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 CORP., d/b/a GLAXOSMITHKLINE, et al., Plaintiffs, v. JON W. DUDAS, et al., Defendants.	)	Civil Action No. 1:07cv1008 (JCC/TRJ)

MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

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Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively "USPTO" or "Office") respectfully submit this memorandum in support of their motions for summary judgment against Plaintiff Triantafyllos Tafas ("Tafas") and the "GlaxoSmithKline" Plaintiffs ("GSK").

INTRODUCTION

The USPTO promulgated the procedural rules under attack in these consolidated cases to improve the timeliness, efficiency, and quality of patent application examination. Facing a backlog of more than 700,000 unexamined patent applications in 2006, the agency had no choice but to act if it was to keep pace with the burgeoning patent system.

The USPTO identified two key problems contributing to the mounting pile of applications: (1) applicants flooding the agency with repetitive and otherwise vexatious "continuing" applications, often for the purpose of strategic delay; and (2) applicants presenting increasingly large numbers of claims for examination. Without rules in place to address these issues, the USPTO faced an increasing backlog and a threat to the quality of its issued patents.

The Office thus developed procedural rules that would continue to allow applicants to pursue patent protection for their inventions to the full extent allowed by law, while also making the patent system more efficient. The USPTO published its proposed rules in January 2006, voluntarily provided a notice and comment period, and, after careful consideration, published final rules in August 2007. The final rules redress the identified problems by: (1) establishing a benchmark for applicants to promptly present claims and arguments for patent examination rather than using limitless continuation applications to do so; and (2) ensuring that the agency will receive greater assistance from applicants through prior art searches and analysis when their applications impose disproportionate burdens on examination by presenting large numbers of

claims. These are modest steps, which the USPTO has the authority and responsibility to take.

The Court should deny Plaintiffs' efforts to derail these crucial reforms. *First,* the USPTO had authority to enact the challenged rules by virtue of Congress's express grants of power to the USPTO to, *inter alia*, "govern the conduct of proceedings in the Office" and "facilitate and expedite the processing of patent applications." 35 U.S.C. § 2(b)(2). Because the USPTO had authority to enact these rules, they are entitled to Chevron deference, irrespective of whether they may be considered "substantive" or "procedural." Moreover, the Federal Circuit decisions that GSK relied on to obtain a preliminary injunction cannot stand in the way of this Court affording Chevron deference to these rules. See Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 982 (2005). Properly viewed in light of these principles, each of the challenged rules is clearly consistent with the Patent Act.

Second, as this Court indicated at the preliminary injunction stage, the rules are not "arbitrary" or "capricious" under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. In its 127-page Federal Register notice announcing the final rules, the USPTO articulated the rationale for its rules, showed how data supported them, and addressed proposed alternatives. The voluminous administrative record further evidences the USPTO's careful and lawful efforts.

Third, the Final Rules are not retroactive. The rules could not impair vested rights because patent applicants do not have such rights. Patent applicants have not sacrificed any "trade secrets" in applying for patents because the USPTO would be willing to keep their applications in confidence; it is the applicants who choose to make their applications public in order to pursue patent protection from other countries. The rules also do not impose new duties on completed transactions, as the mere act of filing an application does not complete any "transaction," and, in any event, the Final Rules do not render invalid any action taken in past applications.

Fourth, the rules do not run afoul of the Fifth Amendment by violating the Due Process Clause or the Takings Clause. Here again, Plaintiffs' claims fail for lack of a cognizable property right. Moreover, these economic regulations are not so "irrational" as to violate due process. The rules also do not effect a taking under the Supreme Court's regulatory takings framework.

Fifth, the Patent Clause of the Constitution, art. I, § 8, cl. 8, simply authorizes Congress to establish a patent system and presents no obstacle to the final rules. The preambular language of the Patent Clause does not constitute an independent factor for the USPTO to "weigh," and even if it did, the USPTO satisfied the interests underlying the Patent Clause.

Sixth, Plaintiffs fail to assert a cognizable challenge under the void-for-vagueness doctrine because that doctrine relates only to regulations or statutes prohibiting conduct, whereas these rules concern the procedures by which an applicant seeks a government benefit. In any event, the rules are sufficiently clear to satisfy due process.

Seventh, the final rules here need not be a "logical outgrowth" of the proposed rules because, as procedural rules, they did not require the agency to undertake APA notice and comment procedures. Even if they did, however, the final rules were reasonably foreseeable and are a logical outgrowth of the proposed rules, addressing concerns raised in the public comments.

Eighth, the USPTO complied with the procedural requirements of the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-612, in promulgating the final rules. The Office properly certified that the final rules would not have a significant impact on small entities and thus did not require a full RFA analysis. Even if the Office had been required to undertake a full RFA analysis, its initial and final certifications fulfill that requirement.

With the USPTO's position now fully briefed for the first time, the Court should grant the USPTO's motions for summary judgment and allow it to implement its crucial reforms.

STATUTORY BACKGROUND

Title 35 of the United States Code – commonly known as the Patent Act – provides the statutory framework for the examination of patents by the USPTO. Sections 111 and 112 of the Patent Act set out the formal requirements for submitting a patent application to the Office. See 35 U.S.C. §§ 111, 112. Section 111 mandates that the application be in writing, describes the required contents of a patent application in general terms, and calls for application fees and an oath. See id. § 111. Section 112 requires an application to contain two primary parts: (1) a **"specification**," which generally describes the invention and how to make and use it; and (2) one or more **"claims**,"which identify the scope of legal protection to which the applicant believes the invention is entitled. Id. § 112. A claim may be in **"independent"** or **"dependent**" form.[1] See id., ¶ 5. The first application an applicant files for a given invention is known as the "parent" or "initial" application.

After receiving an application, a patent examiner will determine whether the claimed invention meets the substantive patentability requirements set forth in Sections 101, 102, 103, and 112 of the Patent Act. See id. §§ 101 (requirement that invention be "new and useful"), 102 (novelty requirement), 103 (nonobviousness requirement), & 112 (written description, enablement, definiteness, and best mode requirements). Section 131 requires the Office to "cause an examination" of each patent application and to grant a patent if the applicant is entitled to one by law. Id. § 131.

If an application does not comply with the patent eligibility requirements, Section 132(a)

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[1] For example, Claims 1 and 2 below are independent claims; Claim 3 is a dependent claim; and Claim 4 is a **"multiple dependent claim."**

1. An automobile comprising: a chassis; an engine; and four wheels.
2. An automobile comprising: a chassis; an engine; four wheels; and four doors.
3. The automobile of claim 1 wherein the engine is an internal-combustion engine.
4. The automobile of claims 1 or 2 wherein the engine has eight cylinders.

requires the examiner to issue a notice of rejection, known as an **"Office action,"** which sets forth the grounds for rejection. 35 U.S.C. §§ 131, 132(a); see also 37 C.F.R. § 1.104(a) (2006). In response, the applicant may (i) amend his or her claims; (ii) argue against the rejection; or (iii) present evidence to show why the claimed invention is believed to be patentable. 37 C.F.R. § 1.111 (2006). The examiner may then "allow"—that is, authorize for patenting—some or all of the claims and issue a patent pursuant to Section 151. 35 U.S.C. § 151. Alternatively, the examiner may issue another rejection. The exchange between an applicant and an examiner is commonly referred to as the **"prosecution"** of an application.

