UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

TRIANTAFYLLOS TAFAS, Plaintiff, v. JON W. DUDAS, et al., Defendants.	)	Civil Action No. 1:07cv846(L) (JCC/TRJ)

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, et al., Plaintiffs, v. JON W. DUDAS, et al., Defendants.	)	Civil Action No. 1:07cv1008 (JCC/TRJ)

DEFENDANTS' MEMORANDUM IN OPPOSITION TO GLAXOSMITHKLINE'S MOTION FOR SUMMARY JUDGMENT

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MISCELLANEOUS

Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively "USPTO" or "Office") respectfully oppose GlaxoSmithKline's ("GSK") cross-motion for summary judgment. To the extent that Plaintiff Triantafyllos Tafas ("Tafas") raises arguments that overlap with that of GSK, those arguments are also addressed in this memorandum. The USPTO addresses Tafas's unique arguments in a separate memorandum, which is intended to be read after this memorandum.

INTRODUCTION

The USPTO demonstrated in its opening summary judgment memorandum that the Final Rules concerning "claims and continuations" practice[1] comply with the Patent Act, 35 U.S.C. § 1 et seq., the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq., the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-612, and the Constitution. The USPTO further explained how, by promoting more focused patent application prosecution and providing additional information to examiners, these procedural rules are critical to helping the agency keep pace with a burgeoning patent system and improve the quality of issued patents.

The Court has now also had the benefit of hearing from a diverse group of *amici* who recognize the lawfulness of the Final Rules and appreciate their importance. Thirteen public interest organizations; intellectual property, administrative law, and public health professors from twelve law schools; and at least one of the top ten patent prosecuting corporations in the United States (Micron Technology, Inc.) have voiced their support for the Final Rules.[2]

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[1] Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule, 72 Fed. Reg. 46716 (Aug. 21, 2007) ("Final Rules") (Ex. 1 to Mem. in Supp. of Defs. Mots. for Summ. J. ("USPTO Mem."), Dkt. No. 127).

[2] See Br. for *Amici Curiae* Public Patent Foundation *et al.* ("Public Interest Br."), Dkt. No. 228; Br. *Amici Curiae* of Intellectual Prop., Admin. Law and Pub. Health Professors . . . ("Prof. Br."), Dkt. No. 232; Br. of *Amicus Curiae* Micron Tech., Inc. . . . ("Micron Br."), Dkt.

Plaintiffs have nevertheless launched a scattershot facial challenge to the Final Rules, hoping that one of their many allegations will prevent the USPTO from achieving its critical reforms. Plaintiffs are joined by "the concentrated group of special interests that benefit from an enlarged patent system, namely patent holders and patent attorneys." Public Interest Br. at 8. The briefs of Plaintiffs and their supporting *amici* reflect their desire to cling to the status quo when new procedures are needed to improve the efficiency and quality of patent application examination. A desire for stasis in the face of reform does not justify enjoining lawful regulations.[3]

RESPONSE TO GSK'S STATEMENTS OF FACTS

The USPTO does not contend that there are any genuine issues of material fact in dispute that would preclude summary judgment in these consolidated cases. See Fed. R. Civ. P. 56(c); Local Civil Rule 56(B). The USPTO objects, however, to GSK's "Statement of Undisputed Facts," which presents facts about GSK that are not "material" to a facial challenge to the Final Rules. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986) (explaining that a fact is material only if it could affect the outcome of the suit). Local Civil Rule 56(B) (calling for listing of disputed material facts); Mem. in Supp. of GSK's Mot. for Summ. J. ("GSK Mem."),

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No. 229. A second top-ten corporation, Intel, also sought leave to participate as *amicus curiae* in support of Defendants' motions for summary judgment, but this Court denied Intel's motion on timeliness grounds. See Order, Dkt. No. 220, Jan. 8, 2007.

[3] Although the USPTO responds in this and its other opposition brief to some arguments by *amici,* the USPTO appropriately does not respond to issues and arguments that were not also raised by Plaintiffs. See Tafas v. Dudas, 511 F. Supp. 2d 652, 660-61 (E.D. Va. 2007) ("Tafas I") ("The Court agrees that it may not consider legal issues or arguments not raised by the parties."). It is worthy of reminder that all *amici* had an opportunity to express their views during the notice and comment period, and many did. The USPTO's 127-page Federal Register notice testifies to the agency's extraordinary efforts to consider and respond to the more than 500 comments it received. See 72 Fed. Reg. at 46744-830. This litigation may not serve as a "do-over" of the administrative process.

Dkt. No. 142, at 7-9 & Ex. 4. As Tafas recognizes, "[s]ince the issues for decision are primarily purely legal in nature and the Final Rules apply across the board to all patent applicants, a determination as to their validity should not turn on facts unique or peculiar to a particular plaintiff or, for that matter, any disputes that might subsequently become apparent as to such background facts." Pl. Triantafyllos Tafas' Mem. of Law in Supp. of Summ. J. Mot. ("Tafas Mem."), Dkt. No. 141, at 2.

The material facts in this case are those set out in the USPTO's Statement of Material Undisputed Facts, which describes the regulatory history of the Final Rules and their key provisions, with reference to the certified administrative record. USPTO Mem. at 7-11; Paulsen v. Gotbaum, No. 90 CIV. 6252, 1992 WL 8361, at *3 (S.D.N.Y. Jan. 15, 1992) ("The material facts in the facial challenge are the existence and application of the regulations."); Comm'y Tel. of Utah, Inc. v. Wilkinson, 611 F. Supp. 1099, 1107 (D.C. Utah 1985) ("Few facts are relevant to a facial challenge, because the law at issue is not analyzed in a factual context."). Accordingly, GSK's "Statement of Undisputed Facts," as well as the declaration of Sherry M. Knowles upon which it relies, should be disregarded.[4] GSK Mem., Ex. 4.

Many of GSK's "factual" assertions about the Final Rules in other background sections are mischaracterizations of the rules and/or the accompanying Federal Register notice, which the USPTO will correct in the context of its legal arguments.

[4] *Amici* who speculate how the Final Rules might affect them likewise do not present material facts that may be considered on summary judgment in a facial challenge.

ARGUMENT

I. THE FINAL RULES ARE CONSISTENT WITH THE PATENT ACT

A. The USPTO Had Authority to Promulgate Final Rules Governing The Conduct Of Proceedings In The Office and the Rules are Entitled to Chevron Deference

The USPTO is entitled to Chevron deference in its interpretation of the relevant Patent Act provisions because Congress has delegated to the USPTO authority to enact the Final Rules. See 35 U.S.C. § 2(b)(2); Chevron USA, Inc. v. NRDC, Inc., 467 U.S. 837 (1984). As the *Amicus* Professors make clear, whether the Final Rules warrant Chevron deference is a threshold issue, which must be resolved in the USPTO's favor because "[t]he Patent Act gives the PTO authority to make regulations governing its internal proceedings" and "[t]he rules at issue are unquestionably directed at the control of PTO procedures." Prof. Br. at 3-4. Plaintiffs err in arguing that the Final Rules exceed the USPTO's rulemaking authority and resist giving the USPTO the deference it is due. See GSK Memo at 17-20; Tafas Mem. at 8-10.

Contrary to Plaintiffs' suggestion, the essential question in determining whether the USPTO had authority to issue the Final Rules and whether they are entitled to Chevron deference is not whether the rules may be labeled "substantive" or "procedural," but whether Congress has delegated to the USPTO rulemaking authority to promulgate the Final Rules.[5] See United States

[5] The USPTO has already explained why the Federal Circuit's *dicta* in Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1550-51 (Fed. Cir. 1996), repeated in *dicta* in Eli Lilly & Co. v. Bd. of Regents of Univ. of Washington, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003), concerning whether the USPTO may enact "substantive rules," does not control whether the Final Rules were a proper exercise of the USPTO's rulemaking authority, or whether the agency is entitled to Chevron deference. USPTO Mem. at 17-18. As the USPTO has also explained, Congress has expressly authorized the USPTO to promulgate rules using APA notice and comment procedures– a type of rulemaking that the APA requires only when an agency is enacting substantive rules. 35 U.S.C. § 2(b)(2)(B) (citing 5 U.S.C. § 553); see USPTO Mem. at 20. GSK thus errs in suggesting that there is "no dispute that the PTO lacks 'any general substantive rulemaking authority.'" GSK Mem. at 17. The USPTO did not concede at the preliminary injunction stage that it lacks substantive rulemaking authority, see id., but simply argued that the

v. Mead Corp., 533 U.S. 218, 229 (2001) (explaining that "express congressional authorizations to engage in the process of rulemaking" are "a very good indicator of delegation meriting Chevron treatment"). It clearly has. Each of the Final Rules falls squarely within the broad, express delegation of 35 U.S.C. § 2(b)(2)(A) to "govern the conduct of proceedings in the Office," and/or the additional grants of rulemaking authority in § 2(b)(2)(C) to "facilitate and expedite the processing of patent applications" and § 2(b)(2)(D) to "govern the . . . conduct of agents, attorneys, or other persons representing applicants or other parties before the Office." See USPTO Mem. at 15. Final Rules 78 and 114 (the "2+1 Rule") merely address how many times applicants may appear before the agency, continuing old applications, before they are required to justify further prosecution by submitting a petition to the Office. Final Rules 75 and 265 (the "5/25 Rule") concern when applicants who file a large number of claims must make a further evidentiary submission to assist the Office in examining those claims. The *Amicus* Professors agree that these rules are within the USPTO's authority: "The rules at issue are unquestionably directed at the control of PTO procedures – under what circumstances applicants can file continuation applications, and what information applicants must disclose along with those applications that are particularly large." Prof. Br. at 4.

GSK errs in suggesting that the USPTO's authority under § 2(b)(2) is narrow or "limited," GSK Mem. at 17, as the Federal Circuit has recognized that "Congress has delegated plenary authority over PTO practice" to the Office under § 2(b)(2)(A). Stevens v. Tamai, 366 F.3d 1325, 1333 (Fed. Cir. 2004) (emphasis added); see also Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006) (describing the USPTO's § 2(b)(2)(A) powers as "broad" and conferring Chevron deference). The courts have thus upheld as proper exercises of USPTO rulemaking

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Final Rules are procedural, see Defs.' Opp. To Pls.' Mot. TRO and Prelim. Inj., Dkt. No. 46 in 1:07cv1008, 21-23.

authority rules that are closely analogous to the Final Rules. For example, it is well-established that the USPTO may, by rule, require applicants to submit additional information under its § 2(b)(2) powers. See Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1281-82 (Fed. Cir. 2005) (discussing 37 C.F.R. § 1.105 (2004)); Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348, 1351 (Fed. Cir. 2005) (discussing 37 C.F.R. § 1.56 (2004) ("Rule 56")); Digital Equip. Corp. v. Diamond, 653 F.2d 701, 708 (1st Cir. 1981) (holding that Rule 56 constitutes "a valid exercise of the Commissioner's rulemaking powers" under § 2(b)(2)(A)).

