

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

TRANTAFYLLOS TAFAS)
)
 Plaintiff,)
)
 v.) 1:07cv846 (JCC)
)
 JON W. DUDAS, et al.,)
)
 Defendants.)
_____)

CONSOLIDATED WITH

_____)
)
 SMITHKLINE BEECHAM)
 CORPORATION, et al.,)
)
 Plaintiffs)
)
 v.) 1:07cv1008 (JCC)
)
 JON W. DUDAS, et al.,)
)
 Defendants.)

MEMORANDUM OPINION

At issue are the United States Patent and Trademark Office's changes to the rules governing the examination of patents. This case presents itself by virtue of cross-motions for summary judgment by Plaintiffs Smithkline Beecham Corporation d/b/a GlaxoSmithKline, et al., Plaintiff Triantafyllos Tafas, and Defendants Jon W. Dudas and the United States Patent and Trademark Office. Defendants also move to strike several

exhibits filed by Tafas and certain *amici curiae*. For the reasons stated below, the Court will grant Plaintiffs' Motions for Summary Judgment, deny Defendants' Motion for Summary Judgment, and deny as moot Defendants' Motion to Strike.¹

I. Background

Plaintiffs Smithkline Beecham Corporation d/b/a GlaxoSmithKline, et al. (collectively, "GSK") and Triantafyllos Tafas ("Tafas") bring this lawsuit pursuant to the Administrative Procedure Act (the "APA") to permanently enjoin Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively, the "USPTO") from enacting the "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46,716-843 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) (the "Final Rules").² GSK and Tafas claim that the Final Rules, which change the patent system by modifying several long-established rules governing patent examination by the USPTO, are unlawful agency action under Section 706(2) of the APA and should be declared null and void.

¹ Also pending is Tafas's Motion for Reconsideration of the Court's January 9, 2008 Memorandum Opinion and Order overruling Tafas's Objection to Magistrate Judge Jones's written Order of November 28, 2007. The Court's Opinion and Order on the underlying Motions for Summary Judgment render Tafas's Motion for Reconsideration moot, and the Court will deny it as such.

² On October 31, 2007, this Court issued a preliminary injunction enjoining the implementation of the Final Rules, which were originally set to take effect on November 1, 2007. To the Court's knowledge, the USPTO has yet to set another effective date.

The USPTO argues that the Final Rules are entirely lawful and that it should be permitted to go forward and implement these much needed changes.

Because this case involves the legality of the Final Rules, a determination of their validity does not turn on facts unique to a particular plaintiff or on any disputes regarding such facts. Thus, it is unnecessary to provide a lengthy factual background specific to the parties. The Court will, however, lay out the existing statutory framework that governs the examination of patents by the USPTO and the manner in which the Final Rules alter the current system.

Patent examination is governed by the Patent Act. See 35 U.S.C. §§ 1 *et seq.* To obtain patent protection on an invention, an applicant first files a written patent application with the USPTO. *Id.* § 111. The first application filed for a given invention is a "parent" or "initial" application. A parent application contains two primary parts: a "specification," which describes the invention and how to make and use it, and one or more "claims," which identify the scope of the legal protection that the invention should receive. *Id.* § 112. A claim may be in either "independent," "dependent," or "multiple dependent" form. *Id.*

Once the application is filed, a patent examiner

determines whether the claimed invention meets certain statutory requirements such as novelty, nonobviousness, and definiteness, among others. See *id.* §§ 102, 103, 112. If an application fails to meet these demands, the examiner will issue an "Office Action" containing the grounds for rejection. *Id.* §§ 131, 132(a). Upon receiving an Office Action, an applicant may amend his claims, argue against the rejection, or present evidence showing why the invention is patentable. 37 C.F.R. § 1.111 (2006). The patent examiner must then respond by either allowing some or all of the claims or by issuing another rejection. 35 U.S.C. § 151. This back-and-forth exchange between an applicant and an examiner is commonly referred to as the "prosecution" of an application.

After receiving a final rejection, an applicant may:

- (1) appeal to the Board of Patent Appeals and Interferences and from there to the United States Court of Appeals for the Federal Circuit;
- (2) file a "request for continued examination" ("RCE") of the application; or
- (3) file a "continuation" or "continuation-in-part" application. *Id.* §§ 120, 132(b), 134, 141, 145; 37 C.F.R. § 1.114 (2006). Continuation and continuation-in-part applications use the same specification as the pending parent application and enjoy the benefit of the filing date of the parent application (the "priority date"), while amending claims or offering further evidence or arguments as to the patentability of the claimed invention. See 35 U.S.C.