The Patent Act affords an applicant several choices upon receiving a final rejection. First, the applicant may appeal to the Board of Patent Appeals and Interferences (**"Board"**) and from there to a federal court. 35 U.S.C. §§ 134, 141, & 145. Second, Section 132(b) authorizes the applicant to file a "**request for continued examination**" **("RCE")** of the application, which typically extends examination for two more rounds. Id. § 132(b); 37 C.F.R. § 1.114 (2006).

Third, under Section 120, the applicant may file a **"continuation"** (or a "continuation-in-part") application of the initial application. 35 U.S.C. § 120. Continuation applications allow applicants to enjoy the benefit of the filing date (a.k.a. **"priority date"**) of the parent application while amending claims or offering further evidence or arguments as to patentability of the claimed invention. Id. An applicant will only receive the benefit of the earlier filing date, however, if the new application meets certain statutory requirements. See 35 U.S.C. § 120 (allowing application earlier priority date "if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application."). Significantly, although applicants may await a final rejection before filing a continuation application, Section 120 does not require them to do so, and applicants regularly file

continuation applications before receiving final rejections.

When an application claims more than one independent or distinct invention, Section 121 of the Patent Act authorizes the patent examiner to issue a **"restriction requirement,"** which requires the applicant to choose one of the claimed inventions to prosecute in the initial application and allows the applicant to file separate **"divisional applications"** to protect each of the applicant's other inventions. 35 U.S.C. § 121. Like a continuation application, a divisional application claims the priority date of the parent application. See id. Collectively, "continuation," "continuation-in-part," and "divisional" applications are commonly referred to as **"continuing applications."** See 37 C.F.R. § 1.53(b) (2006).

Once a patent issues, Section 251 of the Patent Act provides for the **"reissue"** of a defective patent. 35 U.S.C. § 251. Under this section, a patentee who mistakenly claims more or less than it has a right to claim in a patent may surrender that patent and obtain a reissued patent that corrects the error. See id. A reissue patent may expand the scope of the claims, however, only if it is applied for within two years of the original patent's issuance.

While the Patent Act sets out the general framework for the patent examination process, Congress has delegated the USPTO broad authority to "establish regulations, not inconsistent with law," which "(A) shall govern the conduct of proceedings in the Office;" "(C) shall facilitate and expedite the processing of patent applications;" and "(D) may govern the . . . conduct of agents, attorneys, or other persons representing applicants or other parties before the Office." 35 U.S.C. § 2(b)(2). The Patent Act also authorizes the USPTO to promulgate regulations pursuant to APA rulemaking procedures. See id. § 2(b)(2)(B) (citing 5 U.S.C. § 553). In Section 3, Congress expressly charged the Director with "providing policy direction" for the Office by, among other things, engaging in rulemaking. Id. § 3(a)(2). The Patent Act also provides more specific delegations of authority. See, e.g., id. § 132(b) (requiring the Director to "prescribe regulations

for the continued examination of applicants for patent at the request of the applicant"). The USPTO relied on these broad delegations of authority in promulgating its final rules.

STATEMENT OF MATERIAL UNDISPUTED FACTS

I. HISTORY OF THE RULES FOR CONTINUATION AND CLAIMS PRACTICE

Over the past decade, applicants have been filing increasing numbers of continuing applications, as well as applications containing a greater number of claims and more complex claims. See 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, 46718 (Aug. 21, 2007) ("Final Rules").[2] The number of continuing applications (other than divisional applications) as a percentage of overall filings has skyrocketed, from about 11.4 percent in fiscal year 1980 to 29.4 percent in fiscal year 2006. Id.; see also A05072.[3] Likewise, the number of claims per application has grown, from an average of about 14.4 claims in fiscal year 1990 to about 21 claims in fiscal year 2005. A07099. These filings are hindering the Office's ability to examine newly-filed applications and maintain quality examination. See 72 Fed. Reg. at 46716-18. Consequently, as of 2006, the Office's backlog of unexamined applications stood at 701,147 applications. Id. at 46790.

A substantial portion of this backlog is attributable to practices employed by applicants – some negligent, some deliberate – that unnecessarily prolong prosecution through the use of repetitive and vexatious continuing applications. For example, some applicants file deficient initial applications, relying on the availability of an endless stream of continuing applications to work out issues of patentability. See id. at 46719. Other applicants deliberately use the

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[2] The final Federal Register notice is attached hereto as Exhibit 1 and included in the administrative record at A09390-A09518.

[3] Cited excerpts of the administrative record are provided at Exhibit 2.

availability of continuing applications to delay presenting claims for examination, despite current USPTO rules that prohibit filings that intentionally prolong prosecution. See 37 C.F.R. § 10.18 (2006). Such applicants often delay submitting continuing applications to figure out what the most commercially viable form of their invention is or to obtain a competitive advantage over rivals by monitoring marketplace developments for similar inventions which may fall within the scope of yet-to-be-presented claims. See 72 Fed. Reg. at 46719. The growing number of such continuation filings are hobbling the Office's efforts to examine new filings. Without regulations that set a benchmark for the prompt presentation of claims, argument, and evidence in the application process, the USPTO risks being swamped by continuation filings.

Applications containing large numbers of claims also present difficulties for the Office; they absorb an inordinate amount of patent examining resources because they are extremely difficult to properly process and examine. See id. at 46721. The USPTO reasonably concluded that it needed to elicit assistance from applicants who impose such burdens on the Office.

Accordingly, in January 2006, the USPTO proposed new procedural rules to effect more focused and efficient examination. See Changes to Practice for Continuing Applications, Requests for Continuing Applications, Requests for Continued Examination Practice, and Applications Concerning Patentably Indistinct Claims, 71 Fed. Reg. 48 (Jan. 3, 2006); Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61 (Jan. 3, 2006) (collectively "Proposed Rules").[4] Among other rules, "Proposed Rule 78" would have restricted applicants to only one continuation application as a matter of right. See 71 Fed. Reg. at 58-59. "Proposed Rule 75" would have required applicants to provide an examination support document ("ESD") for any application that included more than ten representative claims when the applicant

[4] The initial Federal Register notices are attached hereto as Exhibit 3 and contained in the administrative record at A00001-A00023.

wanted the Office to examine every claim in the application from the outset. See id. at 67-68.

The USPTO solicited public comments on the Proposed Rules over a four month period. 72 Fed. Reg. at 46717. It received more than 500 comments and spent more than a year analyzing and considering the feedback. Id. Responding to the public's concerns, the USPTO modified the Proposed Rules and published Final Rules on August 21, 2007. See generally 72 Fed. Reg. at 46716-843 (Ex. 1).

