. Cir. 2008), holding that "[b]ecause the Patent Office is specifically charged with administering statutory provisions relating to 'the conduct of proceedings in the Office,' 35 U.S.C. § 2([b])(2)(A), we give Chevron deference to its interpretations of those provisions." As Cooper Tech. reflects, the deference to be accorded to the USPTO in its delegated authority to administer its responsibilities does not differ from that accorded to agencies generally. Dickinson v. Zurko, 527 U.S. 150, 152, 165 (1999). The district court therefore committed a fundamental error by failing to engage in any analysis under Chevron and National Cable & Telecommunications Ass'n v. Brand X Internet Servs., 545 U.S. 967 (2005).

Plaintiffs take issue only with our position that USPTO is entitled to Chevron deference for its interpretation of Section 2(b), which sets forth the scope of its rulemaking authority.[1] But that position follows from this Court's own decisions. Bender v. Dudas held that "[t]o the extent" that Section 2(b)(2)(D) "is ambiguous, we defer to the PTO's reasonable interpretation" of its terms, 490 F.3d 1361, 1368 (Fed. Cir. 2007), cert. denied, 128 S. Ct. 2080 (2008); and in Lacavera v. Dudas, where a plaintiff argued that USPTO rules exceeded its authority under Section 2(b)(2), this Court held it would "analyze a challenge to the statutory authority * * * under the Chevron framework," 441 F.3d 1380, 1383 (Fed. Cir.), cert. denied, 127 S. Ct. 1246 (2007). More generally, "it is settled law that the rule of deference applies even to an agency's interpretation of its own statutory authority or jurisdiction." Mississippi Power & Light Co. v. Mississippi ex rel. Moore, 487 U.S. 354, 381 (1998) (Scalia, J., concurring) (collecting cases). See USPTO Br. 21-22. Other circuits have

[1] Tafas' argument that Chevron is inapplicable to cases decided under the Administrative Procedure Act, Tafas Br. 16-17, is meritless. See, e.g., National Cable & Telecommunications Ass'n v. Brand X Internet Servs., 545 U.S. 967 (2005) (applying Chevron in an APA case). Tafas' contention (Tafas Br. 21-22) that there is no Chevron deference for USPTO rules contrary to the Patent Act confuses losing at Chevron step two with the inapplicability of Chevron altogether. Finally, Tafas' argument (Tafas Br. 42-43, 48-49) that Chevron is inapplicable without notice and comment rulemaking is both irrelevant (the Final Rules were subject to notice and comment) and meritless (the argument was rejected in Barnhart v. Walton, 535 U.S. 212, 221-22 (2002)).

likewise endorsed that view. See, e.g., Maine Public Utilities Comm'n v. FERC, 520 F.3d 464, 479 (D.C. Cir. 2008);[2] EEOC v. Seafarers International Union, 394 F.3d 197, 201-202 (4th Cir. 2005).

Plaintiffs cite a variety of cases in an effort to show that USPTO's interpretation of Section 2(b)(2) is not subject to Chevron, but all of their cases are inapt. Cases such as Adams Fruit involve an agency's attempt to interpret the scope of judicial power;[3] in others, Congress had delegated no rulemaking authority at all;[4] and others are ones in which an agency lost on Chevron step one (because Congress had spoken to the precise question at issue) or step two (because the agency's

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[2] New York Shipping Ass'n v. FMC, 854 F.2d 1338 (D.C. Cir. 1988), cert. denied, 488 U.S. 1041 (1989) (cited by GSK Br. 18) accorded no deference where an agency was not interpreting "the meaning of a statute that Congress has charged it to administer." Id. at 1363. Here, Congress has charged the USPTO with administering the Patent Act.

[3] Adams Fruit Co. v. Barrett, 494 U.S. 638, 650 (1990) ("[I]t would be inappropriate to consult executive interpretations * * * to resolve ambiguities surrounding the scope of [a] judicially enforceable remedy" because there was no delegation to the agency "to regulate the scope of the judicial power vested by the statute") (cited GSK Br. 10, 14-15); Fabil Mfg. Co. v. United States, 237 F.3d 1335, 1341 (Fed. Cir. 2001) (no Chevron deference for rule about the "burden of proof in judicial proceedings") (cited GSK Br. 15-16).

[4] NLRB v. United Food & Commercial Workers, Local 23, 484 U.S. 112 (1987) (GSK Br. 14-15; Tafas Br. 43); Bolton v. MSPB, 154 F.3d 1313 (Fed. Cir. 1998), cert. denied 526 U.S. 1088 (1999) (GSK Br. 16, 18).

interpretation was plainly contrary to the governing statute).[5] Those cases have no bearing here. USPTO's Rules do not regulate judicial power; Congress has delegated rulemaking authority to the Office in Sections 2(b) and 132; those provisions do not speak precisely to the question in this case; and as discussed further below, USPTO's interpretations of them are reasonable.

GSK's reliance (Br. 17) on Gonzales v. Oregon, 546 U.S. 243 (2006), is also misplaced. The Court there declined to give Chevron deference because the Attorney General's interpretation would have given him the "extraordinary authority" of "unrestrained" power to "criminalize" certain acts merely because he "deems [them] illegitimate," id. at 262; because the interpretation would allow the Attorney General to "authoritatively interpret 'State' and 'local laws,' * * * despite the obvious constitutional problems in his doing so," id. at 264; and because the Attorney General was asking for authority to make medical judgments well outside his area of expertise, id. at 266-67. None of those considerations apply here.