Furthermore, the Supreme Court has frequently emphasized that delegations of rulemaking authority like § 2(b)(2) must be construed broadly. See Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, 435 U.S. 519, 524 (1978) ("Even apart from the Administrative Procedure Act this Court has for more than four decades emphasized that the formulation of procedures was basically to be left within the discretion of the agencies to which Congress had confided the responsibility for substantive judgments."). Thus, in Federal Communications Commission v. Schreiber, 381 U.S. 279 (1965), the Court discussed the broad authority conferred on the FCC by a statutory provision authorizing it to "'conduct its proceedings in such manner as will best conduce to the proper dispatch of business and to the ends of justice.'" Id. at 289-90 (quoting § 4(j) of the Communications Act of 1934, as amended). The Court remarked that it is an "established principle that administrative agencies 'should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties.'" Id. at 290 (quoting FCC v. Potsville Broad. Co., 309 U.S. 134, 138 (1940)). "This principle, which has been upheld in a variety of applications, is an outgrowth of the congressional determination that administrative agencies and administrators will be familiar with the industries which they regulate and will be in a better position than federal courts or Congress itself to design procedural rules adapted to the

peculiarities of the industry and the tasks of the agency involved." Id. (footnote omitted).

The cases on which GSK relies in trying to diminish the USPTO's rulemaking authority under § 2(b)(2) are readily distinguishable. GSK Mem. at 18-20. Adams Fruit Co. v. Barrett, 494 U.S. 638 (1990), involved an attempt by the Department of Labor to regulate "the scope of judicial power" by finding that state workers compensation laws prevented workers from receiving additional benefits under federal law. Id. at 650. Holding that "Congress has expressly established the Judiciary and not the Department of Labor as the adjudicator of private rights of action arising under the [federal] statute," the Court found it inappropriate to consult executive interpretations of the statute. Id. Similarly, Fabil Mfg. Co. v. United States, 237 F.3d 1335, 1341 (Fed. Cir. 2001), concerned whether a Customs Service decision relating to the burden of proof in an administrative proceeding applied when the case reached the Court of International Trade. Not surprisingly, the Court concluded that it was up to the courts, not an agency, to set burdens of proof in judicial proceedings. Id. Here, by contrast, Congress has delegated to the USPTO, not the courts, the power to enact regulations governing proceedings in the Office, and the Final Rules affect proceedings before the USPTO, not the courts. See 35 U.S.C. § 2(b)(2).

A.T. Massey Coal Co. v. Holland, 472 F.3d 148 (4th Cir. 2006), is likewise inapposite. There, the court declined to afford Chevron deference to the Commissioner of Social Security's interpretation of the term "reimbursement" in the Coal Act because Congress had only delegated the Commissioner authority to perform the ministerial task of making reimbursement calculations. Id. at 167. Here, by contrast, Congress has expressly given the USPTO broad authority to establish regulations, not just perform a ministerial task. See 35 U.S.C. § 2(b)(2).

The creation of the Federal Circuit through the Federal Courts Improvement Act of 1982 is similarly irrelevant. GSK Mem. at 19. In Dickinson v. Zurko, 527 U.S. 150 (1999), the Supreme Court held that notwithstanding that enactment, the USPTO was entitled to the same

deference from the Courts as any other agency. Id. at 152; see Professor's Br. at 1-2. In doing so, the Court abrogated the contrary holding of In re Lueders, 111 F.3d 1569, 1577 (Fed. Cir. 1997), cited by GSK. Since Zurko, the Federal Circuit has given Chevron deference to USPTO rules promulgated under § 2(b)(2), see, e.g., Lacavera, 441 F.3d at 1383, as well as to rules involving other areas of law over which the Federal Circuit has exclusive jurisdiction. See, e.g., Motorola, Inc. v. United States, 436 F.3d 1357 (Fed. Cir. 2006) (review of Customs tariff classifications); Comm. for Fairly Traded Venezuelan Cement v. United States, 372 F.3d 1284 (Fed. Cir. 2004) (review of International Trade Commission decision).

GSK's attempt to read the tea leaves of unenacted legislation is a red herring. GSK Mem. at 18. "Unenacted approvals, beliefs, and desires are not laws" and should not distract this Court from the authority conferred by § 2(b)(2). Puerto Rico Dep't of Consumer Affairs v. ISLA Petroleum Corp., 485 U.S. 495, 501 (1988). Moreover, mere non-adoption of legislation is not probative of congressional intent, as "'several equally tenable inferences' may be drawn from such inaction, 'including the inference that the existing legislation already incorporated the offered change.'" Pension Benefit Guar. Corp. v. LTV Corp., 496 U.S. 633, 650 (1990) (quoting United States v. Wise, 370 U.S. 405, 411 (1962)). Thus, to the extent the bills GSK cites would have – as it contends – expanded the USPTO's rulemaking authority, one could readily conclude that Congress did not enact that legislation because § 2(b)(2) already gave the USPTO the authority it needed and the legislation was thus unnecessary. In fact, the most recent legislation would not have expanded the USPTO's authority, but simply "clarifies the scope of power granted to [it] by paragraph (2) of section 2(b) of title 35." H.R. 1908, 110th Cong. § 14(b) (2007) (emphasis added). The Final Rules are merely an exercise of that already-granted power.

Finally, even if this Court were to accept Plaintiffs' view that the USPTO's rules must be

labeled "procedural" to fall within the agency's rulemaking authority, they are.[6] See USPTO Mem. at 18-20. What qualifies as a "procedural" rule is far broader than Plaintiffs acknowledge. Procedural rules "'ensure that agencies retain latitude in organizing their internal operations'" and "'do not themselves alter the rights or interests of parties, although [they] may alter the manner in which parties present themselves or their viewpoints to the agency.'" Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1047 (D.C. Cir. 1987) (emphasis added) (quoting Batterton v. Marshall, 648 F.2d 694, 707 (D.C. Cir. 1980)). Thus, in JEM Broad. Co. v. FCC, 22 F.3d 320 (D.C. Cir. 1994), the court concluded that "stringent application processing rules designed to streamline the agency's review process and to weed out hastily prepared, incomplete applications" were procedural. Id. at 322. The court looked to an earlier, "almost identical" case, Ranger v. Federal Communications Commission, 294 F.2d 240 (D.C. Cir. 1961), in which the FCC established, without notice and comment, a "cut-off" date by which all applications had to be filed. JEM, 22 F.3d at 327. Like JEM, the appellant in Ranger filed an incomplete application and did not have sufficient time to amend and refile before the "cut-off." Id. Ranger

> held that the rule was procedural, even though "failure to observe it might cause the loss of substantive rights," and that cut-off was a reasonable method of dealing with the Commission's need to establish a terminal point beyond which applicants would not be entitled to a comparative hearing.

Id. (quoting Ranger, 294 F.2d at 244). Here, too, the Final Rules expedite and focus the patent application examination process by establishing benchmarks for the timely submission of continuation applications and requiring additional information about large numbers of claims.

JEM further underscores that the fact of rules having an impact on those they regulate –

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[6] As the USPTO stated in the Federal Register, "these rules changes involve interpretive rules, or rules of agency practice and procedure." 72 Fed. Reg. at 46830 (emphasis added). The USPTO does not separately address in its opposition to Tafas's memorandum the cases he cites because they focus on the meaning of "interpretative," not procedural rules. Tafas Mem. at 8-10.

even to the point of "caus[ing] the loss of substantive rights" – does not render the rules substantive. Id.; see also USPTO Mem. at 19-20. In any event, the Final Rules do not cause the loss of substantive rights because they do not alter the eligibility criteria for obtaining a patent set out in 35 U.S.C. §§ 101, 102, 103, and 112. See Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 930 (Fed. Cir. 1991) ("ALDF"). Any invention that would have met these criteria before the Final Rules will still meet these criteria after them, and Plaintiffs do not contend otherwise.

In sum, the USPTO had authority to enact the Final Rules, and they thus are entitled to Chevron deference. Even if the Court does not afford Chevron deference, however, Plaintiffs err in suggesting that no deference is appropriate. "[E]ven if Chevron deference does not apply, an agency's construction of a statue that it is charged with administering is still subject to some deference under the standard set forth by the Supreme Court in Skidmore v. Swift & Co.," 323 U.S. 134 (1944). Cathedral Candle Co. v. U.S. Int'l Trade Comm'n, 400 F.3d 1352, 1365 (Fed. Cir. 2005). The USPTO certainly has the "expertise" and "the specialized experience" that make deference to its understanding of patent law and procedures particularly appropriate. See id. at 1366 (quoting Mead, 533 U.S. at 228); see also Professors Br. at 5 n.4.

B. Final Rule 78 Places Reasonable Conditions on the Filing of Continuing Applications, Consistent with Section 120 of the Patent Act

Plaintiffs err in arguing that because 35 U.S.C. § 120 does not affirmatively "authorize" the USPTO to place conditions on continuing applications, Final Rule 78 is invalid. Tafas Mem. at 5; see GSK Mem. at 20. Plaintiffs' quest for an affirmative grant of authority turns Chevron on its head. To prevail, Plaintiffs must instead show that the Patent Act unambiguously guarantees unlimited applications regardless of how delayed or abusive they may be. See Chevron, 467 U.S. at 843. To the contrary, "Section 120 does not compel the PTO to give applicants an unlimited numbers [sic] of bites at the apple. Far from it." Prof. Br. at 6.

Plaintiffs focus on the "shall have" language of § 120, but, as the USPTO explained in its opening brief, this language does not compel the USPTO to accept for filing an unlimited number of continuation applications absent a petition and showing. USPTO Mem. at 21-22. The "shall have" language merely assures applicants that the USPTO will not reject a later, properly-filed continuation application on the ground that art published between the filing date of the prior-filed application and the filing date of the later-filed application renders the invention claimed in the later-filed application unpatentable. See id. The section says nothing about whether the USPTO, exercising its authority to "govern the conduct of proceedings before the Office," 35 U.S.C. § 2(b)(2)(A), may place reasonable conditions upon whether the later-filed application may be considered properly filed. Where a statute is silent, the agency may promulgate reasonable regulations. See Chevron, 467 U.S. at 842-43.

The USPTO has already explained why In re Henriksen, 399 F.2d 253 (C.C.P.A. 1968), does not preclude Final Rule 78. USPTO Mem. at 24-26. In re Hogan, 559 F.2d 595 (C.C.P.A. 1977), is inapposite for many of the same reasons. These cases did not involve USPTO rulemaking, nor did they involve anything like the petition and showing requirement. Instead, the Office, without prior notice, simply rejected applications for exceeding an ad hoc, absolute limit on the number of continuations that the plaintiff applicants could file.

In reversing, the Court of Customs and Patent Appeals ("C.C.P.A.") did not read § 120 as unambiguously precluding the USPTO from imposing reasonable conditions on when continuations may be considered properly filed. See Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 982 (2005) ("Brand X") (holding that an agency's construction of a statute is still entitled to Chevron deference even in light of a court's prior judicial construction of a statute so long as the prior court decision does not hold that the statute unambiguously mandates only the court's construction and leaves no room for agency

interpretation); Prof. Br. at 10 (observing, with reference to Henriksen, that "the Brand X Court's declaration that agencies can not, and should not, be precluded from 'revising unwise judicial constructions' of ambiguous statutes . . . is entirely apt"). Nor did either case address the conditions on filing that the USPTO may apply using notice and comment rulemaking. Indeed, Henriksen cites the lack of rulemaking as a critical flaw in the agency decision. 399 F.2d at 262 ("Nothing appears in the Patent Office Rules of Practice or the Manual of Patent Examining Procedure which sanctions such a result."). Accordingly, neither case is controlling.[7] See id.

Plaintiffs selectively quote dicta in Hogan to suggest that only Congress may regulate in this area. GSK Mem. at 21; Tafas Mem. at 6. The full quotation states, "[A] limit upon continuing applications is a matter of policy for the Congress, not for us." Hogan, 559 F.2d at 604 n. 13 (emphasis added). What the court said, therefore, was that it could not judicially impose "limit[s]" on continuing applications, not that the USPTO – to which Congress has delegated rulemaking authority – may not set reasonable conditions on filing by regulation.