II. OVERVIEW OF FINAL RULES CONCERNING CLAIMS AND CONTINUATIONS PRACTICE

A. Final Rules 78 and 114 Permit An Applicant to File Two Continuation or Continuation-In-Part Applications and One Request for Continued Examination Without a Petition and Showing

Seeking to encourage applicants to timely claim their inventions rather than using endless continuing applications and RCEs to do so, Final Rules 78 and 114 allow an applicant to file two continuation or continuation-in-part applications, plus a single RCE, after an initial application as a matter of right. See 72 Fed. Reg. at 46718; see also 37 C.F.R. § 1.78(d)(1)(i), (ii), & (iii) (**"Final Rule 78"**); 37 C.F.R. § 1.114(f) (**"Final Rule 114"**) (collectively **"2+1 Rule"**). If an applicant seeks to further continue prosecution at the examiner level beyond a second continuation or continuation-in-part application and an RCE, it must file a **"petition and showing"** of need. See 72 Fed. Reg. at 46719; 37 C.F.R. §§ 1.78(d)(1)(vi), 1.114(g). That petition and showing must explain why the claims, argument, or evidence could not have been presented previously.[5] If, in an extraordinary situation, an applicant believes that the petition and showing requirement would work an injustice, it may petition for waiver of the rule under 37 C.F.R. § 1.183 (2006). See 72 Fed. Reg. at 46769.

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[5] Final Rules 78(d) and 114(g) originally were to apply to all initial and continuing applications filed on or after November 1, 2007. See 72 Fed. Reg. at 46716, 46736. In light of the Court's preliminary injunction, the original effective date will have to be revised.

B. Final Rule 75 Permits An Applicant to File Five Independent Claims and Twenty-five Total Claims in Any Application Without the Examination Support Document Described in Final Rule 265

Final Rules 75 and 265 require applicants who submit an unusually large number of claims to help expedite the Office's examination by aiding its prior art search efforts. Final Rule 75 permits an applicant to present a total of five independent claims and twenty-five total claims for examination without providing any further information about the claims. See 72 Fed. Reg. at 46721; 37 C.F.R. § 1.75(b)(1) (**"Final Rule 75,"** a.k.a **"5/25 Rule"**). If an applicant wants to present more than five independent claims or twenty-five total claims, Final Rule 75 requires the applicant to provide an **examination support document** (**"ESD"**), which must contain information about the claims, before the Office issues a first Office action on the merits. 72 Fed. Reg. at 46721; 37 C.F.R. § 1.75(b)(1). An ESD is designed to assist the examiner in determining patentability of the claimed invention. 72 Fed. Reg. at 46721. The requirements for an ESD are set out in 37 C.F.R. § 1.265 (**"Final Rule 265"**), see 72 Fed. Reg. at 46842, and in supplemental guidance issued by USPTO.[6] See Ex. 4.

In light of the two continuation or continuation-in-part applications that an applicant may file as of right after the initial application, an applicant may ultimately present fifteen independent claims and seventy-five total claims for each invention without an ESD. Id. at 46718, 46721.

C. Additional Sections of Final Rules 78 and 75 Support the Main Provisions

Other sections of Final Rules 75 and 78 buttress the USPTO's efforts to better focus examination through the 5/25 Rule and the 2+1 Rule. Final Rules 75(b)(2) and (b)(5)(c) define

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[6] Final Rule 75 originally was to apply to all applications filed on or after November 1, 2007, and all pending applications for which a first Office action on the merits was not mailed before November 1, 2007. Id. at 46716, 46728. In light of the Court's preliminary injunction, the original effective date will have to be revised.

how claims referring to different statutory classes of invention[7] and how multiple dependent claims, respectively, will be counted for purposes of the 5/25 Rule. 72 Fed. Reg. at 46836-37; 37 C.F.R. §§ 1.75(b)(2) & (b)(5)(c). Final Rule 78(a) defines the terms "divisional," "continuation," and "continuing application" so that there is no confusion as to how the 2 +1 Rule applies. 72 Fed. Reg. at 46837; 37 C.F.R. § 1.78(a). Final Rule 78(d)(1) clarifies that there is no such thing as a "voluntary divisional" under 35 U.S.C. § 121 and that a continuation-in-part application cannot be filed off a divisional. 72 Fed. Reg. at 46838; 37 C.F.R. § 1.78(d). Finally, Final Rule 78(f)(1) requires patent applicants to identify related patent applications and Final Rule 78(f)(2) sets forth a rebuttable presumption that applications that meet certain conditions contain patentably indistinct claims. These rules prevent applicants from evading the 2 + 1 and 5/25 Rules by attempting to simultaneously prosecute virtually indistinguishable applications. 72 Fed. Reg. at 46840; 37 C.F.R. §§ 1.78(f)(1) & (2).

D. Final Rule 142 Provides Additional Flexibility for Applicants Claiming More than One Invention in a Single Application

Final Rule 142 – which Plaintiffs have not challenged – allows any applicant who has disclosed multiple inventions in a single application to suggest a restriction requirement. See 72 Fed. Reg. at 46726; 37 C.F.R. § 1.142(c) (**"Final Rule 142"**). A **"suggested restriction requirement" ("SRR")** allows the applicant to voluntarily propose the same type of restriction requirement that patent examiners may require under 35 U.S.C. § 121. If the USPTO accepts the SRR, the applicant may file a divisional application for each invention. Each divisional application is treated under the Final Rules as the initial application in a family, thereby enabling

[7] In 35 U.S.C. § 101, Congress set forth four kinds of inventions that may be patented: (i) processes; (ii) machines; (iii) articles of manufacture; and (iv) compositions of matter. These four kinds of inventions are referred to as "statutory classes of invention."

an applicant to file two continuation applications, plus a single RCE, in each divisional application family without any petition and showing. See 72 Fed. Reg. at 46732; 37 C.F.R. § 1.78(d)(1)(ii) & (iii). Final Rule 142 thus helps ensure that an applicant who has multiple inventions will be able to claim each of those inventions under the Final Rules.

E. The USPTO Structured the Final Rules to Ensure that Applicants with Pending Applications Could Receive the Patent Protection They Seek

In promulgating the Final Rules, the USPTO aimed to ensure that applicants would have numerous opportunities to secure patent protection for disclosed, but unclaimed, inventions. First, before the Final Rules were originally to go into effect on November 1, 2007, applicants were given more than two months after the Final Rules were published to file as many continuation or continuation-in-part applications as they desired, or to amend their pending applications. Second, applicants could file "one more" continuation or continuation-in-part application if the applicant (i) had an application family that already contained two continuation or continuation-in-part applications and (ii) did not file any applications in a given application family between August 21, 2007 and the effective date. See 72 Fed. Reg. at 46736-37. In light of the preliminary injunction, the Office intends to revise the time period applicable to the "one more" provision. That is, an applicant will be able to file "one more" continuation or continuation-in-part application so long as it did not file any applications in a given application family between August 21, 2007 and the new effective date of the Final Rules. Third, as noted above, in that "one more" application, the applicant may claim more than one of its disclosed, but unclaimed, inventions and offer an SRR. See 72 Fed. Reg. at 46726; 37 C.F.R. § 1.142(c). If the SRR is accepted, the applicant can start multiple new families of applications by filing separate divisional applications for each invention. See id. at 46732; 37 C.F.R. § 1.78(d)(1)(ii) & (iii). Fourth, the applicant can expand each divisional family by filing as many as two continuation or continuation-in-part applications and

one RCE in the family without presenting any petition and showing. Hence, under the Final Rules, applicants have numerous opportunities to secure patent protection for their previously disclosed, but unclaimed, inventions.