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[5] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 160-61 (2000) (no Chevron deference because "Congress has directly spoken to the question at issue and precluded the FDA from regulating tobacco products"); Fabil Mfg. Co., 237 F.3d at 1341 (agency interpretation was "contrary to * * * the governing statute"); Borlem S.A.-Empreedimentos Idustriais v. United States, 913 F.2d 933, 937 (Fed. Cir. 1990) (cited GSK Br. 10, 16, 18, 19) (although "the trial court gave appropriate deference to the Commission," the agency's interpretation was "an impermissible construction of the statute").

Finally, even if plaintiffs were correct that USPTO is not entitled to Chevron deference for its interpretation of Section 2(b), Chevron deference applies to USPTO's interpretation of the other provisions in the Patent Act at issue in this case.

B. The Final Rules Are Within USPTO's Rulemaking Authority

The language of Section 2(b)(2)(A) does not distinguish between "substance" and "procedure," and the Final Rules fit squarely within the terms of the provision. Even if a non-textual distinction between substantive and procedural rules were grafted onto the statutory language, the Rules are procedural and thus valid.

1. By its terms, Section 2(b)(2)(A) gives USPTO express authority to promulgate regulations "govern[ing] the conduct of proceedings in the Office." All of the rules at issue here come squarely within the terms of this grant of rulemaking authority. Rules 78 and 114 establish the number of continuation applications and RCEs an applicant can file before any showing is required. Those Rules regulate the timing and availability of procedural mechanisms. They do not regulate the substantive criteria that apply in Office proceedings, and do not address whether an invention is patentable. The same is true for Final Rules 75 and 265, which require an applicant to file an ESD if his application contains more than five independent or twenty-five total claims. Those Rules do not impose any limit on how many claims can be presented; they merely require an ESD if the applicant exceeds the prescribed

numbers. Nor do those Rules address or alter the substantive conditions of patentability.[6]

Plaintiffs make no effort to show that the Rules are outside the language of Section 2(b). Nor do they directly confront the fact that USPTO's Rules do not change the substantive criteria for patentability.

2. Plaintiffs argue that this Circuit's cases hold that USPTO may issue "procedural" rules, but cannot promulgate "substantive" ones, as those terms are understood under Section 553 of the Administrative Procedure Act ("APA"). GSK Br. 24-28; Tafas Br. 19-20, 23-24. As noted above, the text of Section 2(b) is not written in those terms. Even if, as plaintiffs argue, the USPTO may issue only rules

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[6] Neither the district court nor the plaintiffs address the Office's alternative rulemaking authority. The Rules are also within the Office's authority to issue rule to "facilitate and expedite the processing of patent applications," 35 U.S.C. § 2(b)(2)(C), because they address the crippling backlog of unexamined applications; encourage due diligence in presenting filings; and reduce the propensity for examiner errors. USPTO Br. 25-26, 28. Similarly, the Rules draw support from the Office's authority to "govern the * * * conduct of agents, attorneys, or other persons representing applicants or other parties before the Office," 35 U.S.C. § 2(b)(2)(D), because Rules 78 and 114 are directed, in part, to stemming the misuse and abuse of the prior rules allowing an unlimited number of filings. USPTO Br. 5-6, 26-27. Finally, USPTO is authorized to promulgate Rule 114 under 35 U.S.C. § 132(b), which directs the Office to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." That is precisely what Rule 114 does. USPTO Br. 27.

that would qualify as procedural rules under the APA, the Final Rules fall on the procedural side of the line.

The D.C. Circuit has considered an FCC rule with effects similar to Final Rules 78 and 114, and concluded that the FCC rule was procedural within the meaning of the APA. JEM Broadcasting v. FCC, 22 F.3d 320 (1994). The FCC's "previous regime" gave applicants "notice of errors" in applications and "a window [to] redress" them, with the corrections to be applied to the date of the original application. Id. at 327. Like the USPTO, the FCC found that it "was receiving a high percentage of carelessly prepared and speculative applications and the staff's acceptance of curative amendments was causing significant delays in processing." Id. at 327. The FCC thus adopted a new rule requiring the dismissal of a flawed application without leave to amend, id. at 322, 327, which "deprive[d] license applicants of the opportunity to correct errors or defects in their filings and submit the applications nunc pro tunc," id. at 327.

The FCC's new rule clearly changed existing law to affect individual rights and obligations, which would have made the rule substantive under the test proposed by the district court, JA 18, and by the plaintiffs, GSK Br. 26; Tafas Br. 14. But the D.C. Circuit, applying APA standards, concluded that the FCC's rule "fall[s] comfortably within the realm of the 'procedural.'" Id. at 327. The FCC's rule simply "embod[ied]

a judgment about what mechanics and process are most efficient," which made the rule procedural rather than substantive. Id. at 328. "The critical fact here," the court explained, "is that the [new] rules did not change the substantive standards by which the FCC evaluates license applications." Id. at 327. See also Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 350 (4th Cir. 2001) (HHS rule dismissing appeals for failure to timely file certain documents "does not alter the substantive standards by which it reviews provider claims," but is "a procedural rule for handling appeals"). Furthermore, GSK's argument (GSK Br. 28-29) that the Final Rules are substantive because they embody a "value judgment" about how many filings are too many, has been expressly rejected. See Public Citizen v. Dep't of State, 276 F.3d 634, 640-41 (D.C. Cir. 2002)(even purely procedural rules contain "value judgments" about "what mechanics and processes are most efficient," but that kind of rule is procedural rather than substantive, otherwise it "would threaten to swallow the procedural exception to notice and comment, for agency housekeeping rules often embody such judgments" and "a judgment about procedural efficiency * * * cannot convert a procedural rule into a substantive one").