In re Bogese makes clear that Final Rule 78 is lawful. See In re Bogese, 303 F.3d 1362, 1368 (Fed. Cir. 2002); USPTO Mem. at 24-25; see also Symbol II, 277 F.3d at 1365-66. Tafas attacks Bogese merely with reference to the dissent. Tafas Mem. at 7. GSK attempts to read into

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[7] GSK also cites Ex Parte Hull, 191 U.S.P.Q. 147, 159-60 (Pat. & Tr. Office Bd. App. 1975), but the Office did not "concede" in that distinguishable case that it lacks the power to issue Final Rule 78. GSK Mem. at 21. Even if it had, an agency may change its interpretation of a statute without losing its entitlement to Chevron deference. See AK Steel Corp. v. United States, 226 F.3d 1361, 1375 n.11 (Fed. Cir. 2000) (quoting Chevron, 467 U.S. at 863 (initial agency interpretation is not "carved in stone")); E.E.O.C. v. Seafarers Int'l Union, 394 F.3d 197, 201 (4th Cir. 2005). Ricoh Co. v. Nashua Corp., No. 97-1344, 1999 WL 88969 (Fed. Cir. Feb. 18, 1999), cited by Tafas, is a nonprecedential case with no binding authority on this Court or the Federal Circuit. The Federal Circuit has declined to follow it for this reason. See Symbol Techs., Inc. v. Lemelson Med. Educ. & Res. Found., L.P., 277 F.3d 1361, 1367-69 (Fed. Cir. 2002) ("Symbol II"); id. at 1370 (Newman, J. dissenting) (criticizing majority's refusal to follow Ricoh). In any event, Ricoh does not unambiguously interpret § 120.

the case a non-existent limit on the USPTO's rulemaking authority by arguing that the "factual underpinnings" of Symbol II and Bogese limit the USPTO "to rejecting claims on a case-by-case basis in light of the doctrine of prosecution laches." GSK Mem. at 23. This argument contradicts what the Federal Circuit actually said in Bogese:

> Indeed, we think the PTO's authority to sanction undue delay is even broader than the authority of a district court to hold a patent unenforceable. The PTO is the administrative agency that is "responsible for the granting and issuing of patents. ..." 35 U.S.C. § 2 (2000). Like other administrative agencies, the PTO may impose reasonable deadlines and requirements on parties that appear before it. The PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications.

Bogese, 303 F.3d at 1367-68 (emphases added). Thus, although the court in Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, 422 F.3d 1378 (Fed. Cir. 2005) ("Symbol IV"), may have cautioned that the courts should be sparing in the use of an equitable doctrine, the Bogese court plainly recognized that the USPTO's inherent authority to regulate the prosecution of applications goes beyond the "factual underpinnings" of any given case. Indeed, in noting that the USPTO could "set reasonable deadlines and requirements for the prosecution of applications," the Federal Circuit implicitly invited the USPTO to exercise its rulemaking authority, for it is rarely, if ever, practical to set deadlines via post-hoc adjudication. As the *Amicus* Professors observe, "[i]t would be perverse to conclude that the PTO has the power to individually reject each one of the plaintiffs' pending applications because they have filed too many continuation applications – something Bogese makes clear they can do – but no power to set general rules that provide guidance and certainty to applicants." Prof. Br. at 7.

C. Final Rule 114's Reasonable Conditions on Requests for Continued Examinations ("RCEs") Are Consistent With Section 132

Plaintiffs likewise err in arguing that 35 U.S.C. § 132 authorizes applicants to file unlimited, unconditional RCEs. Plaintiffs argue that because § 132(b) reads, "[t]he Director

shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant," the Director must grant every RCE. Plaintiffs cite no authority for this reading, which is incorrect even on the face of the statute. See USPTO Mem. at 26-27.

The command to "prescribe regulations" is not a command to "grant every request for continued examination." 35 U.S.C. § 132(b). Instead, the statute authorizes the promulgation of regulations. Final Rule 114 is such a regulation, reasonably providing that an applicant who has received a final Office action may, as a matter of right, file one RCE. After that, the applicant must file a petition and make a showing as to why they could not have previously presented the argument, evidence, or amendment. See 72 Fed. Reg. at 46841, 37 C.F.R. § 1.114(f), (g).

GSK argues from an unremarkable "effective date" provision that because § 132(b) applied to "all applications" filed after June 8, 1995, the USPTO may not place conditions on whether second or subsequent RCEs may be filed. GSK Mem. at 24. The cited section is far less significant.[8] It does not require unlimited RCEs, but simply limits RCEs to those applications that are subject to the 20-year patent term provisions of 35 U.S.C. § 154(a)(2), namely patent applications, other than applications for design patents, that were filed on or after June 8, 1995.

The USPTO applied the "Effective Date" provision accordingly when it published final

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[8] SEC. 4405. EFFECTIVE DATE
(b) AMENDMENTS MADE BY SECTION 4403.--The amendments made by section 4403--
(1) shall take effect on the date that is 6 months after the date of the enactment of this Act, and shall apply to all applications filed under section 111(a) of title 35, United States Code, on or after June 8, 1995, and all applications complying with section 371 of title 35, United States Code, that resulted from international applications filed on or after June 8, 1995; and
(2) do not apply to applications for design patents under chapter 16 of title 35, United States Code.

American Inventors Protection Act of 1990, Pub. L. No. 106-113, § 4405(b)(1), 113 Stat. 1501, 1501A-560 (1999).

rules implementing § 132(b) in 2000. See Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 Fed. Reg. 50,092, 50,095 (Aug. 16, 2000). Contrary to GSK's suggestion, the USPTO did not state in those rules that it could not place conditions on the filing of RCEs; rather, it simply stated that, as a descriptive matter, the rules were not doing so. See id. at 50,096. The USPTO has now established such conditions and has ample authority to do so.

D. Final Rules 78 and 114 Do Not Create a Mechanical Limit on Continuations and RCEs and Are Reasonable Rules

GSK accuses the USPTO of applying a "hard limit" on the number of continuing applications and RCEs and further argues that its representatives will be barred from filing any petition or showing. GSK Mem. at 21-22. GSK's arguments misapprehend the nature of a facial challenge and are factually incorrect.

Plaintiffs are pursuing a facial challenge of these rules, not an as-applied challenge in a particular case. When and if a plaintiff in some future case shows that the USPTO has arbitrarily or otherwise improperly denied an actual petition, the court can rule on that case. See 72 Fed. Reg. at 46778 (explaining that "[t]he denial of a petition under § 1.78(d)(1)(vi) or 1.114(g) may be viewed as a final agency action for the purposes of judicial review under 5 U.S.C. § 704"). Plaintiffs may not ask this Court to decide their facial challenge based on speculation as to how the USPTO may someday apply its petition requirement in hypothetical circumstances. See Ohio Forestry Ass'n, Inc. v. Sierra Club, 523 U.S. 726, 735 (1998) ("The ripeness doctrine reflects a judgment that the disadvantages of a premature review that may prove too abstract or unnecessary ordinarily outweigh the additional costs of—even repetitive—post-implementation litigation."); Abbott Labs. v. Gardner, 387 U.S. 136, 148-49 (1967), overruled on other grounds, Califano v. Sanders, 430 U.S. 99 (1977); cf. Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1056

(D.C. Cir. 1987) ("[W]e think it the most prudent course to await the sharpened facts that come from the actual workings of the regulation in question before striking the objective down as violative of the APA"); Micron Br. at 6 (explaining that to rule on the basis of hypothetical future cases "raises serious questions of ripeness"). In this facial challenge, the Court's role is properly limited to determining whether the Final Rules, as set forth in the Federal Register notice, are unambiguously barred by Section 120 or unreasonable. Because the answer to both questions is "no," the rules must be sustained.

Furthermore, GSK is incorrect in suggesting that the USPTO has created a "hard limit" on continuing applications. Under Final Rules 78(d)(1)(vi) and 114(g), applicants must file a petition and make a showing if they want to file more than an initial application, two continuation applications, and one RCE. See 72 Fed. Reg. at 46839, 46841; 37 C.F.R. §§ 1.73(d)(1)(vi), 114(g). The petition requirement conditions further procedural bites at the apple on a showing that the "amendment, argument, or evidence could not have been submitted" during the prosecution of the prior-filed (or current) application. Id.

As the Federal Register repeatedly emphasizes, petitions will be evaluated on a "case-by-case basis." 72 Fed. Reg. at 46770-79. The Federal Register provides three non-exclusive factors for determining when an applicant meets the "could not have been submitted" standard:

> (i) whether the applicant should file an appeal or petition instead of continuing prosecution;
>
> (ii) the number of co-pending applications with substantially identical disclosures; and
>
> (iii) "whether the evidence, amendments, or arguments are being submitted with reasonable diligence."

72 Fed. Reg. at 46771. The touchstone of the standard is "reasonable diligence," not physical impossibility as GSK suggests. GSK Mem. at 14, 22. The Office will assess "reasonable diligence" by taking the following into account:

> (i) the condition of the application at the time of examination
>
> (ii) the consistency of the Office's position – e.g., whether the Examiner has issued totally new rejections rather than slightly modified rejections that merely address amendments by the applicant, and
>
> (iii) the earnestness of applicant's efforts to overcome outstanding rejections – e.g., whether the applicant kept evidence in reserve until after arguments fail to persuade.

72 Fed. Reg. at 46771.

While emphasizing that petitions will be considered on a "case-by-case" basis, the USPTO provided several examples of when it expects to grant petitions:

> (i) data necessary to overcome a §103 rejection for non-obviousness was diligently pursued and just became available, id. at 46773;
>
> (ii) a final rejection contains a new ground of rejection that could not have been anticipated by the applicant, id. at 46774;
>
> (iii) evidence demonstrating utility or enablement just became available from reasonably diligent testing, id. at 46775-76; and
>
> (iv) the Board of Patent Appeals and Interferences suggests splitting an application subject to an interference, id. at 46776.

Moreover, even where, in responding to comments, the Federal Register notice described situations in which a petition would likely not be granted, the USPTO repeatedly used the term "likely," thus reflecting the case-by-case nature of the analysis and that the facts in a particular application might yield different results. See, e.g., id at 46771-77 (numerous examples). Finally, as the notice also stated, where application of the rule would work an injustice, an applicant may seek a waiver of the rule under 37 C.F.R. § 1.183 (2006). 72 Fed. Reg. at 46769, 46777.

For all of these reasons, GSK cannot seriously contend that the 2 +1 Rule represents a "hard limit." And in view of the flexible criteria that the USPTO will consider, GSK's fear that it will be unable to file a petition without violating ethics rules rings hollow. GSK Mem. at 22.

In the end, "the Final Rules strike a fair and reasonable balance between preserving the

rights of patent applicants to obtain all of the patent protection they deserve and ensuring that those patent applicants who want to game the system for undue advantage are thwarted in such attempts." Public Interest Br. at 9. Final Rules 78 and 114 should thus be upheld.