SUMMARY JUDGMENT STANDARD

Summary judgment should be granted where the evidence in the record "show[s] that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); see Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986). APA suits are well-suited for summary judgment because "when an agency action is challenged . . . [t]he entire case on review is a question of law, and only a question of law." Marshall County Health Care Auth. v. Shalala, 988 F.2d 1221, 1226 (D.C. Cir. 1993). In such cases, the "focal point" for summary judgment review "should be the administrative record already in existence, not some new record made initially in the reviewing court." Camp v. Pitts, 411 U.S. 138, 142 (1973). Here, the USPTO is entitled to judgment as a matter of law on each of Plaintiffs' claims.

ARGUMENT

I. THE FINAL RULES DO NOT VIOLATE THE PATENT ACT

Exercising authority expressly delegated to it by Congress, see 35 U.S.C. §§ 2(b)(2), 132(b), the USPTO promulgated reasonable rules that do not conflict with the Patent Act. The Court should uphold the Final Rules as lawful under the APA. See 5 U.S.C. §§ 706(2)(A), (C).

A. The USPTO's Exercise of Its Rulemaking Authority Qualifies for Chevron Deference

The USPTO qualifies for Chevron deference in its interpretation of the Patent Act because it acted well within its statutory grant of rulemaking authority in enacting the Final Rules. See Chevron USA, Inc. v. NRDC, Inc., 467 U.S. 837 (1984). Under Chevron, if Congress "has directly spoken to the precise question at issue" and its intent is clear, then "the court, as well as

the agency, must give effect to [that] unambiguously expressed intent." Id. at 842-43. If, however, "the statute is silent or ambiguous with respect to the specific issue," the court must defer to the agency's rule as long as it is "based on a permissible construction of the statute." Id. at 843. As the Supreme Court recognized in National Cable & Telecommunications Ass'n v. Brand X Internet Services, 545 U.S. 967, 982 (2005), "Chevron's premise is that it is for agencies, not courts, to fill statutory gaps." This is because such gap-filling "involves difficult policy choices that agencies are better equipped to make than courts," id. at 981, especially in "technical and complex" fields, Chevron, 467 U.S. at 865.

Regulations that are "promulgated pursuant to congressional authority" are reviewed under the Chevron framework. N.L.R.B. v. United Food and Commercial Workers Union, Local 23, AFL-CIO, 484 U.S. 112, 123 (1987); see also Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 696 (1991) ("When Congress, through express delegation or the introduction of an interpretive gap in the statutory structure, has delegated policy-making authority to an administrative agency, the extent of judicial review of the agency's policy determinations is limited."). As the Supreme Court has recognized, "express congressional authorizations to engage in the process of rulemaking" are "a very good indicator of delegation meriting Chevron treatment." United States v. Mead Corp., 533 U.S. 218, 229 (2001).

Congress has expressly delegated the USPTO rulemaking authority. See 35 U.S.C. §§ 2(b)(2), 132. In promulgating the Final Rules, the USPTO acted pursuant to its statutory authority to "establish regulations, not inconsistent with law" to "govern the conduct of proceedings in the Office." Id. § 2(b)(2)(A). The USPTO further exercised its power to establish regulations that will "facilitate and expedite the processing of patent applications," id. § 2(b)(2)(C), and to "govern the . . . conduct of agents, attorneys, or other persons representing applicants or other

parties before the Office," id. § 2(b)(2)(D). As the Federal Circuit has recognized, the Section 2(b)(2) powers are "broad" delegations of authority. Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006). Indeed, 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) (internal quotation marks omitted).

The Final Rules fall squarely within these broad delegations of rulemaking authority. Final Rules 78 and 114 address how many times applicants may appear before the agency, revising their older applications, before they must justify their further continuation applications or RCEs by submitting a petition to the Office. Final Rules 75 and 265 address when applicants who file a large number of claims must assist the Office in understanding those claims by providing information about them. Thus, the Final Rules specifically "govern the conduct of proceedings in the Office" by focusing, "facilitat[ing] and expedit[ing]" the patent application process. 35 U.S.C. § 2(b)(2). To the extent that Final Rules 78 and 114 seek to curtail delays in prosecution – consistent with current prohibitions on deliberate delay, 37 C.F.R. § 10.18(b)(2) (2006) – they support the USPTO's regulation of those practicing before the Office.

Furthermore, Congress has expressly charged the Director with "providing policy direction" for the Office. 35 U.S.C. § 3(a)(2)(A). Director Dudas exercised that authority in enacting the Final Rules. And, as the Supreme Court observed in Mead, "it is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." 533 U.S. at 230 (citing APA notice and comment proceedings in Smiley v. Citibank (South Dakota), N.A., 517 U.S. 735 (1996)). In the Patent Act, Congress authorized the USPTO to promulgate regulations pursuant to APA

rulemaking procedures. See 35 U.S.C. § 2(b)(2)(B) (citing 5 U.S.C. § 553).

Federal Circuit precedent confirms that the Final Rules qualify for Chevron deference. In Lacavera, the Federal Circuit reasoned that "[b]ecause the PTO is specifically charged with administering this statute, we analyze a challenge to the statutory authority of its regulations under the Chevron framework." Lacavera, 441 F.3d at 1383 (upholding a USPTO regulation as a proper exercise of § 2(b)(2) rulemaking authority); see also Centigram Commc'ns Corp. v. Lehman, 862 F. Supp. 113, 117 (E.D. Va. 1994) (Ellis, J.) (applying Chevron framework in upholding USPTO rule). The Federal Circuit likewise deferred to the USPTO's rules in Stevens, holding that rules setting burdens of proof in interference proceedings were "a permissible exercise of the Office's authority" under Section 2(b)(2). See 366 F.3d at 1333. Similarly, in Morganroth v. Quigg, 885 F.2d 843 (Fed. Cir. 1989), the Federal Circuit held that the Director's interpretation of "narrow technical and specialized statutory and regulatory provisions" – like the provisions at issue here – were "entitled to considerable deference."[8] Id. at 848.