JEM Broadcasting disposes of plaintiffs' contention that Rules 78 and 114 are substantive rather than procedural. Indeed, this case is even easier than JEM Broadcasting. The FCC's rule gave no window for correcting errors, while Final

Rules 78 and 114 permit two continuation applications and one RCE as of right, and even more if the requisite showing is made.

The same conclusion follows with respect to Final Rules 75 and 265. In Pennsylvania v. United States, 361 F. Supp. 208 (M.D. Pa. 1973), a three-judge panel – later affirmed by the Supreme Court, 414 U.S. 1017 – concluded that a rule strikingly similar to Rules 75 and 265 was procedural under the APA. Under its old rules, the Interstate Commerce Commission ("ICC") considered an application to abandon a railroad line by weighing the burden on the railroad against the public interest, with the ultimate burden of persuasion on the railroad. 361 F. Supp. at 211. As the ICC began facing a "mounting number of abandonment applications," the agency sought to "accelerate their disposition," id. at 212, by imposing a new rule requiring the party opposing abandonment, in certain situations, to come forward with "a proffer of substantial evidence" about the harms caused by abandonment, id. at 213. The court held that the new rule was "procedural" under the APA. Id. at 220. It noted that the new rule "does not shift the burden of persuasion" – which remained with the party favoring abandonment – but simply "shift[ed] to the [opponent of abandonment] the burden of going forward with the evidence." Id. at 215. The new rule was therefore "a procedural mechanism" about a "production burden," id. at 215, under which the "burden of ultimate persuasion," id. at 215, remained with the party

seeking abandonment, id. at 216, and "[t]he duty of the Commission to weigh all evidence in the record will be maintained," id. at 216. Here too the examiner's Office action rejecting a claim will be required to set forth a prima facie case of unpatentability. She will not be able to reject an application because she finds the arguments in an ESD unpersuasive. Rather, an Examination Support Document ("ESD") will add to the information before her as she prepares an Office action.

3. The approach to distinguishing between procedural and substantive rules in these APA cases is consistent with the approach to the USPTO's rulemaking authority in In re Van Ornum, 686 F.2d 937 (C.C.P.A. 1982). See USPTO Br. 31-32. In Van Ornum, the CCPA held that a rule could be within the USPTO's rulemaking authority even if it has incidental substantive effects "relat[ing] to a condition under which a patent will be granted which otherwise would have to be denied." As the court explained, "[m]uch of the content of the PTO rules is 'substantive' in this respect," yet those rules are valid if they "clearly relate[] to application processing within the PTO." 686 F.2d at 945. As shown in our opening brief, Van Ornum forecloses the district court's narrow reading of USPTO's authority under Section 2(b)(2).

As further explained in our opening brief, USPTO Br. 36-39, that approach is also consistent with the Supreme Court's approach to the scope of judicial rulemaking

authority under the Rules Enabling Act ("REA"), 28 U.S.C. § 2072. In that context, a rule is procedural if it "really regulates procedure – the judicial process for enforcing rights and duties" even if it has "incidental effects" that "alter[] * * * substantive rights of litigants." Hanna v. Plumer, 380 U.S. 460, 464-65 (1965).

In sum, even if the USPTO's rulemaking authority were limited to "procedural" rules rather than "substantive" ones, the Final Rules are procedural because they address the processing of applications before the Office, without changing the patentability standards. The approach taken by the CCPA in Van Ornum and the Supreme Court under the REA reinforces the approach under the APA, and all three approaches confirm the conclusion that USPTO's Final Rules are procedural. The district court thus erred in rejecting the rules as ultra vires under Section 2(b)(2).

4. GSK relies (GSK Br. 19, 26) on Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) ("ALDF"), and Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), to argue that a rule is substantive if it alters a litigant's "rights and obligations." But Stevens v. Tamai, 366 F.3d 1325 (Fed. Cir.), cert. denied, 543 U.S. 944 (2004), and Cooper Tech. show that cannot be the standard. In both cases, the rules of the Office required something more than was explicitly set forth in the Patent Act. Tamai was required to produce certain documents; and Cooper Technologies was forced to participate in inter partes reexamination. The rules in each case were

upheld because "substantive" rules under ALDF do not include rules that govern the conduct of proceedings in the Office, regardless of what burden they may place on applicants. Put another way, these rules each required certain actions from applicants in securing their right to a patent but did not significantly alter that right itself, which meant that the rules conformed with ALDF and Merck.[7]

II. The Final Rules Are Consistent With the Patent Act

A. Rule 78 Is Consistent With 35 U.S.C. § 120

In our opening brief, relying in part on In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002), we explained (USPTO Br. 44-46) that the district court erred in holding that Rule 78 deprives applicants of the supposed unqualified right under 35 U.S.C. § 120 to file "an unlimited number of continuation and continuation-in-part applications as a matter of right." JA 20.[8] Tafas contends (Br. 31) that Bogese is limited to

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[7] Contrary to Tafas' contention (Tafas Br. 4, 20), Congress is plainly authorized to delegate its Article I powers to executive agencies, and Tafas cannot show that the non-delegation doctrine operates more restrictively for patent laws than for the rest of Article I. Cf. Skinner v. Mid-America Pipeline Co., 490 U.S. 212, 220-24 (1989) (rejecting argument that non-delegation doctrine operates more restrictively for Congress's taxing power than it does for the rest of Article I).

[8] See Woodbridge v. United States, 263 U.S. 50, 56 (1923); Webster Elec. Co. v. Splitdorf Elec. Co., 264 U.S. 463, 466 (1924); see also Geneva Pharm. v. GlaxoSmithKline, 349 F.3d 1373, 1382 (Fed. Cir. 2003) ("GSK took about a quarter-century to prosecute the 1985 and 2000/01 patents to issue. This record does not explain that delay.").