§ 120. Although an applicant may wait until a final rejection to file a continuation or continuation-in-part application, they are not required to do so.

In situations where an applicant claims more than one independent and distinct invention in an initial application, the examiner may impose a "restriction requirement" that forces an applicant to separate their multiple independent inventions into "divisional" applications that claim a single invention. *Id.* § 121. The applicant must choose one of the inventions to prosecute in their initial application, and can prosecute the remaining inventions in their divisional applications, which also claim the priority date of the parent application. *Id.*

On January 3, 2006, the USPTO issued two separate notices of proposed rulemaking in the Federal Register: "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," 71 Fed. Reg. 48 (Jan. 3, 2006), and "Changes to Practice for the Examination of Claims in Patent Applications," 71 Fed. Reg. 61 (Jan. 3, 2006) (collectively, the "Proposed Rules"). The Proposed Rules delineated changes to the examination process that would limit the number of continuing applications, RCEs, and claims that an applicant could make as a matter of right. The USPTO justified the proposed changes on the ground that the growing number of continuation applications and

increasing number and complexity of claims in applications had crippled the USPTO's ability to examine newly-filed applications. See 72 Fed. Reg. at 46716-21. After a four-month public comment period where the USPTO received hundreds of written comments, many of which expressed disapproval of the Proposed Rules, see 72 Fed. Reg. at 46744-830, the USPTO published the Final Rules on August 21, 2007.

Under the old system, an applicant could file an unlimited number of continuation or continuation-in-part applications, RCEs, and claims. The Final Rules modify that system in several ways. First, Final Rules 78 and 114 (collectively, the "2+1 Rule") permit an applicant as a matter of right to file two continuation or continuation-in-part applications, plus a single RCE, after an initial application. 72 Fed. Reg. at 46838, 46841; 37 C.F.R. §§ 1.78(d)(1)(i)-(iii), 1.114(f). If the applicant wants to engage in further prosecution, a third continuation or continuation-in-part application or a second RCE can be filed with a "petition and showing" that explains why the amendment, argument, or evidence could not have been presented previously. 72 Fed. Reg. at 46839, 46841; 37 C.F.R. §§ 1.78(d)(1)(vi), 1.114(g). In extraordinary situations, if an applicant believes that the petition and showing requirement would work an injustice, it may petition for a waiver of the rule. 37 C.F.R. § 1.183 (2006). The 2+1 Rule

also applies retroactively to patent applications already filed before the effective date of the Final Rules. See 72 Fed. Reg. at 46716-17.

Second, Final Rule 75 (the "5/25 Rule") permits an applicant to present a total of five independent claims or twenty-five total claims for examination without providing any further information about those claims. 72 Fed. Reg. at 46836; 37 C.F.R. § 1.75(b)(1). An applicant who wants to exceed either limitation must provide an "examination support document" ("ESD") containing information about the claims that may assist the examiner in determining the patentability of the claimed invention. 72 Fed. Reg. at 46836; 37 C.F.R. § 1.75(b)(1). Final Rule 265, as well as certain supplemental guidance issued by the USPTO, establishes the requirements for an ESD. See 72 Fed. Reg. at 46842-43; 37 C.F.R. § 1.265. In addition, both the 5/25 Rule and the ESD requirement apply retroactively to pending applications for which a first Office Action on the merits was not mailed before the effective date of the Final Rules. See 72 Fed. Reg. at 46716.

Final Rules 75 and 78 also alter the existing examination process in other ways. Final Rule 75 defines how claims referring to different statutory classes of invention will be treated and how multiple dependent claims will be counted for purposes of the 5/25 Rule. 72 Fed. Reg. at 46836-37; 37 C.F.R.