Indeed, the tradition of affording substantial deference to USPTO rules dates back to before the Supreme Court even decided Chevron. In Application of Rubinfield, 270 F.2d 391 (CCPA 1959), the Federal Circuit's predecessor court, the Court of Customs and Patent Appeals ("CCPA"), observed that "the rules of the Patent Office have the force and effect of law unless

[8] Notably, the Federal Circuit decided Lacavera, Stevens, and Morganroth after the enactment of the Federal Courts Improvement Act, Pub. L. No. 97-164, 96 Stat. 25 (1982). Thus, GSK's suggestion that this legislation somehow diminished the deference owed to the USPTO is meritless. See GSK Am. Compl. ¶ 36. Indeed, in Dickinson v. Zurko, 527 U.S. 150 (1999), the Supreme Court made clear that the USPTO is owed the same deference under the APA from the Federal Circuit that the typical agency is owed by the courts. Id. at 165. The Court thereby overruled In re Leuders, 111 F.3d 1569, 1577 (Fed. Cir. 1997), upon which GSK relies.

they are inconsistent with statutory provisions."[9] Id. at 395. Finding no "clear conflict" between the USPTO's rule and the Patent Act, the CCPA deferred to "Rule 153," which limited design patents to a single claim. Id. at 395-96. The Final Rules, which do not limit applicants even to 5/25 claims, similarly qualify for Chevron deference.

B. The Final Rules Warrant Chevron Deference Whether They Are "Procedural" or "Substantive," Though They Are Procedural Rules

In applying what would come to be known as Chevron deference, the CCPA in Rubinfield drew no distinction between whether the USPTO's rules could be characterized as "substantive" or "procedural" – a false dichotomy that GSK relies upon, with resort to *dicta* from Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), to suggest that the USPTO lacked authority to promulgate the Final Rules. See GSK Am. Compl. ¶ 9. Besides resting on a distinction that neither the Supreme Court (in Chevron) nor a preceding Federal Circuit panel (in Rubinfield) have recognized, Merck is readily distinguishable. Merck did not involve a rulemaking; rather, the USPTO had issued a policy statement concerning term adjustments on issued patents. Its policy statement was not a regulation that "govern[ed] the conduct of proceedings in the Office." 35 U.S.C. § 2(b)(2)(A). For this reason, the Federal Circuit considered the policy statement to be "substantive."[10] Merck, 80 F.3d at 1550-51.

Merck does not bind this Court for another important reason. As the Supreme Court recently explained in Brand X, "[a] court's prior judicial interpretation of a statute trumps an

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[9] The Federal Circuit has adopted the decisions of the CCPA as binding precedent. See South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

[10] The Federal Circuit's later reference to Merck in Eli Lilly & Co. v. Bd. of Regents of Univ. of Washington, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003), was pure *dictum*, given that Eli Lilly did not involve a challenge to a regulation, but rather to the USPTO's interpretation of its own regulation.

agency construction otherwise entitled to Chevron deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." 545 U.S. at 982 (emphases added). Put differently, an agency may interpret a statute contrary to a court's prior interpretation, so long as the prior interpretation was not held to be the one and only, unambiguous, meaning of the statute. Id. at 984-85.

When referencing an earlier version of Section 2(b)(2)(a) – then codified at 35 U.S.C. § 6(a) – the Federal Circuit in Merck did not purport to interpret the statute at all, much less to define its unambiguous meaning. 80 F.3d at 1549-50. Instead, the court simply restated what it perceived to be an earlier interpretation of Section 6 in Animal Legal Defense Fund ("ALDF") v. Quigg, 932 F.2d 920 (Fed. Cir. 1991). See Merck, 80 F.3d at 1550 (citing ALDF). In ALDF, however, the Federal Circuit was not interpreting Section 6 to decide whether the USPTO should receive Chevron deference, but rather to determine if the agency should have used APA notice and comment procedures when it issued a policy notice. ALDF, 932 F.2d at 931. Moreover, the court was not contrasting "substantive" and "procedural" rules at all; rather, it was trying to determine if the USPTO's policy notice was "substantive" or "interpretative" under 5 U.S.C. § 553(b). Id. at 927 (emphasis added). Thus, far from limiting the USPTO's Section 6 rulemaking to "procedural" rules, the ALDF court did not even address the issue.

Even if it were relevant whether the USPTO had engaged in "procedural" or "substantive" rulemaking, which it is not, the USPTO's rulemaking is not "substantive" even under the Federal Circuit's understanding of that term in ALDF. There, the court noted that "a substantive declaration with regard to the Commissioner's interpretation of the patent statutes, whether it be section 101, 102, 103, 112 or other section, does not fall within the usual interpretation of" the USPTO's Section 6 powers. 932 F.2d at 930. The Final Rules do not implicate the core

patentability requirements set out in 35 U.S.C. §§ 101, 102, 103, or § 112. Rather, they impose procedural requirements that aim, in the case of Final Rules 78 and 114, to curb repetitive or otherwise vexatious filings by requiring applicants who submit more than two continuation applications or one RCE in an application family to justify their excess filings, and, in the case of Final Rule 78, to assist the agency in examining particularly burdensome applications through submission of an ESD.

That these requirements are procedural is underscored by the similarity between Final Rules 78 and 114 and 28 U.S.C. § 358(a), which authorizes the judicial councils of the federal circuits to prescribe rules "for the conduct of proceedings" relating to complaints of judicial misconduct or disability. Pursuant to § 358(a), Federal Circuit Rule 1(f) Governing Complaints of Judicial Misconduct and Disability bars complaints from anyone who has previously "filed vexatious, repetitive, harassing, or frivolous complaints" or who "has otherwise abused the complaint procedure." Similarly, under the Rules Enabling Act, 28 U.S.C. § 2071(a), the Supreme Court has the authority to prescribe rules "for the conduct of [its] business." Pursuant to that authority, the Supreme Court may not only deny *in forma pauperis* status to a frivolous filer, see Sup. Ct. Rule 39.8, but can refuse to accept any civil petitions for *certiorari* at all from a repeat frivolous filer, see Martin v. D.C. Court of Appeals, 506 U.S. 1 (1992) (per curiam). Just as these rules are undoubtedly "procedural," Final Rules 78 and 114 are similarly procedural rules.

Furthermore, as the CCPA and Federal Circuit recognized before and after Merck, even if the Final Rules – like any procedural rules – have some collateral substantive consequences, this would not render them "substantive." In re Van Ornum, 686 F.2d 937, 945 (CCPA 1982); see also Stevens, 366 F.3d at 1333-34 (post-Merck case upholding use of regulations to establish burden of proof). As the CCPA stated in deferring to and upholding a USPTO rule:

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

In re Van Ornum, 686 F.2d at 945.

In any event, even if the Court understood the Final Rules to be substantive in nature, Congress has expressly authorized the USPTO to promulgate rules using APA notice and comment procedures. See 35 U.S.C. § 2(b)(2)(B) (citing 5 U.S.C. § 553). Under Section 553 of the APA, notice and comment procedures need only be employed when a rule is "substantive." 5 U.S.C. § 553(b). The USPTO utilized notice and comment procedures in this rulemaking.