E. Final Rules 75 and 265 Comport With Section 112 In Reasonably Requiring Information From Applicants Who Present Large Numbers of Claims

Contrary to GSK's representation, the USPTO has not conceded that it is placing a "limit" on the number of claims an applicant may file. GSK Mem. at 25. Final Rule 75(b) does not limit the number of claims that may be filed in an application, but instead requires the submission of additional information if an application contains more than 5/25 claims. See 72 Fed. Reg. at 46788 ("The rules do not impose a per se limit on the number of claims . . . . Rather, applicants may file any desired number and scope of claims necessary to adequately protect the applicant's invention so long as an examination support document is provided . . . [in an] application that presents more than five independent claims or twenty-five total claims.") (emphasis added).[9] The USPTO has merely established a procedure – similar to one already in use by other applicants in the Accelerated Examination Program – whereby applicants who submit large numbers of claims must assist the agency by filing an Examination Support Document ("ESD"). See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 Fed. Reg. 36323-01 (June 26, 2006). As the USPTO has explained, this is not inconsistent with the Patent Act. USPTO Mem. at 27-29.

GSK points to a series of inapposite cases where examiners set limits on the number of

[9] The Federal Register notice repeatedly makes this point. See, e.g., id. at 46758 ("changes being adopted in this final rule do not place a per se limit on the number of claims presented . . ."); 46760 ("final rule does not place any per se limit . . . on the number of claims an applicant may present in an application."); 46761 ("The changes being adopted in this final rule do not place per se limits on the number of claims which applicant may present. . ."); 46825 ("The Office is not seeking to limit the number of claims in an application. Instead, the Office aims to improve the quality of examination.").

claims and the C.C.P.A. reversed. GSK Mem. at 26-27. See In re Wakefield, 422 F.2d 897 (C.C.P.A. 1970); In re Flint, 411 F.2d 1353 (C.C.P.A. 1969); In re Chandler, 319 F.2d 211 (C.C.P.A. 1963); In re Clark, 97 F.2d 628, 631 (C.C.P.A. 1938). In those cases, the examiners rejected claims on the merits based on "undue multiplicity," a violation of 35 U.S.C. § 112, ¶ 2.[10] Under the Final Rules, however, the USPTO will not reject an application on this substantive ground, nor will it purport to "determine the necessary number and scope" of the applicants' claims. Wakefield, 422 F.2d at 900-01. Rather, it will simply require an applicant who presents a large number of claims to submit additional information about its claims. If the applicant refuses to do so, the application will not be rejected on the merits, but instead be abandoned – a procedural step subject to petition within the office and challenge under the APA in district court.[11] Unlike the examiners in the cases on which GSK relies, the USPTO will not make a substantive judgment as to the necessity of any particular claims.

Moreover, even if the USPTO had placed a flat limit on the number of claims that could be presented (which it has not), the cited cases – none of which involved a rulemaking – would not be dispositive. Final Rules 78 and 265 would still warrant Chevron deference under Brand X, because the court did not hold in those cases "that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." 545 U.S. at

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[10] 35 U.S.C. § 112, ¶ 2 requires applicants to "particularly point[] out and distinctly claim the subject matter which the applicant regards as his invention."

[11] There is a critical distinction between the Office rejecting on the merits an application that fails to meet the substantive eligibility criteria for a patent, and the Office deeming an application abandoned or otherwise procedurally defective. While the former is appealed to the Board of Patent Appeals and Interferences ("Board") under 35 U.S.C. § 134, the latter is petitioned to the Director pursuant to 37 C.F.R. § 1.181. See, e.g., In re Makari,708 F.2d 709, 711 (Fed. Cir. 1983); U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure ("MPEP") § 1201 (8th ed. 2001, rev. Aug. 2006) ("The line of demarcation between appealable matters for the Board of Patent Appeals and Interferences (Board) and petitionable matters for the Director of the U.S. Patent and Trademark Office (Director) should be carefully observed.").

982; see USPTO Mem. at 27-29. The courts have never held that § 112 unambiguously precludes requiring information from applicants who submit burdensome numbers of claims.

Far from it, in Application of Rubinfield, 270 F.2d 391 (C.C.P.A. 1959), the C.C.P.A. rejected the notion that § 112 guarantees applicants as many claims as they desire. USPTO Mem. at 28-29. The court upheld a rule that restricted applications for design patents to only one claim, with no exceptions.[12] Rubinfeld, 270 F.2d at 395. If the USTPO could impose an absolute limit of one claim, consistent with § 112, it can certainly, without trespassing that section, require applicants who file more than five independent or twenty-five total claims to submit information to assist in examination. The USPTO's reasonable attempt to assist examiners is entitled to deference.[13] See 72 Fed. Reg. at 46721 (explaining benefit of ESDs).

II. THE FINAL RULES ARE NOT ARBITRARY OR CAPRICIOUS

As this Court recently observed, the standard of review governing Plaintiffs' claims that the USPTO acted in an arbitrary or capricious manner is the highly deferential State Farm standard. Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 43 (1983); see Tafas v. Dudas, — F. Supp. 2d —, 2008 WL 112043, at *3 (E.D. Va. Jan. 9, 2008) ("Tafas II"); 5 U.S.C. § 706(2)(A). In its opening brief, the USPTO showed that its 127-page Federal Register notice, backed by a 10,000 page administrative record, more than

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[12] Former Rule 153 corresponds to current Rule 154(b)(6) and is still the law today. See 37 C.F.R. § 1.154(b)(6) (2006).

[13] GSK argues in a footnote that 35 U.S.C. § 41, which sets filing fees, indicates that "Congress has determined that applicants be permitted to file any number of claims provided that the applicant pays the fee and that the claims otherwise comply with the statutory provisions of the patent laws." GSK Mem. at 27 n.4. Section 41 does not unambiguously make this guarantee. In any event, the USPTO is not stopping applicants from submitting "any number of claims" they want. Id. Applicants with more than 5/25 claims must simply file an ESD. Moreover, § 41(d) makes clear that the filing fee provision that GSK cites is not the only cost that the USPTO may impose on applicants. See 35 U.S.C. § 41(d) ("The Director shall establish fees for all other processing, services, or materials relating to patents not specified in this section . . . .").

satisfies this standard. See USPTO Mem. at 34-39. GSK fails to show otherwise.

As to GSK's first contention, the two cases upon which GSK relies do not stand for the proposition that rules are "*per se* arbitrary and capricious" when an agency "mistake[s] the limits of its statutory authority." GSK Mem. at 41-42 (citing SEC v. Chenery Corp., 318 U.S. 80, 94 (1943); Prill v. NLRB, 755 F.2d 941 (D.C. Cir. 1985)). Neither Prill nor Chenery even addressed the "arbitrary or capricious" standard of 5 U.S.C. § 706(2)(A), much less involved an agency rulemaking. In any event, the USPTO has already shown that it did not exceed its rulemaking authority in promulgating the Final Rules. See supra Part I.A; USPTO Mem. at 13-20.

GSK next summarily argues that the rules are "arbitrary or capricious" because the USPTO failed to adequately explain its administrative efficiency rationale, which, of course, is only one of the stated rationales for the Final Rules. See 72 Fed. Reg. at 46719, col. 3 (listing other goals). GSK fails, however, to indicate what more might be required on top of the USPTO's already comprehensive explanation of the Final Rules. See GSK Mem. at 42. The USPTO cannot be expected to guess. As the USPTO's opening brief sets out in detail, the Federal Register notice explains the efficiency gains the agency expects from the Final Rules, as well as how each rule will achieve them. See, e.g., 72 Fed. Reg. at 46718-21, 46754, 46825. In particular, the Federal Register explains how both the claims and continuations rules will induce applicants to engage in more diligent and focused prosecution, thereby allowing the USPTO to examine more applications with greater efficiency. See, e.g., id. at 46721, 46754.

GSK otherwise nitpicks a particular document – a budget model that was not even created for purposes of supporting this rulemaking but that shows that the USPTO will realize efficiency gains. GSK Mem. at 43 (citing A05645).[14] GSK critiques this budget model for resting upon

[14] Cited excerpts of the administrative record are attached, in numerical order, as Ex. 1.

"unexplained assumptions" and suggests that it "fails to support the PTO's assertions." GSK Mem. at 42. These critiques of one document – amidst 4,000 pages of data in the record – do not render the Final Rules arbitrary or capricious, particularly when others have frequently commented on the need to reform continuations and claims practice. See U.S. Patent and Trademark Office: Transforming To Meet the Challenges of the 21st Century, at 13, 38-39, 50, 63, 69-70 (National Academy of Public Administration 2005) (A03860, A03885-86, A03897 A03909, A03915-16); To Promote Innovation: The Proper Balance of Competition and Intellectual Property Law and Policy, Ch. 4 at 26-31 (Federal Trade Commission 2003) (A03393-98); To Promote the Progress of Useful Arts, Report of the President's Commission on the Patent System, at 17-19 (1966) (A04937-39). GSK points to no conflicting or contrary evidence, and even if it could, it is for the agency, not the court, to weigh that evidence. See Marsh v. Oregon Natural Res. Council, 490 U.S. 360, 378 (1989).

The single document on which GSK focuses is a model that the USPTO submitted to the Office of Management and Budget (OMB) as part of its budget package to map out the impact of expected efficiency gains from the Final Rules and other initiatives.[15] A05645. The model shows that even if the 2+1 and 5/25 Rules yielded an efficiency gain of only 1% in FY 2008 and 2% in FY2009-13, the Final Rules, along with various other initiatives, would allow the pendency of patent applications before first Office actions ("PEND FA") to quickly level off.[16]

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[15] As the USPTO noted in its opening brief, the Final Rules are only one of many measures the USPTO is undertaking to improve the quality and efficiency of patent examination. USPTO Mem. at 36, n.21. Contrary to GSK's suggestion, there is nothing improper about the USPTO modeling for the OMB anticipated efficiency gains from these other rules, including the "IDS Rule," alongside that of the Final Rules. GSK Mem. at 43.

[16] GSK incorrectly asserts that the USPTO may not help the Court understand its budget model at the summary judgment stage. See GSK Mem. at 43 n.9. The case GSK cites does not stand for this proposition, nor is it consistent with other case law GSK itself cites that calls on an agency to explain its models at summary judgment. See, e.g., Owner-Operator Independent

A05645. A leveling of pre-first Office action pendency periods supports the USPTO's administrative efficiency rationale because it shows that the Final Rules will help the agnecy begin to keep pace with its backlog rather than continuing to fall further and further behind.

The assumptions in the budget model, which are based on agency expertise and experience, are not the sort of concrete statistics that are subject to mathematical precision, nor need they be in order for the Final Rules to be upheld. Consumers Union of U.S., Inc. v. Fed. Trade Comm'n, 801 F.2d 417, 425 (D.C. Cir. 1986) (statistical support is neither readily available nor necessary where agency's prediction about commercial behavior or consumer perception is uniquely within agency's expertise); Natural Res. Def. Council v. SEC, 606 F.2d 1031, 1052 (D.C. Cir. 1979) (predictive judgments based on agency's expert knowledge tend to be infused with policy considerations that are not appropriate subjects of close judicial scrutiny). An agency does not act arbitrarily or capriciously by using projections to derive efficiency gains. See, e.g., FCC v. Nat'l Citizens Comm'n for Broad., 436 U.S. 775, 813-14 (1978) (complete factual support for the Commission's judgment or prediction is not possible or required).

Furthermore, while an agency may be expected to explain its model's assumptions and methodology, the "scientific nature of a model does not easily lend itself to judicial review, and [a court's] review proceeds with considerable deference to the agency's expertise." U.S. Air Tour Ass'n v. Fed. Aviation Admin., 298 F.3d 997, 1008 (D.C. Cir. 2002) (internal quotation marks omitted). "The principal question . . . is whether the agencies' explanation of the model's assumptions and methodology is reasonable." Id. (emphasis added).