§§ 1.75(b)(2) & (b)(5)(c). Final Rule 78 defines the terms "divisional," "continuation," and "continuing application" to eliminate any confusion over how the 2+1 Rule applies, and clarifies that a "voluntary divisional" application does not exist under Section 121 of the Patent Act and that a continuation-in-part application cannot be filed off of a divisional. 72 Fed. Reg. at 46837-38; 37 C.F.R. §§ 1.78(a) & (d). Finally, Final Rule 78 requires patent applicants to identify related patent applications and sets forth a rebuttable presumption that applications meeting certain conditions contain patentably indistinct claims, thereby preventing applicants from evading the 2+1 and 5/25 Rules by attempting to simultaneously prosecute indistinct applications. 72 Fed. Reg. at 46840; 37 C.F.R. §§ 1.78(f)(1) & (2).

On August 22, 2007, Tafas filed a Complaint against the USPTO. He then filed an Amended Complaint on September 7, 2007, seeking, among other things, preliminary and permanent injunctions prohibiting the USPTO from implementing the Final Rules and a declaratory judgment that the Final Rules violate the Constitution, the Patent Act, the APA, and the Regulatory Flexibility Act ("RFA"). On October 9, 2007, GSK filed a Complaint against the USPTO, and two days later filed an Amended Complaint, seeking relief largely similar to that sought by Tafas. On October 15, 2007, GSK moved for a Temporary

Restraining Order and preliminary injunction enjoining the implementation of the Final Rules, which this Court granted on October 31, 2007. GSK, Tafas, and the USPTO then filed their respective Motions for Summary Judgment on December 20, 2007, and the USTPO followed on January 22, 2008 with a Motion to Strike certain exhibits filed by Tafas, *Amici Curiae* Polestar Capital and Norseman Group, and *Amicus Curiae* Dr. Ron D. Katznelson in connection with summary judgment. These motions are currently before the Court.

II. Standard of Review

Because Tafas and GSK bring these claims pursuant to the APA, the ordinary standard for summary judgment applies. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005).³ Summary judgment is appropriate only if the record shows "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); see also *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). In cases involving judicial review of agency action under the APA, the focal point of summary judgment review is "the administrative record already in

³ This lawsuit, while brought pursuant to the APA, raises substantial questions of federal patent law. Consequently, appellate jurisdiction over this case lies in the U.S. Court of Appeals for the Federal Circuit, whose law governs the standard applied at summary judgment. *Star Fruits*, 393 F.3d at 1281 (citing *Helfgott & Karas, P.C. v. Dickenson*, 209 F.3d 1328, 1333-35 (Fed. Cir. 2000)).

existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). Agency action may be set aside if, upon reviewing the administrative record, the court finds that the agency action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to constitutional right, power, privilege, or immunity," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. §§ 706(2)(A)-(D).

III. Analysis

GSK, *Tafas*, and the USPTO make numerous arguments for summary judgment in their favor. After thorough examination of the parties' briefs, the arguments of roughly two dozen *amici curiae*, and the extensive administrative record, the Court finds that the Final Rules are substantive in nature and exceed the scope of the USPTO's rulemaking authority under 35 U.S.C. § 2(b)(2). Consequently, the Court will grant summary judgment to GSK and *Tafas* and void the Final Rules as "otherwise not in accordance with law" and "in excess of statutory jurisdiction [and] authority." 5 U.S.C. § 706(2). In addition, because the Court believes that one who judges least judges best, it will not reach the other issues raised by the parties, resting instead on

the determination of a single dispositive issue.⁴

Section 2(b)(2) of Title 35 empowers the USPTO to “establish regulations, not inconsistent with law,” to “govern the conduct of proceedings in the Office.” 35 U.S.C. § 2(b)(2)(A). The USPTO may promulgate regulations that “facilitate and expedite the processing of patent applications,” *id.* § 2(b)(2)(C), and “govern the . . . conduct of agents, attorneys, or other persons representing applicants or other parties before the Office,” *id.* § 2(b)(2)(D). See also *Lacavera v. Dudas*, 441 F.3d 1380, 1383 (Fed. Cir. 2006) (interpreting Section 2(b)(2) as providing the USPTO with the “broad authority to govern the conduct of proceedings before it”); *In re Borgese II*, 303 F.3d 1362, 1368 (Fed. Cir. 2002) (finding that Section 2(b)(2) empowers the USPTO to “set reasonable deadlines and requirements for the prosecution of applications”).

Under Federal Circuit precedent, however, Section 2(b)(2) does not vest the USPTO with any general substantive rulemaking power. *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996); see also *Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1269 n.1 (Fed. Cir.