"extreme" cases, but Final Rule 78 is an even easier case than Bogese. First, Rule 78 is supported not just by the USPTO's "inherent authority," id. at 1368, but by its statutory rulemaking authority. Second, while the doctrine of prosecution history laches in Bogese leaves the applicant without clear guidance as to how much delay is "too much," Rule 78 tells applicants expressly when they must justify their delay and what justifications must be provided. JA 109-112 (72 Fed. Reg. 46773-76). Third, while prosecution history laches imposes the penalty of final rejection, Rule 78 does not result in the rejection of any filings: the first two continuation applications are accepted as of right, and even if a third or subsequent continuation application does not make the showing required by Rule 78, it is still accepted, albeit without the earlier priority date.

GSK argues that Rule 78 imposes a "hard limit" on the number of continuation applications, GSK Br. 33, which in GSK's view distinguishes it from Bogese, in which the Office made a "case-by-case" determination, GSK Br. 37-38. But Rule 78 "do[es] not set a per se limit on the number of continuing applications." JA 56 (72 Fed. Reg. 46720). It simply requires that an applicant make the requisite showing before exceeding two continuation applications. JA 175 (72 Fed. Reg. 56839) (Rule 78(d)(1)(vi)). And USPTO will make that determination "on a case-by-case basis." JA 107 (72 Fed. Reg. 46771). The rule will not operate "categorically" with a "hard

limit." When USPTO addressed public comments, it responded that it would take a case-by-case approach, not "*per se*" or "*pro forma*," and discussed hypothetical circumstances it views as "likely to," "less likely to," "not likely to," or "not" meriting a continuing application. 72 Fed. Reg. 46770-77 (comments 77-102). USPTO's interpretation of its own regulation – that it does not impose a hard limit – "is entitled to substantial deference and will be accepted unless it is plainly erroneous." Star Fruits v. United States, 393 F.3d 1277, 1282 (Fed. Cir. 2005); see also Haas v. Peake, 525 F.3d 1168, 1186 (Fed. Cir. 2008) ("[A]n agency's interpretation of its own regulations is controlling unless plainly erroneous or inconsistent with the regulations being interpreted.") (quoting Long Island Care at Home, Ltd. v. Coke, 127 S. Ct. 2339, 2346 (2007)).[9]

If there were any remaining doubt on what Section 120 permits, USPTO's reasonable interpretation of Section 120 as allowing Rule 78, see, e.g., JA 147 (72 Fed. Reg. 46811), is entitled to Chevron deference. And even if this Court's prior cases had taken a different view, USPTO is still entitled to deference under Brand X.

[9] Contrary to plaintiffs' argument (GSK Br. 34: Tafas Br. 9), Rule 78 is not a hard limit simply because it does not grant a "right" to "deliberately prolonging prosecution in order to be able to" claim a competitor's product. JA 98 (72 Fed. Reg. at 46762); see also JA 97 (72 Fed. Reg. 46761 (Federal Circuit cases do not "support * * * an applicant [who] files * * * a stream of continuation applications just to wait for any competitor to develop and market an invention not claimed in the initial application").

Contrary to plaintiffs' suggestion (GSK Br. at 36-37, Tafas Br. 27-28), neither Transco Prods. v. Performance Contracting, 38 F.3d 551 (Fed. Cir. 1994), cert. denied, 513 U.S. 1151 (1995), nor In re Hogan, 559 F.2d 595 (C.C.P.A. 1977), unambiguously forecloses USPTO's interpretation of Section 120. Those cases' references to the "unambiguous" language did not hold that Section 120 precludes USPTO from imposing any reasonable requirements on the filing of a continuation application. Moreover, Hogan did not address the permissible number of continuation applications, but involved the Board's failure to consider Section 120 altogether. Id. at 603. Nor did Hogan hold that an applicant is guaranteed the earlier priority date under Section 120 regardless of whether he complies with reasonable requirements established by USPTO.

Finally, plaintiffs (GSK Br. 32-33, 35-36, 39; Tafas Br. 29) erroneously rely on In re Henriksen, 399 F.2d 253 (C.C.P.A. 1968). Bogese explained that the "limited holding" in Henriksen is that "the statute itself" does not provide any fixed limit on the number of continuation applications. 303 F.3d at 1368 n.6. But that does not negate the USPTO's "inherent authority" to set "reasonable deadlines and requirements for the prosecution of applications," Bogese, 303 F.3d at 1368, particularly where (as here) the Office's limit is not a "mechanical rule," id. at 1368 n.6, and is issued through notice and comment rulemaking.

B. Rule 114 Is Consistent With 35 U.S.C. § 132

Rule 114 requires an applicant who files more than one RCE to show that the amendment, argument, or evidence sought to be submitted could not have been presented earlier. The district court held that Rule 114 deprives applicants of rights conferred by 35 U.S.C. § 132(b). Section 132(b), however, simply requires USPTO to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." It does not specify the conditions and requirements for RCEs, leaving that task to the USPTO through its exercise of rulemaking authority.