Ultimately, this Court must apply the law of the Supreme Court, and Chevron itself draws no distinction between "substantive" and "procedural" rules for purposes of deciding how much deference they are owed. Under Chevron, as long as the USPTO's rule fits within a reasonable construction of its statutory rulemaking authority and does not offend express statutory provisions, deference is required. That is exactly the case here. Thus, Chevron deference is warranted.

Even if the Final Rules did not qualify for Chevron deference, the agency would still be entitled to Skidmore deference, and the Final Rules would still withstand judicial scrutiny under that deferential standard.[11] See Merck, 80 F.3d at 1550 (citing Skidmore v. Swift & Co., 323 U.S. 134 (1944)).

C. The Final Rules are Consistent with the Patent Act

1. Final Rule 78 Concerning Continuing Applications Comports With Section 120 of the Patent Act

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[11] Under Skidmore, the weight accorded to the exercise of administrative judgment "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." Skidmore, 323 U.S. at 140.

Plaintiffs err in alleging that Final Rule 78 conflicts with Section 120 of the Patent Act. 35 U.S.C. § 120. For Final Rule 78 to run afoul of that section, the Patent Act would have to unambiguously provide that a patent applicant may file an unlimited number of continuing applications – no matter how delayed those applications might be or how much they burden the USPTO. It does not. Nothing in the text, history, or case law interpreting Section 120 supports Plaintiffs' view that the section is a license for delay, depriving the USPTO of authority to make regulations requiring the timely presentation of claims, evidence and argument.

Section 120 provides:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in [a previously filed application], which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. . . .

35 U.S.C. § 120. Section 120 simply establishes a mechanism by which a later-filed application may take the priority date of a pending prior-filed application. In short, it provides that an applicant will benefit from the prior-filed application's filing date only "if" the applicant complies with the requirements of the statute. Id. The section says nothing about whether the USPTO may impose reasonable conditions on how many later-filed continuation applications may properly be filed without justification. Id. Where a statute is silent, the agency may promulgate reasonable regulations. See Chevron, 467 U.S. at 842-43.

By stating that a continuation application "shall have the same effect as" the prior-filed application, Section 120 provides the benefit that the Office will not reject a later, properly-filed continuation application on the ground that art published between the prior-filed application and the later-filed application renders the invention in the later-filed application unpatentable, see 35

U.S.C. §§ 102, 103. More importantly, it assures against such a challenge in court, an assurance that had only been provided in case law prior to Section 120's enactment in 1952. See, e.g., Godfrey v. Eames, 68 U.S. 317, 324 (1863). Under Final Rule 78, properly-filed continuation applications will also still be accorded Section 120's protections against invalidation by prior-filed applications. Final Rule 78 merely puts reasonable conditions on when continuation applications may be considered properly "filed" under that section. 35 U.S.C. § 120. Thus, the rule goes to the core of the USPTO's power to "govern the conduct of proceedings in the Office," id. § 2(b)(2)(A), while still allowing applicants to obtain the benefits afforded by Section 120.

If Section 120 were the license for indefinite delay that Plaintiffs claim, it would impermissibly conflict with at least three other sections of the Patent Act. See Regions Hosp. v. Shalala, 522 U.S. 448, 466 (1998) ("[T]he words of a statute are not to be read in isolation; statutory interpretation is a 'holistic endeavor.'") (emphasis original) (quoting United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., 484 U.S. 365, 371 (1988)). First, Section 112 directs that a patent application's specification "shall conclude with 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. The section thus assumes that applicants will, in good faith, claim what they regard as their invention at the time they file an application – not at some later, commercially advantageous time. Thus, in Johnson & Johnston Assocs. v. R.E. Service Co., 285 F.3d 1046, 1055 (Fed. Cir. 2002), the court reiterated that what a patent disclosed but did not claim was dedicated to the public. As the court noted, this rule was not only for the benefit of the public after a patent issued, but also for the benefit of the examiner during the application process. Id. at 1052. If Section 120 permitted applicants to delay claiming their inventions at will, as Plaintiffs contend, the command to "conclude with one or more claims particularly pointing out

and distinctly claiming" the invention would be severely undermined. 35 U.S.C. § 112, ¶ 2.

Second, Section 121 grants discretion to the Director whether to restrict an application to a single invention and thus allow for delayed examination of claims in a separate divisional application. See 35 U.S.C. § 121. Under Plaintiffs' reading of Section 120, however, applicants can use continuation filings to negate that discretion simply by delaying presentation of claims to the Office when an application discloses multiple inventions.

Third, under Section 251, a patentee may surrender a patent and obtain reissue of it to correct good faith errors. See 35 U.S.C. § 251. Such a reissue patent may only expand the scope of the claims, however, if applied for within two years of the original patent's issuance. Plaintiffs' theory would allow applicants to nullify Section 251 by filing continuations solely to delay prosecution after a first patent has issued and enter broadened claims in some future continuation long after the two-year limit. "Statutory interpretations that 'render superfluous other provisions in the same enactment' are strongly disfavored." Nat'l Endowment for the Arts v. Finley, 524 U.S. 569, 609 (1998) (quoting Freytag v. Commissioner, 501 U.S. 868, 877 (1991)).

The history of Section 120 reinforces what is evident from the Patent Act's text. As GSK has conceded, when Congress enacted Section 120 as part of the Patent Act of 1952, it intended to codify certain practices that the USPTO had adopted without explicit statutory authority. See S. Rep. No. 82-1979 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2400 ("Sections 120 and 121 express in the statute certain matters which exist in the law today but which had not been written into the statute…."); see, e.g., Godfrey, 68 U.S. at 324 (providing for continuation applications). In codifying these agency practices, the Congress of 1952 would not have intended for Section 120 to give patent applicants the sole and complete discretion to delay presenting claims, arguments, or evidence to the agency. Before 1952, the Supreme Court had already held that deliberate delay by applicants was unacceptable:

> Any practice by the inventor and applicant for a patent through which he deliberately and without excuse postpones beyond the date of the actual invention, the beginning of the term of his monopoly, and thus puts off the free public enjoyment of the useful invention, is an evasion of the statute and defeats its benevolent aim.

Woodbridge v. United States, 263 U.S. 50, 56 (1923) (emphasis added). Likewise, in Webster Elec. Co. v. Splitdorf Elec. Co., 264 U.S. 463 (1924), the Court held that, absent special circumstances, a patent could not be enforced against an intervening user of the invention if the applicant had delayed more than two years before presenting the claims for examination. Thus, Section 120, in codifying continuations practice, was not intended to override the law's prohibition on intentional delay.

Indeed, contrary to Plaintiffs' interpretation of Section 120, the Federal Circuit has definitively interpreted that section as preserving the USPTO's authority to place reasonable conditions on continuation filings. In In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002), the court concluded that the USPTO could – even without enacting a regulation – reject a continuation application on the ground of "prosecution laches," that is, on the ground that the applicant delayed too long in filing the application. See id. at 1367-68; see also Symbol Techs., Inc. v. Lemelson Med. Educ. & Research Found., L.P., 277 F.3d 1361, 1365-66 (Fed. Cir. 2002). The court found that this authority was inherent in the USPTO's authority under 35 U.S.C. § 2. Id. at 1368.