⁴ The Court emphasizes that its conclusion here renders it unnecessary to decide whether the USPTO’s interpretation of the Patent Act should be given *Chevron* deference or whether the Final Rules run contrary to the Act’s provisions. Instead, the Court need only explain why the Final Rules are substantive in nature and why they fall outside the scope of Section 2(b)(2). This holding is sufficient to compel the result that the Final Rules are null and void under 5 U.S.C. § 706(2).

2003) (citing *Merck*); *Brand v. Miller*, 487 F.3d 862, 869 n.3 (Fed. Cir. 2007) (same). *Merck* involved an interpretive "Final Determination" by the USPTO regarding the interrelationship between the Hatch-Waxman Act and the Uruguay Round Agreements Act. See 80 F.3d at 1550. In concluding that the USPTO's interpretation was not entitled to *Chevron* deference, the Federal Circuit found that the USPTO's broadest rulemaking power - Section 6(a), the identical predecessor to Section 2(b)(2)(A) - "authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [USPTO]'; it does NOT grant the Commissioner the authority to issue substantive rules." *Id.* at 1549-50 (emphasis in original) (quoting *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991)). Furthermore, "substantive declaration[s] with regard to the Commissioner's interpretation of the patent statutes, whether it be section 101, 102, 103, 112 or other section," also fall outside the bounds of Section 2(b)(2)'s mandate to regulate the "conduct of proceedings" before the Office. *Animal Legal Def. Fund*, 932 F.2d at 930.

In addition, the fact that 35 U.S.C. § 2(b)(2)(B) requires the USPTO to engage in notice and comment rulemaking in accordance with 5 U.S.C. § 553 does not empower the USPTO to promulgate substantive rules. While Section 553 of the APA ordinarily requires notice and comment rulemaking only when an

agency intends to promulgate a substantive rule, notice and comment must also occur when required by statute. See 5 U.S.C. § 553(b). Here, the various provisions of Section 2(b)(2) are joined by an "and," not an "or." This 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 that those rules must be made in accordance with 5 U.S.C. § 553. 35 U.S.C. § 2(b)(2) (emphasis added). In other words, the 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.").

This reading of Section 2(b)(2) is further supported by the fact that, since 2005, Congress has debated and considered whether it should grant the USPTO substantive rulemaking authority but has declined to do so. See, e.g., H.R. 2795, 109th Cong. § 8 (June 8, 2005) ("The Director may by regulation limit the circumstances under which an application for patent, other

than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date for a prior-filed application.”); S. 3818, 109th Cong. § 6(e) (Aug. 3, 2006) (granting the USPTO authority to promulgate rules to “carry out” the Patent Act); H.R. 1908, 110th Cong. § 14(a) (Sept. 10, 2007) (“The powers granted under paragraph (2) of subsection (b) include the authority to promulgate regulations to ensure the quality and timeliness of applications and their examination, including specifying circumstances under which an application for patent may claim the benefit under sections 120, 121, and 365(c) of the filing date of a prior filed application for patent.”). The Court may rely on congressional inaction when it signals Congress’s satisfaction with the status quo. *See Zuni Pub. Sch. Dist. No. 89 v. Dep’t of Educ.*, __ U.S. __, 127 S. Ct. 1534, 1540-41 (2007) (highlighting congressional inaction as bearing on a dispute concerning agency authority).

While GSK and Tafas accept and rely upon the notion of “substantive” and “procedural” regulations, the USPTO rejects this distinction and argues that the question before the Court is simply whether the Final Rules fall within the expressly delegated rulemaking authority of Section 2(b)(2). According to the USPTO, the 2+1 Rule and the 5/25 Rule fall within the reach of Section 2(b)(2) because they “govern the conduct of

proceedings in the Office" by "facilitat[ing] and expedit[ing]" the application process. USPTO's Mem. in Support of Summ. J. at 15. The USPTO also argues that, to the extent the 2+1 Rule seeks to curtail delays in prosecution, it is consistent with the USPTO's ability under Section 2(b)(2) to regulate those practicing before the Office. The USPTO further posits that the Final Rules constitute an exercise of "providing policy direction" to the Office, which the USPTO is permitted to do under 35 U.S.C. § 3(a)(2)(A). *Id.*