Plaintiffs point to the word "shall" in Section 132(b), see GSK Br. 39-40; Tafas Br. 32, but that merely requires USPTO to issue RCE regulations; it does not specify what reasonable conditions those regulations may impose. Plaintiffs also point to the phrase "at the request of the applicant," but that language only describes how a continuing examination is initiated; it does not say that the USPTO is precluded from imposing reasonable conditions on an RCE, or that the Office must entertain an RCE each and every time an applicant does no more than request it. Nor does plaintiffs' suggestion (GSK Br. 40) to read the statute "as a whole" alter the analysis. Reading the word "shall" together with "at the request of the applicant" does not produce any result different from reading those words independently. Here too, because the

statutory text does not specifically and unambiguously resolve the issue, USPTO's reasonable interpretation is entitled to Chevron deference. Plaintiffs allege (GSK Br. 40; Tafas Br. 33) that USPTO changed its prior interpretation of Section 132(b). But the Office's prior rulemaking simply described its then-existing practice of unlimited RCEs; the Office did not state that Section 132 required that practice. 65 Fed. Reg. 50092, 50096 (Aug. 16, 2000). And in any event, even if USPTO had changed its view, an agency's change of position does not render Chevron inapplicable. Chevron, 467 U.S. at 863; Smiley v. Citibank, 517 U.S. 735, 742 (1996) (opining that a change in agency position "is not invalidating since the whole point of Chevron is to leave the discretion provided by the ambiguities of a statute with the implementing agency"); Haas, 525 F.3d at 1190.

Contrary to plaintiffs' argument (GSK Br. 39), Rule 114 does not impose a "mechanical limit" of one RCE. Rule 114 permits an applicant to file additional RCEs so long as it provides the required explanation. Moreover, even if plaintiffs were correct, they point to nothing in Section 132(b) precluding a "mechanical limit" on the number of RCEs.

Finally, plaintiffs argue that Rule 114 is contrary to Section 132 because it limits an applicant to one RCE per application family, rather than providing a separate RCE for each application in the family. GSK Br. 41-42. Plaintiffs rely on

Section 132's use of the word "application" rather than "application family." But as explained in our opening brief, USPTO Br. 52-53, the word "application" simply identifies the subject matter of Section 132; it does not support or compel a reading in which any limitations on RCEs cannot apply to application families. And in any event, Rule 114 leaves applicants free to seek a second or subsequent RCE with respect to every application in a family provided that the requisite showing is made.

C. Rules 75 and 265 Are Consistent With the Patent Act

Under Rule 75, an application containing more than five independent claims or twenty-five total claims must be accompanied by an ESD. Rule 265 sets forth the requirements for an ESD. Nothing in either rule is contrary to the Patent Act.

Plaintiffs argue that 35 U.S.C. § 112 ¶ 2, which requires applications to include "one or more claims," means that "there is no statutory ceiling to the number of claims an applicant may seek," a principle that Rule 75 supposedly violates by imposing a "mechanical limit" on the number of claims an applicant may present, GSK Br. 42-43. The argument is doubly wrong.

First, Rule 75 does not impose a "mechanical limit," or a limit of any kind. Rather, an applicant "is always free to file as many claims as necessary." JA 150 (72 Fed. Reg. 46814). Rule 75 merely requires an ESD if the number of claims exceeds the numbers set forth in the rule. Second, even if Rule 75 were a "mechanical limit,"

nothing in Section 112 ¶ 2 precludes that. The statute's reference to "one or more claims" sets a floor on the number of claims, but does not give a statutory right to an unlimited number of claims. Indeed, that argument is foreclosed by In re Rubinfield, 270 F.2d 391, 395 (C.C.P.A. 1959), cert. denied, 362 U.S. 903 (1960), which sustained a USPTO rule providing that "[m]ore than one claim is not permitted" in a design application because the court was "unable to find any clear conflict" between that rule and Section 112. If there were any remaining doubt, USPTO's reasonable construction of Section 112 to permit Rule 75 would be entitled to Chevron deference.

Plaintiffs argue that Rubinfield involved design patents, not utility patents, GSK Br. 44-45; Tafas Br. 36, but that is a distinction without a difference. Rubinfield sustained USPTO's rule because it was consistent with Section 112, not because design patents are exempt from Section 112. 35 U.S.C. § 171 makes it clear that "[t]he provisions of this title relating to patents for inventions shall apply to patents for designs, except as otherwise provided," and nothing "otherwise provides" that Section 112 ¶ 2 is inapplicable to design patents, or means something different when applied to them. See In re Daniels, 144 F.3d 1452, 1456 (Fed. Cir. 1998) ("Although linguists distinguish between a drawing and a writing, the drawings of the design patent are viewed in terms of the 'written description' requirement of § 112.").

Plaintiffs' reliance on three cases involving undue multiplicity, GSK Br. 43-44; Tafas Br. 35, have no bearing here, since Rule 75 does not address undue multiplicity. Moreover, the cases hold only that the USPTO must act reasonably in imposing limits on the number of claims. See USPTO Br. 56. Rule 75 does not limit the number of claims at all, and the ESD requirement for claims exceeding the requisite number is a reasonable imposition. And even if those cases did narrowly construe Section 112 in the way plaintiffs suggest, USPTO's contrary interpretation of the statute is a reasonable one and therefore is entitled to Chevron deference under Brand X.

The statute is silent on searching, and thus the USPTO may fill the gap. Here, the Office is doing exactly that – promulgating a regulation for searching by an applicant because examiners make more errors as the number of claims increase. The requirement for information does not shift the examination burden. Instead, the Office will examine the record, including applicant ESD information and the results of the examiner's own search. 37 C.F.R. § 1.104(a)(1). After that examination, the Office will notify the applicant of the findings and conclusions, per 35 U.S.C. § 132. Kingsdown Medical Consultants v. Hollister Inc., 863 F.2d 867, 874 n.8 (Fed. Cir. 1988) ("Blind reliance on presumed candor would render examination unnecessary, and nothing in the statute or Manual of Patent Examining Procedure would justify

reliance on counsel's candor as a substitute for an examiner's duty to examine the claims.").