The court further opined that the USPTO's power went beyond mere enforcement of prosecution laches. "Like other administrative agencies," the Federal Circuit held, "the PTO may impose reasonable deadlines and requirements on parties that appear before it." Id. Final Rule 78 is merely an effort to impose reasonable requirements on the filing of continuing applications.

In re Henriksen, 399 F.2d 253 (CCPA 1968), relied on by Plaintiffs, is not to the contrary and does not preclude this Court from deferring to the Final Rules. There, an examiner issued a rejection on the ground that Section 120 imposed an absolute limit on the number of continuation applications one could file under that provision, and the Board sustained the rejection. Id. at

1386-87. As an initial matter, Henriksen is irrelevant to this Court's Chevron analysis because the CCPA did not hold that Section 120 unambiguously disallows putting conditions on continuation filings. See Brand X, 545 U.S. at 982. Rather, the CCPA merely reversed the Board's decision that Section 120 affirmatively imposed an absolute limit on the number of continuing applications without the agency first engaging in notice and comment rulemaking. Id. at 262. The court did not hold that Section 120 unambiguously precludes efforts like the USPTO has undertaken here, where the Office has engaged in notice and comment rulemaking and has not imposed any absolute limit on the number of continuing applications.[12]

As the Federal Circuit explained in Bogese, the holding of Henriksen was "limited." Bogese, 303 F.3d at 1368 n. 6. "Nowhere does Henriksen suggest or imply that the PTO must allow dilatory tactics in the prosecution of applications or that the PTO lacks inherent power to prohibit unreasonable delay in prosecution." Id. Final Rule 78 represents a reasonable effort to ensure that undue delay in the prosecution of continuing applications does not continue to hamper the quality and efficiency of patent examination. See generally 72 Fed. Reg. at 46716-18. As Bogese recognized, Section 120 was not intended to authorize purposeful and indefinite delay in presenting claims to the Office, as GSK has conceded is its regular practice.[13] See 1:07cv1008, Dkt. No. 14, Mem. in Support of Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, p. 5.

Although continuation practice, when properly employed, may help assist the give-and-

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[12] Henriksen also did not account for the waiver provision of 37 C.F.R. § 1.183 (2006), which provides that if extraordinary circumstances exist that would cause application of the Final Rules to create an injustice, the applicant may seek waiver of the requirement.

[13] The Federal Circuit has taken note of GSK's delay tactics. See Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1382 (Fed. Cir. 2003) ("GSK took about a quarter-century to prosecute the 1985 and 2000/01 patents to issue. This record does not explain that delay.").

take between examiner and applicant, neither Congress nor the courts contemplated that it should be a device for indefinite patent prosecution or that it would prevent the USPTO from reasonably regulating the proceedings of the Office.

2. *Final Rule 114 Concerning RCEs Is Consistent with Section 132*

Plaintiffs similarly err in arguing that 35 U.S.C. § 132 requires the USPTO to allow patent applicants to file unlimited, unconditional requests for continued examination. Section 132(a) provides that an applicant whose claim is rejected may seek continued examination of that claim, but it does not speak in terms of multiple continued examinations or provide any right to unlimited continued examinations.[14] See 35 U.S.C. § 132(a). Under Section 132(b), Congress has expressly directed the USPTO to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." 35 U.S.C. § 132(b). Final Rule 114 does so, 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 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). Nothing in Section 132

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[14] Section 132(a) provides:

> Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. § 132(a).

unambiguously precludes this reasonable requirement.[15]

While many of the same arguments that apply to Final Rule 78 also apply to Final Rule 114, the command in Section 132(b) to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant" is an additional affirmative grant of rulemaking authority, beyond Section 2(b)(2), which supports Final Rule 114. This sweeping grant of authority does not have any of the supposed "procedural" limitations that Plaintiffs mistakenly contend circumscribe the USPTO's authority under Section 2(b)(2). Consequently, even if the Court were to question the USPTO's authority to enact Final Rule 78 pursuant to Section 2(b)(2), Final Rule 114 should still stand.

3. Final Rules 75 and 265 Concerning Claims and the Examination Support Document Are Consistent with Sections 111, 112, 131 and 151

The Court should also uphold Final Rules 75 and 265 as a reasonable exercise of the USPTO's Section 2(b)(2) authority. Sections 111, 112, 131, and 151 of the Patent Act simply do not address whether the Office may require applicants who file a burdensome number of claims to submit an ESD in order to aid the Office in examining their claims. See 35 U.S.C. § 111 & 112. The Court should thus afford Chevron deference to the USPTO's reasonable regulations.

Section 111(a) merely sets forth certain required elements of a patent application. See 35 U.S.C. § 111(a) (explaining that a written application must include a specification, a drawing, and an oath, along with fees). It says nothing about whether the USPTO may require additional information after the application is filed, or in aid of its examination of the application.

Accordingly, the Federal Circuit has repeatedly upheld USPTO rules that require

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[15] Section 132(b) was promulgated in 1999, and to date, there is no case law definitively interpreting the section. See Fiscal Year 2000 Consolidated Appropriations Act, Pub. L. No. 106-113, § 4403, 113 Stat. 1501, 1501A-560 (1999). There also is no significant legislative history that might shed further light on the section.

applicants to submit information beyond the application itself. See, e.g., 37 C.F.R. § 1.56 (2006) (imposing duty on applicants to disclose all information that the applicant knows to be material to patentability); id. § 1.105 (2006) (allowing patent examiners, in the course of examination, to "require the submission . . . of information as may be reasonably necessary to properly examine or treat" the application). For example, in Bruno Independent Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348 (Fed. Cir. 2005), the Federal Circuit upheld the Office's finding of inequitable conduct by an applicant who failed to disclose information pursuant to Rule 56. Similarly, in Star Fruits S.N.C. v. United States, 393 F.3d 1277 (Fed. Cir. 2005), the court upheld Rule 105 as being in accordance with the "inherent authority of the Office to require information from an applicant." Id. at 1282 (citing 35 U.S.C. § 2(b)(2)); see also Hyatt v. Dudas, 492 F.3d 1365 (Fed. Cir. 2007). Final Rules 75 and 265 similarly comply with Section 111.

Section 112 requires that the specification of the application have "one or more claims." 35 U.S.C. § 112, ¶ 2. Thus, while Section 112 sets a floor on the number of claims that must be submitted in an application, it does not prohibit the Office from requiring applicants who file a great number of claims to assist the Office by providing additional information. The CCPA rejected a similar reading of Section 112 in a challenge to a much more restrictive rule in Rubinfield, 270 F.2d at 395. There, the USPTO rule at issue, former Rule 153, imposed an absolute limit on the number of claims in a design patent.[16] Rule 153 restricted applications for design patents to only one claim, with no exceptions. The applicant believed that he was entitled to three claims, but the Office rejected his claims under the single claim limit of Rule 153. See id. at 392. The Rubinfield Court found no clear conflict between Section 112 and a rule that limits design applicants to a single claim:

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[16] 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).