GSK provides no reason to believe that the assumptions in the OMB budget model are unreasonable. For example, in the referenced model, the USPTO assumed that the Final Rules

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Driver Ass'n, Inc. v. Fed. Motor Carrier Safety Admin., 494 F.3d 188, 204 (D.C. Cir. 2007).

would cause a 1% reduction in pendency in FY 2008 and a 2% reduction in pendency for FY 2009 - FY 2013. A05645. These assumptions were necessarily based on the experience and expertise of agency officials. As the USPTO stated in the Federal Register, the number of applications filed in FY 2006 involving three or more continuations was 2.7%. 72 Fed. Reg. at 46755. In the absence of the Final Rules, that number could be expected to continue to grow. Thus, the assumption of a 1% or 2% efficiency gain (instead of a number closer to 2.7%) was not only reasonable but modest. As the USPTO explained in its opening brief, even modest efficiency gains are significant in light of the extraordinary backlog. USPTO Mem. at 37.

GSK's other allegations reflect its own misunderstandings, not a flaw in the USPTO's rulemaking process. The USPTO's projected efficiency gains do, in fact, account for the limit on RCEs. GSK Mem. at 43. Throughout the rulemaking process, the USPTO has used the broad term "continuations" as a shorthand for the changes to continued examination filings (continuations, continuations-in-part, and RCEs) generally.[17] The same shorthand was used in the OMB model. Likewise, the USPTO's assumptions, such as the 1% efficiency gain, are so modest in part because the USPTO had to account for the agency's need, under the Final Rules, to process ESDs and petitions related to additional continued examination filings. Contrary to GSK's suggestion, the USPTO did not overlook these filings but rather lowered its estimates to account for them. GSK Mem. at 44-45.

GSK also claims that two references in the Final Rules to examiner bonus structure are internally inconsistent. GSK Mem. at 43. Once again, GSK misapprehends the Final Rules. One reference relates to retention bonuses, see 72 Fed. Reg. at 46817, and the other reference relates to performance bonuses, see id. at 46818. The USPTO explained that even providing

[17] See, e.g., "Claims and Continuations Final Rules to Publish in Late Summer," http://www.uspto.gov/web/patents/notices/pclaimscont.htm (last modified 7/25/07).

examiners with these two different types of bonuses, the Final Rules are nevertheless necessary.[18] Id. at 46817, 46818.

In sum, GSK's misunderstanding of a single document in a 10,000-page record fails to establish that the Agency's rules are arbitrary or capricious under State Farm.[19]

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[18] GSK raises red herrings when it asserts that there are inconsistencies in the budget model – a model that, as noted above, was simply developed as part of a budget package, not to justify the Final Rules. GSK Mem. at 44-45. As noted above, the models included information about other USPTO initiatives, one of which involved Patent Cooperation Treaty ("PCT") applications. Although GSK observes a discrepancy between the "Chap I reduction" and "Chap II reduction" lines on A05645 and A05646 (which relate to the USPTO's PCT initiative), the USPTO only sent OMB A05645 as part of its budget package; A05646 was designed for internal use only. The USPTO used the percentages reflected on A05645 to derive the expected "Total PCT PU savings" on A05646, but simply did not update its internal notes on A05646 to reflect this. Likewise, the "Efficiencies Gains" on A05646 do not match the Efficiency Gains on A05645 because the "Efficiencies Gains" line on A05646 refers to net gains that take into account that the projected gains from the current initiatives would not be realized for the entire fiscal year 2008. The numbers on A05656 are also offset by the efficiency losses that occur annually due to the increasing complexity of patent applications (a.k.a. "technology creep"). None of these facts reveal a defect in the USPTO's rationale for the rules.

[19] GSK smuggles into its "arbitrary and capricious" discussion a claim concerning the USPTO's compliance with 5 U.S.C. § 553, but the claim is not pled in GSK's amended complaint and does not go to whether the USPTO acted arbitrarily or capriciously under 5 U.S.C. § 706(2)(A). The claim is not properly before the Court. See, e.g., New Motor Vehicle Bd. of Ca. v. Orrin W. Fox Co., 439 U.S. 96, 125 n.29 (1978) ("Although the Court has endorsed the modern relaxation of pleading rules, it has never receded from the requirement that civil complaints provide parties defendant with "fair notice" of the claims against them."); Ribis v. Mike Barnard Chevrolet-Cadillac, Inc., 468 F. Supp. 2d 489, 495 (W.D.N.Y. 2007) ("[A] plaintiff may not use a memorandum of law or similar paper to assert a claim that is not contained in the complaint."); GSK Am. Compl. Ct. 6 (raising solely a logical outgrowth claim).

Even if the Court reaches the argument, the USPTO did not violate 5 U.S.C. § 553(c) by not publishing and explaining its OMB budget model during the notice and comment period. See GSK Mem. at 44 (citing Owner-Operator, 494 F.3d at 202). As an initial matter, the USPTO was not even required to undertake "notice and comment" rulemaking because the Final Rules are procedural. See USPTO Mem. at 59-60. Moreover, unlike the model in Owner-Operator, the OMB model, which is dated "7/31/07" – more than a year after the comment period closed – was not developed for the purpose of justifying the Final Rules, but rather to submit to OMB to justify the USPTO's budget. A05645. Although the model confirmed the benefits that agency officials anticipated, based on their experience and expertise, would accrue from the Final Rules, it was never intended to provide information "critical" to the decision to promulgate the Final Rules. Cmty. Nutrition Inst. v. Block, 749 F.2d 50, 58 (D.C. Cir. 1984). The Proposed Rules did

III. PLAINTIFFS FAIL TO ESTABLISH THAT THE FINAL RULES ARE RETROACTIVE

Plaintiffs further fail to establish that the Final Rules are retroactive under the relevant prongs of Landgraf v. USI Film Products, 511 U.S. 244 (1994).[20] That the Final Rules in some ways apply to pending applications do not automatically render them retroactive. Id. at 269. The Final Rules have future effect and thus do not exceed the USPTO's rulemaking authority under Bowen v. Georgetown University Hospital, 488 U.S. 204 (1988). USPTO Mem. at 39-45.

A. The Final Rules Do Not Impose New Duties on Completed Transactions

Contrary to GSK's contention, the Final Rules do not impose new duties with respect to completed transactions. Landgraf, 511 U.S. at 280; GSK Mem. at 32.[21] First, although some of the procedural devices are new, the duties they implicate are not. The Final Rules merely ensure across-the-board compliance with existing obligations so that the USPTO need not enforce applicants' duties on a case-by-case basis.

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not implement the results of any particular studies, but rather were based on experience-based assumptions explained in the initial Federal Register notices. See Defs. Mem. in Opp. to Pl. Triantafyllos Tafas's Mot. for Summ. J. ("USPTO Tafas Opp."), Part V.B. GSK also could not have been prejudiced by the USPTO not disclosing the model during the notice and comment period when its own declarant, Harry F. Manbeck, would have used the very same model when he was Assistant Secretary and Commissioner of Patents and Trademarks. See 5 U.S.C. § 706 (requiring court to take "due account . . . of the rule of prejudicial error."). Moreover, now having the model, GSK fails to mount a "credible challenge" as to justify remand. Owner-Operator, 494 F.3d at 202 (holding that "a petitioner must show that on remand [it] can mount a credible challenge . . . and [was] thus prejudiced by the absence of an opportunity to do so before.") (internal quotation marks omitted).

[20] Tafas alleges that the USPTO violated 5 U.S.C. § 551(4) by promulgating rules that do not have "future effect," but that inquiry is coextensive with the Landgraf inquiry and is thus subsumed by the ensuing discussion. See USPTO Mem. at 40 n.25; Tafas Mem. at 27.

[21] The Federal Circuit recently clarified that it uses a three-part test to consider whether the Landgraf factors are implicated. See Rodriguez v. Peake, — F.3d —, 2008 WL 60423, at *5 (Fed. Cir. Jan. 7, 2008). Resort to this test should not change the result because the Final Rules do not run afoul of the plain language of the Landgraf factors, and the Federal Circuit's test merely elaborates those factors.

With respect to the 2+1 Rule, existing rules already preclude applicants from engaging in delay when filing papers with the USPTO. 37 C.F.R. § 10.18(b)(2)(i) (2006) provides that by presenting any paper to the Office, the applicant certifies that "[t]he paper is not being presented for any improper purpose, such as . . . to cause unnecessary delay or needless increase in the cost of prosecution before the Office." Consistent with this language, the USPTO could have chosen to rein in rampant continued examination filings by ordering each applicant to explain why any particular continued examination filing is justified. It also could have imposed sanctions, including termination of proceedings, if the applicant's explanation were inadequate. See 37 C.F.R. § 10.18(c) (2006) (providing for sanctions). Such a case-by-case approach would, however, be impractical in view of the large scale of the problem the Final Rules aim to redress.

Similarly, with respect to the 5/25 Rule, one commentator has suggested that it is a violation of existing USPTO rules forbidding practitioners to handle legal matters without adequate preparation to file an application without having conducted a prior art search. See 72 Fed. Reg. at 46806 (citing Thomas Schneck, The Duty to Search, 87 J. PAT. & TRADEMARK OFF. SOC'Y, 689, 696-701 (2005)). While the USPTO has not previously adopted this interpretation as a general matter, it would certainly be within its discretion to find that preparation is inadequate when an application presents a large number of claims without research as to whether such claims are warranted in view of the prior art. See 37 C.F.R § 10.77(b) (2006) (precluding a practitioner from handling a legal matter without preparation adequate in the circumstances). Through the 5/25 Rule, the USPTO has simply adopted an across-the-board approach rather than regulating case-by-case using existing regulations.[22] Thus, GSK errs in suggesting that the Final

[22] The same is true with respect to Final Rule 78(f), which GSK does not challenge but some *amici* address. 37 C.F.R. § 1.78(b) (2006) provides that applicants can be required to remove conflicting claims from more than one application, and 37 C.F.R. § 1.105 (2006) provides that applicants can be required to provide factual information pertinent to patentability (i.e., why claims are patentably distinct).

Rules impose "new duties," as opposed to new ways of enforcing old duties.[23] GSK Mem. at 32.

Second, any duties imposed by the Final Rules do not affect "transactions already completed." Landgraf, 511 U.S. at 269. GSK suggests that the mere filing of a patent application is a completed transaction, but courts have rejected this notion. See USPTO Mem. at 43-44 (citing cases). The completed transaction under Landgraf is not the initial filing of a patent application, but the later issuance (or rejection) of a patent. Id.

Even if the filing of an applications were a completed transaction, however, Landgraf makes clear that the essential question is "whether the provision attaches new legal consequences to events completed before its enactment."[24] Landgraf, 511 U.S. at 269-70 (emphasis added); see also Khattak v. Ashcroft, 332 F.3d 250, 253 (4th Cir. 2003). The 2+1 Rule does not impose new legal consequences on pending applications; it merely requires a petition and showing with any third or subsequent continuation and any second or subsequent RCE that has not yet been filed. Similarly, the 5/25 Rule does not automatically nullify pending applications or claims, but simply requires the filing of an ESD if an applicant wishes to pursue more than 5/25 claims.[25] Nor do the Final Rules prevent applicants from claiming all of their inventions, as previously discussed. See USPTO Mem. at 12-13; see also infra Part III.B. For these reasons, too, the Final Rules are not retroactive under the first Landgraf prong.