Plaintiffs (GSK Br. 46-49; Tafas Br. 38-39) also argue that Rules 75 and 265 conflict with 35 U.S.C. §§ 102, 103, and 131, which have collectively been understood to assign the USPTO the burden of examination and the burden of establishing a prima facie case of unpatentability. But Rules 75 and 265 do not "shift[] the burden to the applicant to make a prima facie case of entitlement to a patent," but "simply requires the applicant to" come forward with "additional information" via an ESD. JA 151 (72 Fed. Reg. 46815). See Pennsylvania 361 F. Supp. at 215 (rule requiring a party to come forward with certain evidence "does not shift the burden of persuasion" but simply "shift[ed] to the [opponent of abandonment] the burden of going forward with the evidence") (discussed supra at 9-10). See also In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (characterizing prima facie case doctrine as a "procedural tool of patent examination" when considered as an allocation of the burden of coming forward); In re Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, Cowen, JJ., concurring) (observing that prima facie case procedure is consistent with various rules requiring applicant to come forward with information, citing, e.g., Rule 56).

Indeed, 35 U.S.C. § 132 expressly provides that the Director may respond to an application by issuing a "requirement" rather than a rejection. In Star Fruits, this Court upheld USPTO's Rule 105 requiring an applicant to submit additional information that is "reasonably necessary to properly examine the matter," 393 F.3d at 1279, even though no rejection issued. It did not hold such a requirement shifts the burden of proof to the applicant or relieves USPTO of its burden to determine whether a claim is patentable. The rules at issue – requiring an ESD to assist substantive examination, because the likelihood of errors rises with the number of claims presented – is a reasonable procedural alternative to following the route of rejection or allowance. Section 132(a) contemplates that alternative procedure. Thus, plaintiffs' reliance on Oetiker is inapposite because that case concerned a rejection in the absence of any requirement. That applicants may be reluctant because of the doctrines of inequitable conduct and prosecution history estoppel to provide information absent a rejection is likewise inapposite. Such court-made doctrines cannot affect USPTO's express authority to issue requirements rather than rejections.

Finally, Plaintiffs' reliance (GSK Br. 46-47) on Frazier v. Roessel Cine Photo Tech., 417 F.3d 1230 (Fed. Cir. 2005), and Bruno Indep. Living Aids v. Acorn Mobility Servs., 394 F.3d 1348 (Fed. Cir. 2005), is misplaced. Those cases held only that the rule at issue (Rule 56) did not impose a duty to search prior art. But those

cases did not hold that USPTO is precluded from exercising its authority over proceedings by imposing additional obligations beyond those approved in Rule 56.

III. Notice and Comment Is Not Required for All USPTO Rulemaking

The district court concluded that Section 2(b)(2) requires USPTO to use notice-and-comment procedures in all rulemaking proceedings, even those that indisputably involve procedural rules. JA 12-13. That conclusion is contrary to the statutory text. Section 2(b)(2)(B) requires that the Office's rules "shall be made in accordance with section 553 of title 5." Section 553, in turn, incorporates both the notice and comment requirement, and the exception to that requirement for procedural rules. 5 U.S.C. § 553(b).

The same conclusion is dictated by circuit precedent, as explained in our opening brief. USPTO Br. 39-40. More recently, this Court has determined that Section 553 "[b]y its own terms * * * does not require formal notice of proposed rulemaking for interpretative rules" and that USPTO's interpretive rule "was therefore not subject to the formal notice-and-comment requirements of section 553." Cooper Tech., 536 F.3d at 1336-37.

IV. Plaintiffs' Alternative Arguments Are Meritless

Plaintiffs present several other arguments as alternative bases for affirmance. GSK Br. at 52-59; Tafas Br. 4, 6. GSK's retroactivity argument, however, is not an alternative basis for affirming the district court's prospective invalidation of the Rules, and its vagueness argument is directed exclusively at Final Rule 265. Nevertheless, USPTO briefly addresses plaintiffs' alternative claims.

A. Rule 265 Is Not Vague

GSK argues that Rule 265 is unconstitutionally vague, because it does not understand what a prior art search entails. GSK Br. 50. GSK's vagueness challenge fails because the vagueness doctrine is not aimed at regulations or statutes concerning government benefits or entitlements, like Final Rule 265. Instead, the doctrine is aimed only at regulations or statutes prohibiting conduct or regulating a First Amendment right such as speech. See Nyeholt v. Sec'y of Veterans Affairs, 298 F.3d 1350, 1356 (Fed. Cir. 2002), cert. denied, 537 U.S. 1109 (2003) ("[U]nder the standard set forth in Grayned [v. City of Rockford, 408 U.S. 104 (1972),] and other decisions of the Supreme Court, a void-for-vagueness challenge must be directed to a statute or regulation that purports to define the lawfulness or unlawfulness of speech or conduct."). In any event, Rule 265 is not vague.

USPTO made it clear that "[t]he standard for the preexamination search that is required [for an ESD] is the same standard that the Office uses to examine patent applications, which is set forth in [the Manual of Patent Examination procedure] * * * If applicant follows the search guidelines set forth in the MPEP, then the preexamination search should be sufficient." JA 136 (72 Fed. Reg. 46800). Such agency guidance cures any vagueness problem. Go Leasing, Inc. v. NTSB, 800 F.2d 1514, 1525 (9th Cir. 1986) ("potential vagueness may be mitigated by * * * executive interpretation of the challenged provision"). Furthermore, even if an uncertain applicant provides an insufficient ESD, the USPTO will give him notice and an opportunity for correction, JA 179 (72 Fed. Reg. 46843); 37 C.F.R. § 1.265(e), which cures any potential vagueness concern. Village of Hoffman Estates v. Flipside, Hoffman Estates, 455 U.S. 489, 498 & n.12 (1982).