Despite this attempt to abolish the substantive-procedural distinction, however, the balance of the case law in the Federal Circuit and the Supreme Court indicates that the distinction exists, and that it is pertinent to this dispute. Both *Merck* and *Animal Legal Defense Fund* acknowledge the divide, and the law in those cases is clear: Section 2(b)(2)'s authority is limited to rules governing the "conduct of proceedings" before the Office, the USPTO does not have the authority to issue substantive rules, and it does not have the authority to make substantive declarations interpreting the Patent Act. *See Merck*, 80 F.3d at 1549-50; *Animal Legal Def. Fund*, 952 F.2d at 930. Contrary to the USPTO's contention, the holding in *Merck* is not mere *dicta*. Instead, the Court's delineation of the USPTO's rulemaking authority under Section 2(b)(2) formed the basis for its conclusion that the "Final Determination" at issue in that

case was not entitled to *Chevron* deference. See *Merck*, 80 F.3d at 1549-50. Furthermore, while the USPTO is correct that the ultimate issue in *Animal Legal Defense Fund* was whether a USPTO policy notice should have been subject to notice and comment rulemaking, in deciding that question the Court nevertheless made a strong statement about the procedural, rather than substantive, nature of Section 2(b)(2)'s statutory predecessor. See 932 F.2d at 930-31. Accordingly, the Court finds that Section 2(b)(2) does not permit the USPTO to promulgate substantive rules, and any rules that may be deemed substantive will be declared null and void.

The USPTO then argues that even if the substantive/procedural distinction matters, the USPTO has the authority to promulgate the Final Rules because they are clearly procedural. To support its claim, the USPTO highlights the fact that the Final Rules "do not implicate the core patentability requirements set out in 35 U.S.C. §§ 101, 102, 103, or § 112." USPTO's Mem. in Support of Summ. J. at 18-19. According to the USPTO, the Final Rules are procedural in nature because, rather than altering the substantive requirements for novelty, nonobviousness, or definiteness, they instead aim to curb repetitive filings by requiring applicants to justify those excess filings and to assist the agency in examining burdensome applications. In addition, the USPTO asserts that, even if the

procedures created by the Final Rules have collateral substantive consequences, that does not place them beyond the scope of the USPTO's rulemaking authority. To support this assertion the USPTO cites *In re Van Ornum*, where the Federal Circuit's predecessor court, the Court of Customs and Patent Appeals (the "CCPA"), upheld a USPTO rule requiring a particular disclaimer from applicants seeking more than one patent on an invention. 686 F.2d 937, 945 (C.C.P.A. 1982). The CCPA stated that:

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

Id. *In re Van Ornum* stands for the proposition that procedural rules with collateral substantive consequences are permissible under Section 2(b)(2).

While the APA does not define a "substantive rule," any rule that "affect[s] individual rights and obligations" is substantive. *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979); see also *Animal Legal Def. Fund v. Quigg*, 932 F.2d at 927 (stating that substantive rules are those that "effect[] a change in existing law or policy which affect[] individual rights and obligations"); *Am. Hosp. Assoc. v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (defining substantive rules as those that "grant

rights, impose obligations, or produce other significant effects on private interests . . . or which effect a change in existing law or policy”) (internal citations omitted). Despite the USPTO’s arguments, the Court finds that the Final Rules are neither procedural rules nor rules relating to application processing that have substantive collateral consequences, but substantive rules that change existing law and alter the rights of applicants such as GSK and Tafas under the Patent Act. The 2+1 Rule and the 5/25 Rule, which limit continuing applications, RCEs, and claims, and the ESD requirement, which shifts the examination burden onto applicants, constitute a drastic departure from the terms of the Patent Act as they are presently understood. By so departing, the Final Rules effect changes in GSK’s and Tafas’s existing rights and obligations. The Court will now explain why the provisions of the Patent Act compel this conclusion.

As the Court described in Part I of this Opinion, under the existing patent system an applicant may file an unlimited number of continuation or continuation-in-part applications, RCEs, and claims. As to continuation and continuation-in-part applications, Section 120 provides that such applications “shall have” the benefit of the priority date of the initial application. 35 U.S.C. § 120. The CCPA has interpreted this language to mean that “there is no statutory basis for fixing an arbitrary limit to the number of [continuing] applications” that

may be filed and that retain the benefit of the priority date. *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968); see also *In re Hogan*, 559 F.2d 595, 604 n.13 (C.C.P.A. 1977) (finding that "a limit upon continuing applications is a matter of policy for the Congress"). Though Final Rule 78 does not completely prohibit applicants from filing more than two continuation or continuation-in-part applications, because the USPTO intends to deny additional applications in almost all circumstances, see 72 Fed. Reg. at 46769-77,⁵ the "could not have been submitted" standard of the petition and showing requirement effectively imposes a hard limit on additional applications. Moreover, while the USPTO may presently wield the doctrine of prosecution laches to prohibit the use of dilatory tactics in the prosecution of applications, see *In re Bogese II*, 303 F.3d at 1368 & n.6; *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 277 F.3d 1361, 1364-66 (Fed. Cir. 2002) ("*Symbol II*"), the mechanical rule