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[23] As discussed in more detail below, the fact that the USTPO currently has rules prohibiting the conduct at issue in the Final Rules undercuts Plaintiff's arguments that they have "relied upon" the existing law and have a "right" to expect continuation of the existing law. Plaintiff has no "right" to avoid future compliance with the law. If a driver is not ticketed for speeding on one occasion, he has no "right" to speed in the future because speeding is prohibited.

[24] 37 C.F.R. § 1.53(b)-(d) (2006) pertain to the filing of national patent applications and §1.431(b) pertains to the filing of PCT applications. The Final Rules simply do not pertain to application filing requirements.

[25] Likewise, failure to comply with Rule 78(f) results in a presumption that applications contain patently indistinct claims, but does not void a pending application.

B. The Final Rules Do Not Impair Rights a Party Possessed When It Acted

GSK asserts that it has given up trade secret rights by filing its pending patent applications with the USPTO. GSK Mem. at 32. As *Amicus* AIPLA explains, that is incorrect: "The filing of an initial application does not immediately cause the loss of the trade secrets disclosed in the application." Br. for *Amicus Curiae* Am. Intellectual Prop. Law Ass'n ("AIPLA"), Dkt. No. 185, at 2. Instead, an applicant chooses whether or not to give up his trade secrets, for the U.S. patent system does not require universal publication of patent applications, but rather calls for publication only if an applicant chooses to pursue international patents in foreign countries that require publication of applications. See 35 U.S.C. § 122(b)(2)(B)(i); 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999) ("Any pending U.S. application filed only in the United States (e.g., one that does not have a foreign counterpart) will not be published if the applicant so requests. Thus, an applicant wishing to maintain her application in confidence may do so merely by filing only in the United States and requesting that the USPTO not publish the application."). In choosing to pursue patents abroad, therefore, GSK gives up its own trade secrets and any rights that it would otherwise have in them. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1002 (1984) ("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"). The USPTO does not require it do so.

Furthermore, the Final Rules do not alter the trade secret ramifications of filing a patent application; they operate the same in this regard as the pre-existing rules. The only change from pre- to post-rulemaking is the procedures governing claims and continuations practice. But procedures themselves do not give rise to property rights, Olim v. Wakinekona, 461 U.S. 238, 250 (1983); Fleury v. Clayton, 847 F.2d 1229, 1231 (7th Cir. 1988). Nor, by extension, are there rights in the continued operation of particular regulatory regimes, Prometheus Radio Project v.

F.C.C., 373 F.3d 372, 430 (3d Cir. 2004). GSK's trade secrets argument is simply dress for an attempt to claim rights in an old set of rules.

GSK also cannot seriously argue that the Final Rules impair any "right" to broadly claim all disclosures they have already made in their initial applications. GSK Mem. 32-33. The Patent Act requires an applicant to submit "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, ¶ 2. GSK admits to using continuing application practice as a means of delaying having to point out and distinctly claim its inventions. GSK Am. Compl. ¶ 57. It cannot, however, claim a "right" at variance with the law.

Moreover, even if GSK legitimately did not know what its invention was at the time it filed any pending applications, it cannot assert that it has a "right" in subject matter that it continues to regard as unworthy of claiming as its invention. Applicants had more than two months between the publication of the Final Rules on August 21, 2007 and the effective date of November 1, 2007 to submit as many continuations as they wanted without a petition. Because of the preliminary injunction, applicants can still – even today – file continuations without a petition. Additionally, even after the Final Rules take effect, GSK will be able to file at least "one more" continuation application in many of its application families without a petition or showing. See 72 Fed. Reg. at 46716. A suggested restriction requirement ("SRR") also may be used, where appropriate, to create additional lines of divisional applications. See 72 Fed. Reg. at 46726; 37 C.F.R. § 1.142(c). Thus, there are numerous ways for GSK to pursue patents for its disclosed, but as yet unclaimed, inventions. If it decides not to do so, that is its choice. But it may not then lament the loss of a purported "right" in inventions it chooses not to claim.[26]

[26] With respect to the ESD requirement, *Amicus* AIPLA suggests that filing an ESD is too costly to be a real alternative, and thus argues that Final Rule 75 impairs applicants' right to exceed 5/25 claims. AIPLA Br., at 4-5, 10-12. Not surprisingly, GSK does not argue that it

For all of these reasons, the Final Rules are not retroactive under Landgraf.

IV. GSK'S TAKINGS CLAIM FAILS

GSK stops short of asking the Court to hold that the Final Rules effect a taking under the Fifth Amendment.[27] U.S. Const. Am. V; GSK Mem. at 38-39. Instead, GSK asks the Court to hold that the USPTO acted arbitrarily or capriciously in failing to more carefully consider whether they effect a constitutional taking, and to remand for more careful determination of the issue. Id. The USPTO adequately considered the takings issue. Moreover, remand is unnecessary because even if the USPTO inadequately considered the issue, any purported failure was harmless since the Final Rules could not and do not effect a taking.

A. The USPTO Adequately Considered the Takings Issue

GSK relies on two cases for the proposition that the USPTO rules should be remanded for further consideration of the takings issue, but neither supports its claim. GSK Mem. at 36, 38. In State Farm, the Court noted that a rule is arbitrary or capricious if the agency has "entirely

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could not afford an ESD. But even as to smaller entities, the USPTO specifically studied the costs of ESDs in connection with the RFA and concluded that they would not have a significant economic impact on a substantial number of small entities. See A08287-90, A08299-300. The USPTO did not abuse its discretion in reaching that conclusion. See USPTO Tafas Opp., Part VI. Moreover, AIPLA's concern is overshadowed by the reality that, to date, hundreds of applicants have voluntarily filed Accelerated Examination Support Documents ("AESD"s) in order to obtain faster examination of their application. See 71 Fed. Reg. at 36323-27; "AE Petition Status," http://www.uspto.gov/web/patents/accelerated/ae_stat_charts.pdf (showing 650 accelerated examination submissions filed). The AESD contains more requirements than the ESD and must be submitted within a much shorter time frame. Id.

[27] Tafas does ask the Court to hold that the Final Rules effect a taking, but he should not be heard on this claim because it is not in his amended complaint. Tafas Mem. at 24-26. New Motor Vehicle Bd. of California, 439 U.S. at 125 n.29 (1978); Ribis, 468 F. Supp. 2d at 495. The only Fifth Amendment claim Tafas pleads is a Due Process claim. See Tafas Am. Compl. ¶ 61. The Due Process Clause and Takings Clause are distinct clauses of the Fifth Amendment, and the inquiries under the two clauses are different. See Lingle v. Chevron U.S.A., Inc., 544 U.S. 528, 543 (2005); USPTO Mem. at 46-47. Tafas has not pursued his Due Process claim on summary judgment, except to the narrow extent that he joins GSK's void-for-vagueness inquiry, and it is thus waived.

failed to consider an important aspect of the problem." 463 U.S. at 43 (emphasis added). In National Wildlife Federation v. Interstate Commerce Comm'n, 850 F.2d 694 (D.C. Cir. 1988), the D.C. Circuit remanded to the agency a regulation concerning the "Rails-to-Trails" program because the ICC never addressed the specific takings issue before the court. See id. at 705 (finding that the ICC's posed a different question that did "not resolve the question" of whether a taking had occurred). Whereas the ICC missed the takings issue "entirely," State Farm, 463 U.S at 43, the USPTO confronted it in several ways.

The USPTO most directly addressed the takings issue in the section quoted by GSK:

> [T]he changes in this final rule do not preclude an applicant from filing an application or obtaining a patent containing any number of claims, but simply changes the procedures for applications containing more than five independent claims or more than twenty-five total claims. Therefore, there is no support for the proposition that the changes in this final rule amount to a 'taking' by the government.

72 Fed. Reg. at 46828. The USPTO also explicitly addressed it in certifying that "[t]his rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630." Id. at 46834. While these two references are enough to distinguish this case from National Wildlife Foundation and State Farm, they are not the only evidence that the USPTO considered the issue.

Underlying the takings issue are at least three questions that the USPTO also specifically discussed. First, the USPTO addressed whether patent applications give rise to property rights – a prerequisite to a Fifth Amendment taking. The USPTO concluded that they did not, stating, "[t]he filing of an application for patent does not create a vested right," and citing two relevant cases. 72 Fed. Reg. at 46826-27 (citing Community TV, Inc. v. FCC, 216 F.3d 1133, 1143 (D.C. Cir. 2000); Chadmore Commc'ns v. FCC, 113 F.3d 235, 240-41 (D.C. Cir. 1997)). Second, the USPTO considered whether the Final Rules are retroactive – a critical issue to the takings inquiry, as GSK admits that the Final Rules only implicate takings concerns to the extent they are

retroactive.[28] GSK Mem. at 5, 38; see also Tafas Mem. at 26. The USPTO specifically addressed retroactivity, with express reference to both the claims and continuations rules. 72 Fed. Reg. at 46826-27. Third, the USPTO considered the extent to which the Final Rules would prevent applicants from claiming all of their inventions, an inquiry essential to determining whether the rules "take" anything from applicants. The USPTO found that it did not, reasoning that the rules are merely procedural and that there are avenues for applicants to claim the inventions disclosed in their pending applications under the Final Rules. See id. at 46827.

Accordingly, even if the USPTO only used the word "taking" twice, the agency understood and considered the constellation of issues underlying it. Remand would be unjustified and unduly formalistic under these circumstances.

B. The Final Rules Do Not Effect a Taking

The Court also need not remand because any inadequacy in the USPTO's consideration of the takings issue was harmless, as the Final Rules do not effect a taking. See 5 U.S.C. § 706 ("[D]ue account shall be taken of the rule of prejudicial error"); cf. National Wildlife Federation, 850 F.2d at 708 (remanding where court had grave concerns that a taking had actually occurred).

1. Plaintiffs Lack Any Cognizable Property Right

GSK rests its claim to a Fifth Amendment property right on the erroneous contention that patent applications are property. GSK Mem. at 34. GSK fails to cite any case that directly stands for this proposition, and the Supreme Court has held to the contrary. Marsh v. Nichols, Shepherd, & Co., 128 U.S. 605, 612 (1888) ("Until the patent is issued, there is no property right in it."); see also Exxon Chem. Patents, Inc. v. Lubrizol Corp., 935 F.2d 1263, 1266 (Fed. Cir. 1991) (Newman, J. concurring); USPTO Mem. at 41 (citing additional cases holding that patent

[28] For this reason, if the Court concludes that the Final Rules are not retroactive, it need not consider the takings issue.

applications and applications for other government benefits are not property). GSK relies primarily on Ruckelshaus, 467 U.S. at 1002-04, but that case concerns trade secrets, a form of property that, unlike a patent application, does not depend on the government determining whether or not a benefit should be granted.[29] See Boyden v. Comm'r of Patents, 441 F.2d 1041, 1043 (D.C. Cir. 1971) ("No person has a vested right to a patent, but is privileged to seek the protected monopoly only upon compliance with the conditions Congress has imposed.").

The enactment of 35 U.S.C. § 261 only underscores that patent applications – as contrasted with granted patents – are not property. The first sentence of that section states, "Subject to the provisions of this title, patents shall have the attributes of personal property." 35 U.S.C. § 261 (emphasis added). The next sentence distinguishes between "applications for patent" and "patents," showing that Congress did not intend to create a property interest in patent applications in making them transferable and assignable.[30] Id. ("Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing."); cf. Leatherman v. Tarrant County Narcotics Intel. & Coordination, 507 U.S. 163, 168 (1993) ("*Expressio unius est exclusio alterius.*"). Indeed, when one company receives compensation for transferring or assigning its patent applications to another, it is being paid for the inchoate expectation interest in a future patent (discounted, of course, by the probability that a patent will not be granted), not for

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[29] The USPTO has already explained why Plaintiffs' reliance on the notion that it has sacrificed trade secrets in exchange for a patent application is flawed. See supra Part III; USPTO Mem. at 42-43.