B. The Rules Are Not Impermissibly Retroactive

A law does not "operate 'retrospectively' merely because it is applied in a case arising from conduct antedating the statute's enactment," nor is a law "made retroactive merely because it draws upon antecedent facts for its operation." Landgraf v. USI Film Prods., 511 U.S. 244, 269 & n.24 (1994). Thus, GSK's allegation of a "strong connection" between the Final Rules and past events, GSK Br. 55, does not demonstrate that the Rules are retroactive.

As explained above, the Final Rules are procedural. And as the Supreme Court emphasized, "[c]hanges in procedural rules may often be applied in suits arising before their enactment without raising concerns about retroactivity," because there are "diminished reliance interests in matters of procedure," given that "rules of procedure regulate secondary rather than primary conduct." Id. at 275. To be sure, not all procedural rules may be applied retroactively. Id. at 275 n.29. But the Final Rules are precisely the kind of procedural regulations that do not implicate retroactivity concerns, because they do not change the criteria used by an examiner to evaluate whether an application meets the statutory requirements for patentability, but address only how an applicant must present his application to the Office and what information he must provide. See Combs v. Commissioner of Social Security, 459 F.3d 640, 647 (6th Cir. 2006) (new Social Security Administration rule requiring an applicant to provide more information demonstrating disability was a procedural rule that did not raise retroactivity concerns, because it did not change "[t]he ultimate criteria of disability," or "a change in substantive obligations as opposed to a change in the way in which the same obligation is adjudicated," even though the new rule "may be outcome-determinative for some claimants").[10]

[10] Landgraf noted, in dicta, that "[a] new rule concerning the filing of complaints would not govern an action in which the complaint had already been (continued...)

Furthermore, the Final Rules do not affect "vested rights," Landgraf, 511 U.S. 268-69, "contractual or property rights," id. at 271, or "transactions already completed," id. at 280. A patent application that has simply been filed is neither a vested right, a property right, or a transaction "completed." See Pine Tree Med. Assocs. v. HHS, 127 F.3d 118, 121 (1st Cir. 1997) ("[M]ere filing of an application is not the kind of completed transaction in which a party could fairly expect stability in the relevant laws of the transaction date."). And even if the initial filing of an application were a completed transaction, the Final Rules do not render the applications invalid. Rules 78 and 114 do not invalidate any previously filed continuation application or RCE, nor does an applicant need to make the requisite showing for a filing pre-dating the Final Rules. And if an applicant has already

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[10](...continued)
properly filed under the old regime." 511 U.S. at 275 n.29. That proposition makes sense where "retroactive application of new complaint rules * * * risked dismissal and a resulting time bar to plaintiff's cause of action." Covino v. Reopel, 89 F.3d 105, 108 (2d Cir. 1996); see also Brown v. Angelone, 150 F.3d 370, 373 (4th Cir. 1998) (procedural rules can have impermissible retroactive effects where they "would wholly eliminate claims for substantive rights or remedial actions considered timely under the old law"). That is not the case here. The Final Rules do not result in the invalidation of any filings made before the Rules were enacted. Nor do the Final Rules threaten the "dismissal" of any patent application made after the Rules were enacted: an applicant can exceed the requisite number of applications, RCEs, or claims simply by making the required showing; and even without that, a continuation application over the limit is not dismissed, it is just not given the benefit of the earlier priority date.

received a first office action on the merits, Rules 75 and 265 do not require the applicant to file an ESD even where the claims exceed the requisite number. JA 52, 54 (72 Fed. Reg. 46716, 46718).

Finally, contrary to GSK's assertion (Br. 54), the Final Rules do not impair an applicant's trade secret rights. "If an individual discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished." Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1002 (1984). Here, GSK has extinguished its own trade secret rights by failing to ask the USPTO to maintain an application in confidence. 35 U.S.C. § 122(b)(2)(B)(i); 37 C.F.R. § 1.213. If the applicant asks the USPTO to maintain its application in confidence, then it need never disclose trade secrets.[11]

[11] Tafas also argues (Tafas Br. 40-41) that Final Rule 78(f)(2) changes the standard of review for double patenting rejections. But under that rule, double patenting rejections remain reviewable by the Board and would receive de novo review in this Court. The rule thus neither deprives the Board or court of jurisdiction, nor alters the applicable de novo standard of review. 72 Fed. Reg. 46786, 46789.

CONCLUSION

For the foregoing reasons and those in USPTO's opening brief, the district court's judgment should be reversed.

Respectfully submitted,

JAMES A. TOUPIN
General Counsel

SYDNEY O. JOHNSON, JR.
Acting Solicitor

JANET A. GONGOLA
WILLIAM G. JENKS
NATHAN K. KELLEY
WILLIAM LaMARCA
JENNIFER M. McDOWELL
STEPHEN WALSH
Attorneys for the Director of the U.S. Patent & Trademark Office
P.O. Box 15667
Arlington, VA 22215
(571) 272-9035

CARL J. NICHOLS
Acting Assistant Attorney General

CHUCK ROSENBERG
United States Attorney

SCOTT R. McINTOSH
(202) 514-4052
JOSHUA WALDMAN
(202) 514-0236
Attorneys, Appellate Staff
Department of Justice
950 Pennsylvania Avenue N.W.
Civil Division, Room 7232
Washington, D.C. 20530-0001