⁵ For example, the USPTO states that it will bar an applicant from obtaining additional continuation applications to submit claims to cover a competitor's product. See 72 Fed. Reg. at 46775. But the Federal Circuit has unambiguously approved of applicants filing continuing applications for this purpose:

It should be made clear at the outset of the present discussion that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988). Thus, Final Rule 78 deprives applicants of an important right that they currently possess under Section 120.

adopted here goes far beyond simply prohibiting unreasonable delays. Instead, Final Rule 78 and the hard limit it imposes changes existing law and deprives applicants of their valuable rights under 35 U.S.C. § 120 to an unlimited number of continuation and continuation-in-part applications as a matter of right. By so doing, it may also impact applicants' rights under Sections 102 and 103 and result in the denial of otherwise meritorious patents. For these reasons, the Court finds that Final Rule 78 is a substantive rule.

With respect to the limitations placed on an applicant's ability to file more than one RCE per application family, Final Rule 114 changes existing law in two ways. First, it places a limit on RCEs as of right on the basis of application family, rather than on the basis of each individual application, whether it be a parent application or a continuation or continuation-in-part application. See 72 Fed. Reg. at 46,737. While there is no case law interpreting the scope of Section 132, limiting RCEs based on application family is a clear departure from the plain language of the statute, which states that the USPTO must provide for the continued examination of each *application*. See 35 U.S.C. § 132(a) (requiring the USPTO to notify the applicant of any rejection or objection to "his application" and stating that if "the applicant persists in his claim for a patent . . . the application shall be reexamined");

Id. § 132(b) (ordering the USPTO to “provide for the continued examination of applications for patent at the request of the applicant”). This conclusion is bolstered by Congress’s pronouncement, upon enacting Section 132(b), that the RCE provisions “shall apply to all applications” filed on or after June 8, 1995. American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1), 113 Stat. 1501, 1501A-560 to 1501A-561 (1999).

Second, and most importantly, the words “shall” and the phrase “at the request of the applicant” in Section 132(b) are best read as evidence that Congress intended to allow for an unlimited number of RCEs and intended to commit the invocation of the continued examination process to the discretion of the applicant, not the USPTO.⁶ In contrast to this mandate, Final Rule 114 limits the number of RCEs per application family to one as a matter of right. Additionally, Final Rule 114’s “petition and showing” requirement is identical to Final Rule 78’s in that it imposes the same type of hard limit on the filing of further RCEs. As a result, Final Rule 114 significantly changes existing

⁶ Interestingly, when the USPTO initially enacted regulations to provide for RCEs under Section 132(b), it read the statute in a similar manner. See Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 Fed. Reg. 50,092, 50,095-96 (Aug. 16, 2000) (noting that the section applied to “all applications filed . . . on or after June 8, 1995” and that “an applicant . . . is not limited in the number of times” he can file an RCE); see also Changes to Application Examination and Provisional Application Practice, 65 Fed. Reg. 14,865, 14,868 (Mar. 20, 2000) (interim rule).

law and alters applicants' rights under 35 U.S.C. § 132 to an unlimited number of RCEs per application at their discretion.⁷ For these reasons, the Court finds that Rule 114 is substantive.

As to the 5/25 Rule, Section 112 expressly permits an applicant to file "one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. Since 1938, the CCPA has consistently held that the Patent Act does not place any mechanical limits on the number of claims an applicant may file. In the case of *In re Clark*, the CCPA held that:

As we understand it, under the patent law and the prevailing Patent Office practice, an inventor, where it is difficult to express his invention in the form of claims, has the right to, and ordinarily for his own protection does, express the same invention in more than one claim. If by so doing he more clearly defines his invention and does not by undue multiplicity obscure the same, he is acting within the rights granted and the duties required by the patent laws.