[30] Contrary to GSK's suggestion that § 261's enactment in some way transformed the law, the assignment and transferability language of § 261 simply perpetuated a statutory provision existing before the Patent Act of 1952. See H. Rep. No. 7794, at 27 (1952) ("The second paragraph is the same as in the corresponding section of existing statute."). Thus, its enactment would not have rendered the USPTO's cited cases "outdated." GSK Mem. 7 at n. 35. It is remarkable that GSK even makes this accusation when it relies on cases dating from 1923, 1931, and 1933, none of which bind this Court. See GSK Mem. at 34.

any intrinsic value that might exist in the patent application itself.[31] Section 261 thus does not create a property right where the Supreme Court has recognized none exists.

2. The Final Rules Do Not Effect a "Per Se" or Other Regulatory Taking

Here, the Final Rules cause no assignment or transfer of Plaintiffs' applications to the USPTO so as to effect either a "per se" taking, or any other regulatory taking. See UPSTO Mem. at 47-50. GSK errs in relying on Lucas v. South Carolina Coastal Council, 505 U.S. 1003 (2002), which stands for the proposition that a "per se" taking occurs only when there is a "total taking of the entire parcel." Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency, 535 U.S. 302, 331 (2002) (discussing categorical rule of Lucas). As the Supreme Court has explained, "Lucas is for the 'extraordinary case' in which regulation permanently deprives property of all value." Id. (emphasis added). This is not that "extraordinary case," as the Final Rules simply establish new procedures, and there are numerous ways to claim one's inventions.

GSK speculates that the Final Rules will take its "ability to fully and adequately patent its invention" by not allowing it to file an endless stream of continuation applications and by requiring it to submit an ESD if its application contains more than 5/25 claims.[32] GSK Mem. at 35. As to continuations, GSK's assertion rests on the premise that the 2+1 Rule creates "hard limitations." Id. As discussed above, this is not only inaccurate, but also inappropriate in the context of a facial challenge. See supra Part I.D. Moreover, under the Final Rules, GSK may still claim the inventions disclosed in its pending applications; it simply must follow different procedures to do so. GSK will have to submit a petition and make a showing for its third

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[31] A transferee or assignee may also be purchasing any trade secrets described in a patent application, but in that case, the property interest lies in the trade secret itself, Ruckelshaus, 467 U.S. at 1002-04, not the 'casing' of the patent application. See, e.g., Aronson v. Quick Point, 440 U.S. 257 (1979).

[32] GSK again refers to the 2+1 Rule as creating "hard limitations," but this is neither an appropriate argument on a facial challenge nor an accurate one. See supra Part I.B.3.

continuation application or second RCE in an application family, or it may alternatively submit an SRR and begin new application families for each of its inventions – an option that is particularly useful to GSK given its prosecution strategy of using one broad disclosure to patent numerous inventions. See GSK Am. Compl. ¶ 57. GSK has offered no reason to discount the latter option.[33] What GSK can no longer do, and what it never had a right to do, is delay claiming its inventions.[34] See GSK Mem. at 11-12; 37 C.F.R. § 10.18 (prohibiting intentional delay of prosecution). Thus, even assuming arguendo that patent applications may be considered property, GSK's property has not remotely lost "all value," as required to proceed under Lucas. Tahoe-Sierra, 535 U.S. at 330.

Nor do the Final Rules effect a regulatory taking under the framework of Penn Central Transportation Co. v. City of New York, 438 U.S. 104, 124 (1978), the three-factor test that applies when regulation does not deprive property of all its value. See Tahoe-Sierra, 535 U.S. 313. While Plaintiffs cite Penn Central, they fail to discuss all of its factors, particularly the first factor – the character of the governmental action – which negates their claim. Penn Central, 438 U.S. at 124; GSK Mem. at 36, Tafas Mem. at 25. As the USPTO has explained, the Penn

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[33] AIPLA discounts the utility of an SRR by stating that an examiner is not obligated to accept it. AIPLA Br. at 9. However, the standard for accepting an SRR is the same as the standard for an examiner to make its own restriction requirement. See 72 Fed. Reg. at 46745, 46797. Given the presumption of regularity that attaches to agency action, there is no basis for concluding that the USPTO will not implement the SRR provision properly. Moreover, to the extent the USPTO denied an SRR, that denial would be petitionable under 37 C.F.R. § 1.181, and ultimately appealable to the federal courts under the APA.

[34] Historically, applicants have not had an unfettered right to keep a never-ending string of continuations pending. See Woodbury Patent Planing Mach. Co. v. Keith, 101 U.S. 479, 485 (1879) ("[A]n inventor cannot, without cause, hold his application pending during a long period of years, leaving the public uncertain whether he intends ever to prosecute it, and keeping the field of his invention closed against other inventors") (emphasis added); Kendall v. Winsor, 62 U.S. 322, 329 (1858) (an inventor "may forfeit his rights . . . by an attempt to withhold the benefit of his improvement from the public until a similar or the same improvement should have been made and introduced by others").

Central factors strongly weigh against a taking.[35] See USPTO Mem. at 48-49.

For all of these reasons, this Court need not remand the takings question to the USPTO because even if the USPTO failed to adequately address the issue, which it did not, any such error was not "prejudicial" in the absence of a true taking. 5 U.S.C. § 706.

V. PLAINTIFFS FAIL TO RAISE A COGNIZABLE VOID-FOR-VAGUENESS CHALLENGE

Plaintiffs contend that the putatively undefined scope of the preexamination search required by Final Rule 265 renders that rule void-for-vagueness under the Due Process Clause. U.S. Const. Am. V; GSK Mem. at 28; Tafas Mem. at 36.[36] GSK further contends that the Office's reliance on the MPEP and subsequently-issued guidance is misplaced, and in any event, that such guidance fails to provide precise, detailed instructions regarding how to perform a search under Final Rule 265. GSK Mem. at 29-30. As explained in the USPTO's opening brief, Plaintiffs' vagueness challenge fails because (i) the void-for-vagueness doctrine only concerns regulations or statutes that prohibit conduct or concern a First Amendment right; and (ii) Final Rule 265 is sufficiently clear to pass constitutional muster.

A. The Void-for-Vagueness Doctrine Is Inapplicable

The vagueness doctrine does not apply to regulations or statutes concerning government

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[35] Because the Final Rules do not effect a taking under the Fifth Amendment, Plaintiffs reference to the law of eminent domain is inapt. GSK Mem. at 38 n.8. The USPTO is not purporting to exercise the power of eminent domain.

[36] GSK's Amended Complaint also challenged Final Rule 75(b)'s "not unduly multiplied" language as vague. See GSK Am. Compl. at ¶ 143. GSK's motion for summary judgment does not address this argument, and therefore, GSK has waived this challenge. Tafas, however, has now seized upon both of GSK's vagueness challenges, now raising for the first time that Rules 265 and 75(b) are vague. See Tafas Mem. at 26 n.8 & 36. Because Tafas failed to assert any void-for-vagueness allegations in his complaint, he cannot raise the issue for the first time in his motion for summary judgment. New Motor Vehicle Bd., 439 U.S. at 125; Ribis, 468 F. Supp. 2d at 495. Should the Court entertain Tafas's belated Rule 75(b) challenge, the USPTO rests upon the arguments raised in its opening brief showing why the claim fails. USPTO Mem. at 58.

benefits or entitlements. Instead, the doctrine is aimed only at regulations or statutes prohibiting conduct or regulating First Amendment rights 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) ("[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."); Walker v. Bain, 65 F. Supp. 2d 591, 599 & n.3 (E.D. Mich. 1999) ("[T]he void for vagueness doctrine [has] little or no application outside of the first amendment or criminal contexts."), aff'd in part, vacated & rev'd in part on other grounds, 257 F.3d 660 (6th Cir. 1999). This is because "[t]he essential purpose of 'void for vagueness' doctrine is to warn individuals of the criminal consequences of their conduct." Jordan v. De George, 341 U.S. 223, 230 (1951); see also Grayned v. City of Rockford, 408 U.S. 104, 108-09 (1972).

Here, Plaintiffs rely solely on one case, United States v. Lanier, 520 U.S. 259, 266 (1997), to support their vagueness challenge. That case, however, involved a statute making it a crime to willfully and under color of law deprive a person of rights protected by the Constitution or law of the United States. Thus, Lanier supports that a vagueness challenge is limited to regulations or statutes that prohibit conduct or implicate a First Amendment right.

B. The Preexamination Search Requirement of Final Rule 265 Is Not Vague, and Determination of the Question is, in any Event, Premature

Even assuming the applicability of the vagueness doctrine, Plaintiffs' challenge nevertheless fails. The Constitution does not require agencies to draft regulations with "mathematical certainty" or "meticulous specificity." Grayned, 408 U.S. at 110; United States v. Powell, 423 U.S. 87, 94 (1975). Rather, agency pronouncements need only be "sufficiently specific that a reasonably prudent person, familiar with the conditions the regulations are meant to address and the objectives the regulations are meant to achieve, would have fair warning of what the regulations require." Freeman United Coal Mining Co. v. Fed. Mine Safety & Health

Rev. Comm'n, 108 F.3d 358, 362 (D.C. Cir. 1997) (citations omitted); see also Nat'l Indus. Contractors, Inc. v. OSHRC, 583 F.2d 1048, 1054 (8th Cir. 1978).

That standard is more than satisfied in this case. Final Rule 265 requires applicants to conduct a search of the prior art for the claimed invention, giving the applicant the discretion to determine where to search, how to search, or how much money to spend based upon their own understanding of their own invention. 72 Fed. Reg. at 46842; 37 C.F.R. § 1.265(a)(1), (2). Because the nature of a search depends on the type of invention claimed, the USPTO could not have crafted a one-size-fits-all rule to instruct every potential applicant how to conduct a search for every possible invention. In that spirit, Final Rule 265 embodies "flexibility and reasonable breath," Grayned, 408 U.S. at 110, and was "drafted with as much exactitude as possible in light of the myriad conceivable situations which could arise." Ryder Truck Lines, Inc. v. Brennan, 497 F.2d 230, 233 (5th Cir. 1974). That Final Rule 265 does not – and cannot – provide the specific detailed instructions that GSK demands does not mean it is impermissibly vague.

This is particularly true in light of the cure provision of Final Rule 265, which provides that the Office will give an applicant notice and an opportunity to correct any search that is deemed to be insufficient. See 72 Fed. Reg. 46843; 37 C.F.R. § 1.265(e). In giving such notice, the Office will provide reasons why the search is non-compliant, as it is required to do by statute and regulation. See 35 U.S.C. § 132(a) (providing that when a requirement is imposed on an applicant, the Office must "stat[e] the reasons for such . . . requirement, together with such information and references as may be useful"); see also 37 C.F.R. §§ 1.104, 1.135(c); MPEP § 714(F).[37] Because the Office will provide additional information to individual applicants who

[37] Indeed, special program examiners currently review ESD-like documents in connection with the accelerated examination program and provide notices explaining the reasons for non-compliance, similar to what the Office plans to do for ESDs. See USPTO Mem., Ex. 4a at 2, 6.

submit non-compliant ESDs beyond what exists on the face of the regulation (and guidance that has already issued), the determination of whether the Final Rules are vague is premature and should await an as-applied challenge to the rule. See Abbott Labs., 387 U.S. at 148-49; Ohio Forestry Ass'n, 523 U.S. at 735; Reg'l Mgmt. Corp. v. Legal Servs. Corp., 186 F.3d 457, 465 (4th Cir.1999) (explaining that ripeness inquiry requires considering, *inter alia*, "(1) the agency's interest in crystallizing its policy before that policy is subject to review; and (2) the court's interest in avoiding unnecessary adjudication and in deciding issues in a concrete setting.").