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CERTIFICATE OF SERVICE

I hereby certify that on October 15, 2008, I caused to be filed an original and 12 copies of the foregoing REPLY BRIEF FOR THE APPELLANTS and 12 copies of the JOINT APPENDIX by sending them by hand delivery to the Clerk of the Court. I further certify that on October 15, 2008, I caused to be served two copies of the foregoing REPLY BRIEF FOR THE APPELLANTS and two copies of the JOINT APPENDIX by sending them via Federal Express or U.S. mail as indicated to each of the following counsel:

Christopher Mizzo
Jeffrey Bossert Clark
D. Sean Trainor
Scott Abeles
Kirkland & Ellis LLP
655 15th Street, N.W.
12th Floor
Washington, DC 20005

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

Daniel B. Ravicher
Public Patent Foundation
1375 Broadway, Suite 600
New York, NY 10018

Craig Crandall Reilly
Richard McGettigan Reilly & West PC
1725 Duke St
Suite 600
Alexandria, VA 22314

Joseph D. Wilson III
Joanna Elizabeth Baden-Mayer
Kelley Drye & Warren, LLP
3050 K Street, N.W.
Suite 400
Washington, DC 20007-5108

Dawn-Marie Bey
King & Spalding LLP
1700 Pennsylvania Avenue
Suite 200
Washington, DC 20006

Jackson David Toof
Arent Fox LLP
1050 Connecticut Ave., NW
Washington, DC 20036-5339

Maurice Francis Mullins
Spotts Fain PC
411 E Franklin St
Suite 600
PO Box 1555
Richmond, VA 23218-1555

James Murphy Dowd
Wilmer Cutler Pickering Hale & Dorr LLP
1455 Pennsylvania Ave NW
Washington, DC 20004

Randall Karl Miller
Arnold & Porter LLP
1600 Tysons Blvd
Suite 900
McLean, VA 22102

Ronald A. Schechter
Arnold & Porter LLP
555 Twelfth Street, NW
Washington, DC 20004

Scott Jeffrey Pivnick
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Blvd
Suite 1400
McLean, VA 22102

Kevin T. Kramer
Vincent J. Napoleon
Stephanie F. Goeller
Pillsbury Winthrop Shaw Pittman LLP
2300 N St NW
Washington, DC 20037-1122

Thomas J. O'Brien
Morgan, Lewis & Bockius
1111 Pennsylvania Ave, NW
Washington, DC 20004

Jerry R. Selinger
Morgan, Lewis & Bockius LLP
1717 Main Street, Suite 3200
Dallas, TX 75201

Charles Gorenstein
Birch Stewart Kolasch & Birch LLP
8110 Gatehouse Rd
PO Box 747
Falls Church, VA 22040-0747

Robert Emmett Scully, Jr.
Stites & Harbison, PLLC
1199 North Fairfax St.
Suite 900
Alexandria, VA 22314

Craig James Franco
Odin Feldman & Pittleman PC
9302 Lee Highway
Suite 1100
Fairfax, VA 22031

Matthew Christian Schruers
Computer & Communications
Industry Association
900 17th St NW
Suite 1100
Washington, DC 20006

Jonathan Dyste Link
Townsend and Townsend and Crew
LLP
1301 K St NW
9th Floor, East Tower
Washington, DC 20005

John C. Maginnis, III
1350 Connecticut Avenue, N.W.
Suite 301
Washington, DC 20036

Timothy A. Molino
Bingham McCutchen LLP
2020 K St NW
Washington, DC 20006

Mark Fox Evens
Kenneth Carrington Bass, III
Sterne, Kessler, Goldstein & Fox
1100 New York Ave NW
Suite 600
Washington, DC 20005

Robert C. Gill
Saul Ewing LLP
2600 Virginia Ave NW
Suite 1000
Washington, DC 20037

Kevin Michael Henry
Sidley Austin Brown & Wood LLP
1501 K St NW
Washington, DC 20005

Dean Alderucci
CFPH, LLC
110 East 59th Street
New York, NY 10022

Blair Elizabeth Taylor
Covington & Burling
1201 Pennsylvania Ave NW
Washington, DC 20004-7566

David Wayne Long
Howrey Simon Arnold & White LLP
1299 Pennsylvania Ave NW
Washington, DC 20004

Jennifer Sue Martinez
Stanford Law School
559 Nathan Abbott Way
Stanford, CA 94305
(650) 725-2749

Robert Christian Bertin
Swidler Berlin LLP
3000 K St NW
Suite 300
Washington, DC 20007-5116
(202) 373-6672

Colby B. Springer
Carr & Ferrell LLP
2200 Geng Road
Palo Alto, CA 94303

Charles E. Miller
Dickstein Shapiro LLP
1177 Avenue of the Americas
47th Floor
New York, NY 10036

John M. Neukom
Susan Godfrey LLP
1201 Third Avenue, Suite 3800
Seattle, WA 98101

Matthew C. Rainey
Intellectual Ventures, LLC
227 Bellevue Way, PMB 502
Bellevue, WA 98004

Buckmaster De Wolf
General Electric Co.
3135 Easton Turnpike
Fairfield, CT 06828

Heath Hoglund
Dolby Laboratories, Inc.
100 Potrero Avenue
San Francisco, CA 94103

Paul H. Berghoff
Jeffrey A. Steck
McDonnell Boehnen Hulbert &
Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606

_____

Joshua Waldman
Counsel for Appellant

CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32

Pursuant to Federal Rule of Appellate Procedure 32, I certify that the attached Reply Brief for Appellants uses a proportionally spaced 14-point typeface in compliance with Fed. R. App. P. 32(a)(5), and contains no more than 6989 words, in compliance with Fed. R. App. P. 32(a)(7)(B)(ii).

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JOSHUA WALDMAN
Counsel for Appellants