97 F.2d 628, 631 (C.C.P.A. 1938); see also *In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970) ("[A]n applicant should be allowed to determine the necessary number and scope of his claims."); *In re Chandler*, 319 F.2d 211, 225 (C.C.P.A. 1963) ("[A]pplicants

⁷ The USPTO's claim that Section 132(b) provides the Office with rulemaking authority beyond the powers granted by Section 2(b)(2) - thereby placing Final 114 within its regulatory authority - is without merit. Section 132(b) is best read as providing the USPTO with the ability to promulgate procedural rules that enable it to carry out the new RCE procedure created in 1999. It does not expand the scope of the USPTO's authority beyond that which is granted by Section 2(b)(2).

should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged.”). Certainly, Section 112 permits the USPTO to reject claims on a case-by-case basis for undue multiplicity. See *In re Flint*, 411 F.2d 1353, 1357 (C.C.P.A. 1969) (noting that the USPTO should evaluate the propriety of the number of claims in an application “on the basis of the relevant facts and circumstances in each individual case”) (quoting *In re Chandler*, 319 F.2d at 225). The 5/25 Rule, by contrast, imposes a mechanical limit of five independent claims or twenty-five total claims on every application unless the applicant provides additional information in the form of an ESD. Absent satisfaction of the ESD requirement, the USPTO will abandon an otherwise meritorious application that has six or more independent claims or twenty-six or more total claims. See 72 Fed. Reg. at 46836-37; 37 C.F.R. § 1.75(b)(3).

The USPTO contends that Final Rules 75 and 265 simply establish a procedure by which applicants may submit more than five independent or twenty-five total claims, and that the abandonment of an application that fails to comply with the ESD requirement is no more than a procedural step. This argument fails, however, because these rules go far beyond merely

requiring additional information. Instead, the ESD requirement changes existing law and alters the rights of applicants under the current statutory scheme by shifting the examination burden away from the USPTO and onto applicants. Final Rule 265 demands that applicants conduct a broad search of patents, patent applications, and literature, and provide, among other things, a "detailed explanation" of "how each of the independent claims is patentable over the cited references." 72 Fed. Reg. at 46842; 37 C.F.R. § 1.265(a). However, the Federal Circuit has stated that applicants have "no duty to conduct a prior art search" and "no duty to disclose art of which an applicant could have been aware." *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1238 (Fed. Cir. 2005) (quoting *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 n.6 (Fed. Cir. 1987)); see also *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1351 n.4 (Fed. Cir. 2005) (stating that "there is no general duty to conduct a prior art search").

In addition, Sections 102 and 103 provide that "[a] person 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 and 103, and Section 131 states that the USPTO "shall cause an examination to be made of the application," *id.* § 131. The Federal Circuit has read these provisions as placing the burden of examination and the burden of proof to make a *prima*

facie case of unpatentability on the USPTO. *In re Warner*, 379 F.2d 1011, 1016 (C.C.P.A. 1967). It is only after the USPTO makes a demonstration of unpatentability that the burden shifts to the applicant to rebut that showing. *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. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.”). Thus, by requiring applicants like GSK and Tafas to perform prior art searches and by shifting the examination burden away from the USPTO, the ESD requirement manifestly changes existing law and alters applicants’ rights under Sections 102, 103, and 131. Applicants must now undertake new substantive responsibilities if they wish to file more than five independent or twenty-five total claims, which represents a significant departure from Section 112’s rule of unlimited – though not unduly multiple – claims. For these reasons, the Court finds that Final Rules 75 and 265 are substantive rules.

Because the USPTO’s rulemaking authority under 35 U.S.C. § 2(b)(2) does not extend to substantive rules, and because the Final Rules are substantive in nature, the Court finds that the Final Rules are void as “otherwise not in accordance with law” and “in excess of statutory jurisdiction [and] authority.” 5 U.S.C. § 706(2).

IV. Conclusion

For the reasons stated above, the Court will grant GSK's and Tafas's Motions for Summary Judgment, deny the USPTO's Motion for Summary Judgment, and deny as moot the USPTO's Motion to Strike.

An appropriate Order will issue.

April 1, 2008
Alexandria, Virginia

_____/s/_____
James C. Cacheris
UNITED STATES DISTRICT COURT JUDGE