C. The Office Properly Relied on Guidance Clarifying any Putative Vagueness

Even if the Court decides the issue now, however, the Office properly provided significant guidance in the Federal Register (by, inter alia, reference to the MPEP) and through subsequently-issued documents regarding how to conduct the required preexamination search. A court must consider such guidance in evaluating constitutional vagueness challenges. See USPTO Mem. at 53; Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498 (1982) (noting that the "regulated enterprise" has "the ability to clarify the meaning of the regulation by its own inquiry, or by resort to the administrative process"); Aeronautical Repair Station Ass'n v. FAA, 494 F.3d 161, 173 (D.C. Cir. 2007) ("In this case, employers can clarify the term's meaning as they always have -- by recourse to the written guidance which the [agency] routinely provides . . . ."); Go Leasing, Inc. v. Nat'l Transp. Safety Bd., 800 F.2d 1514, 1525 (9th Cir. 1986) ("[P]otential vagueness may be mitigated by judicial or executive interpretation of the challenged provision."); accord Gen. Elec. Co. v. EPA, 53 F.3d 1324, 1329 (D.C. Cir. 1995); Diamond Roofing Co. v. OSHRC, 528 F.2d 645, 649 (5th Cir. 1976); Posely v. Eckerd Corp., 433 F. Supp. 2d 1287, 1312-13 (S.D. Fla. 2006).

GSK contends that the MPEP and USPTO's subsequently-issued guidance cannot cure any putative vagueness because such interpretative guidance was not submitted for "notice and

comment" and lacks the full effect of law. This proposition is directly contrary to the extensive authority allowing the use of such material to mitigate any vagueness in a regulation. See id. It also conflicts with 5 U.S.C. § 553(b)(A), which exempts "interpretative rules" and "general statements of policy" from notice and comment rulemaking.

The cases cited by GSK, see GSK Mem. at 29-30, do not prohibit an agency from issuing subsequent guidance or referencing existing guidance to interpret a rule. Rather, those cases prohibit an agency from changing, introducing, or terminating a rule via guidance in circumvention of statutorily-required notice and comment rulemaking. See Appalachian Power Co. v. EPA, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (holding that EPA guidance regarding the periodic monitoring of air pollutants altered the substantive requirements of the rule – and was therefore "legislative" rather than merely "interpretative" – could not stand without complying with proper rulemaking procedures); Gen. Elec. Co. v. EPA, 290 F.3d 377, 385 (D.C. Cir. 2002) (holding that a guidance document that provided binding directions regarding the manner in which risk assessments must be conducted under a regulation was not merely a policy statement, but a legislative rule that required notice and comment rulemaking); CropLife Am. v. EPA, 329 F.3d 876, 881-82 (D.C. Cir. 2003) (vacating an EPA press release that banned third party human studies in evaluating the safety of pesticide because it constituted a regulation that changed the law and was issued without notice and comment rulemaking).[38] Unlike in the cases GSK cites,

[38] The remaining case, Nathan Katz Realty, LLC v. NLRB, 251 F.3d 981, 988 (D.C. Cir. 2001), is irrelevant. It concerned a property manager's challenge to NLRB's determination that the manager engaged in unfair labor practices in refusing to bargain with union representing its employees. Id. at 983-84. The Board challenged jurisdiction, arguing that it did not receive adequate notice of the issue raised by property manager. The Court suggested that the Board issue a rule, requiring a petitioner to make specific objections to ensure it receives adequate notice. Id. at 988. The Court commented in dicta that such a rule would govern internal procedure and therefore not be subject to notice and comment. Id. Nathan Katz Realty has nothing to do with whether the MPEP and guidance documents must be subjected to notice and comment before the USPTO may rely on them to cure any putative vagueness in the Rules.

the USPTO did not alter Final Rule 265's search requirement via the MPEP or other guidance.

Finally, it is widely acknowledged that practitioners and applicants are familiar with and have been conducting prior art searches for years. See, e.g., Kimberly A. Moore, Worthless Patents, 20 BERKELEY TECH. L. J. 1521, 1537-38 (Fall 2005) ("It seems logical that applicants who more highly value a particular patent would be likely to file more claims and do a more thorough prior art search prior to filing.") (emphasis added). For those rare applicants unfamiliar with conducting search, the MPEP and the Office's subsequently-issued guidance provide more than adequate instruction. See USPTO Mem. at 56-57 & Exs. 4d, 4e. In sum, the USPTO has sufficiently informed the public how to comply with the search requirement of Final Rule 265 and thereby complied with all that the Due Process Clause requires.

VI. THE APA'S NOTICE AND COMMENT PROVISIONS ARE INAPPLICABLE, AND, IN ANY EVENT, THE PROPOSED RULES PROVIDED SUFFICIENT NOTICE OF THE 5/25 RULE

A. The APA's Notice and Comment Provisions Do Not Apply to Procedural Rules

Contrary to Plaintiffs' implicit assumption, the notice and comment requirements of the APA are inapplicable here because the Final Rules are procedural rather than substantive. ALDF, 932 F.2d at 927 (explaining that the APA's notice requirements apply only to substantive rules). As set forth above and in the USPTO's opening brief, the Final Rules have not altered, and in no way affect, the substantive eligibility requirements for obtaining a patent, as expressed in 35 U.S.C. §§ 101, 102, 103, and 112. See JEM, 22 F.3d at 326-27 (concluding that a regulation was "procedural" because it did not change the substantive standards by which the agency evaluated applications and was thus exempt from APA notice and comment). Thus, the APA's notice requirements do not apply to the Final Rules. ALDF, 932 F.2d at 927.

B. The Proposed Rules Provided Sufficient Notice of the "5/25 Rule"

Even assuming the notice provisions of the APA apply to the Final Rules, the 5/25 Rule

was not a "drastic" shift, nor was it "surprisingly different," from the Proposed Rules. GSK Mem. at 39. Instead, the 5/25 Rule was "reasonably foreseeable" in light of the Proposed Rules. Long Island Care at Home, Ltd. v. Coke, — U.S. —, 127 S. Ct. 2339, 2351 (2007). As explained in the USPTO's opening brief, the Office has maintained a consistent approach throughout the rulemaking process, i.e., a threshold number of claims beyond which an applicant must submit an ESD. The Proposed Rules themselves referred to an earlier request for comments on a proposal "to limit the number of total and independent claims that would be examined in an application." Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61, 62 (Jan. 3, 2006) (citing Changes to Implement the Patent Business Goals, 63 Fed. Reg. 53497, 53506-508 (Oct. 5, 1998)). Thus, interested parties were well aware that a total claims threshold was a possible approach for relieving the burden on the Office caused by high numbers of claims.

GSK primarily contends that the 5/25 Rule marks an "over 1800% increase in affected applications" and thus could not be a logical outgrowth of Proposed Rule 75. GSK Mem. at 40-41. To arrive at that artificially high number, GSK combines apples and oranges, comparing the 23.7% of total applications that exceeded the 5 independent and 25 dependent claim threshold in 2006, id. at 40, with the 1.2% of applications identified in the Proposed Rules as containing more than ten independent claims, without regard to any dependent claims. Id. But the USPTO never asserted that only "1.2% of all applications would be affected by the representative claims proposal." Id. Indeed, the Proposed Rules would have affected many more applications. Those rules required any application with more than ten total claims – and any application with even a single dependent claim – to designate representative claims. See 71 Fed. Reg. at 63 ("[T]he applicant must expressly designate which (if any) dependent claims are to be given initial examination."). Thus, while the Proposed Rules identified the relatively small percentage of pending applications that would not have had all independent claims examined, comments from

the public made clear that many more applications would be affected.[39] For example, under the Proposed Rules, the typical patent application, filed with 2-3 independent claims and 10-20 total claims, A04754-55, would not have had all of its claims examined without an ESD, and the applicant would have been required to designate claims. Under the Final Rules, however, the Office will examine all the claims in that typical application; the applicant will not be required to make any designation. In short, GSK's 1800% figure is meaningless because it does not compare applications affected under the Proposed Rules with those affected under the Final Rules.

Moreover, GSK fails to appreciate that under the Proposed Rules, the threshold of ten designated claims spanned any related patent or pending continuation application. Under Proposed Rule 1.75(b)(4), any designated claims in a patented or pending prior application would count towards the ten designated claims in a pending related continuation. 71 Fed. Reg. at 68. Thus, an applicant with ten designated claims in a pending parent application would be subject to the ESD requirement, irrespective of the number of claims examined in a pending related continuation. Under the Final Rules, however, the 5/25 threshold applies for each continuation, resulting in a 15/75 threshold across an initial and two continuation applications in a family.

Contrary to Plaintiffs' suggestions, the logical outgrowth question does not turn on comparative harshness, or on an increase in the number of affected applications. See, e.g., Am. Coke & Coal Chems. Inst. v. EPA, 452 F.3d 930, 939-40 (D.C. Cir. 2006) (upholding final rule that resulted in more stringent regulations than those proposed as a logical outgrowth because overall methodology remained the same); Omnipoint Corp. v. FCC, 78 F.3d 620, 632 (D.C. Cir. 1996) (concluding that FCC's final rule that defined eligibility preferences for bidding on new wireless spectrum in a way that excluded more participants than under proposed rule was a

[39] In fact, the USPTO moved away from the representative claims approach partly in response to comments that a total claims approach is preferable to burdening all applicants with the requirement to designate claims. Compare 71 Fed. Reg. at 161, with 72 Fed. Reg. at 46787.

logical outgrowth because it was consistent with the FCC's overall approach in its proposed rules). The Fourth Circuit's decision in Chocolate Manufacturers Ass'n v. Block, 755 F.2d 1098 (4th Cir. 1985), is particularly instructive. Whereas the final rules in that case were "a complete reversal" from, id. at 1103, "exactly opposite," id., and "contrary to," id. at 1104, the proposed rules, and thus not reasonably foreseeable, the Final Rules maintain a consistent approach by focusing on a threshold number of claims that may be submitted before triggering the ESD requirement. Such a consistent approach from Proposed Rule to Final Rule unquestionably constitutes a permissible logical outgrowth. See Mfr. Housing Inst. v. EPA, 467 F.3d 391, 400 (4th Cir. 2006) (observing that an agency's notice and comment process is proper if the adopted regulation is "a logical outgrowth" of the proposed regulation and the final rule does not "reach[] a conclusion exactly opposite to that proposed."); BASF Wyandotte Corp. v. Costle, 598 F.2d 637, 642 (1st Cir. 1979) (upholding an agency action even though it "contract[ed] rather than expand[ed]" the number of permissible categories at issue because the public nevertheless had an opportunity to present their views on the content of the plan). Accordingly, the Court should reject Plaintiffs' challenge to the 5/25 Rule.

CONCLUSION

For the foregoing reasons, the Court should grant the USPTO's cross-motion for summary judgment against GSK and deny GSK's cross-motion for summary judgment.

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