> While 35 U.S.C. § 112 states that 'The specification shall conclude with one or more claims,' that provision does not necessarily mean that every applicant shall, as a matter of right, be entitled to present a plurality of claims regardless of the nature of the invention involved.

Id. at 707 (emphasis added). If the USTPO can impose an absolute limit of one claim, consistent with Section 112, in design cases, it certainly can require applicants who file more than five independent claims or more than twenty-five total claims to submit additional information to assist in examination without contravening Section 112.

Finally, Sections 131 and 151 merely require the Director to issue a patent if the applicant is entitled to one under the law. See 35 U.S.C. §§ 131, 151. These sections say nothing about whether the USPTO may require submission of an ESD if the 5/25 threshold is met to aid the patent examiner in determining whether the applicant is, in fact, entitled to a patent under the law.

In the absence of language in Sections 111, 112, 131, or 151 prohibiting Final Rules 75 and 265, and in view of USPTO's authority to issue regulations that "govern the conduct of proceedings in the Office" and "facilitate and expedite the processing of patent applications," 35 U.S.C. §§ 2(b)(2)(A), (C), the USPTO's reasonable rules to assist examiners are entitled to the Court's deference.

4. Tafas's Remaining Challenges to Final Rules 75 and 78 Are Meritless

Finally, the USPTO will briefly address the additional challenges that Tafas alone raises to other sections of the Final Rules. See Tafas Am. Compl. ¶ 56. Each of these allegations misapprehends the Final Rules, existing USPTO rules, the Patent Act, and/or the APA.[17]

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[17] Tafas has not alleged that he has the types of applications that form the basis for many of his alleged theories. For example, Tafas's referenced applications do not contain any multiple dependent claims or claims referencing different statutory classes of invention. Tafas Am. Compl. ¶ 56 (a). Further, Tafas has not alleged that he has any: (1) divisional applications, id. ¶¶ 56(b), (f), (g) & (n); (2) reissue applications, id. ¶ 56(k); (3) applications subject to federal march-in rights, id. ¶¶ 56(l) & (m); or (4) applications maintained in confidence, id. ¶ 56(h).

a. Final Rules 75(b)(2) and (b)(5)(c) Do Not Violate the Patent Act

In paragraph 56(a) of his Amended Complaint, Tafas challenges Final Rule 75 on two grounds. Tafas first asserts that Final Rule 75(b)(5)(c)[18] violates 35 U.S.C. §§ 41 and 112 by altering the way multiple dependent claims are counted for purposes of determining whether an application exceeds the 5/25 Rule. The provision in Final Rule 75 relating to multiple dependent claims is not new. Final Rule 75(b)(5)(c) provides in pertinent part: "For fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein." 72 Fed. Reg. at 46837 (emphasis added). Current Rule 75(c) contains nearly identical language, except for the additional phrase "and for purposes of paragraph (b) of this section." See 37 C.F.R. § 1.75(c) (2006) ("For fee calculation purposes, under § 1.16, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein."). The added language in Final Rule 75(b)(5)(c) is intended to address the 5/25 Rule, which is a new circumstance under which multiple dependent claims must be counted. Final Rule 75(b)(5)(c), like existing Rule 75(c), is consistent with the Patent Act, as it does not change the methodology for counting multiple dependent claims. See 35 U.S.C. §§ 41(a)(2), 112.

Tafas next alleges that Final Rule 75(b)(2) improperly alters the way the Patent Act counts claims to multiple statutory classes of inventions. Tafas Am. Compl. ¶ 56(a). Final Rule 75(b)(2) appropriately treats claims that reference different statutory classes of inventions as independent claims. It is well-settled that a single claim directed to multiple statutory classes of inventions is improper. See, e.g., IPXL Holdings v. Amazon.com, Inc., 430 F.3d 1377, 1384 (Fed. Cir. 2005). Further, dependent claims necessarily include and further limit the claims to which they refer. 35

[18] In paragraph 56(a) of his Amended Complaint, Tafas incorrectly cites Final Rule 75(b)(4) rather than Final Rule 75(b)(5)(c) regarding the definition of multiple dependent claims.

U.S.C. § 112, ¶ 4. Accordingly, if a claim drawn to one statutory class of invention refers to another claim of a different statutory class of invention, it would be improper to treat it as a dependent claim because it would necessarily incorporate the elements of the other claim and include two statutory classes of invention within a single claim. Thus, that Final Rule 75 treats such a claim as independent is consistent with the Patent Act.

b. Tafas's Remaining Final Rule 78 Allegations Lack Merit

Tafas's numerous theories concerning how Final Rule 78 allegedly violates the Patent Act are also in error. *First*, Tafas alleges that Final Rule 78(d)(1)(iii) will prevent him from filing "continuation-in-part applications off of divisional applications," Tafas Am. Compl. ¶ 56(b), and from filing "continuation-in-part/divisional application hybrid[s]," id. ¶ 56(g). Final Rule 78(d)(1)(iii) simply follows the longstanding requirement that a "divisional" application can claim only subject matter that was disclosed and claimed in an earlier parent application and carved out by a restriction requirement. 35 U.S.C. § 121. If a divisional application includes new subject matter, it is properly called a continuation-in-part. See e.g., In re Tenney, 117 F.2d 377 (CCPA 1941) (affirming examiner's finding that because an application was not "a true division" of the patent application, the word "divisional" should be changed to "continuation-in-part"); see also Archie R. McCrady, Patent Office Practice 111-12 (1928) ("A divisional application is one that is carved out of a prior or parent application. . . . If there is a substantial departure from the subject-matter of the parent application, it is not a division, although it may be a continuation in part."); U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure ("MPEP") § 201.06 (8th ed. 2001, rev. Aug. 2006) (providing same definition for a "divisional" application). The law has never allowed an applicant to file a continuation-in-part application off of a divisional application and obtain the protections of 35 U.S.C. § 121.

Second, Tafas alleges that Final Rule 78(d)(iv)(C) will prevent him from claiming priority

to "a divisional application from which priority has already been claimed in an international application." Tafas Am. Compl. ¶ 56(n). Tafas is mistaken. The Final Rules do not prohibit such a practice. If a restriction requirement is issued under 35 U.S.C. § 121, an applicant is free to file a divisional application claiming priority to the parent application in which the restriction issued.

Third, Tafas alleges that Final Rule 78(d) violates the Patent Act because it prevents him from filing an "involuntary divisional with additional claims beyond those originally existing in the parent application or, once filed, amending the claim[s], so as to include disclosed but not claimed subject matter." Tafas Am. Compl. ¶ 56(f). Tafas misunderstands Final Rule 78(d). As already explained, an applicant may file a divisional application when the USPTO issues a restriction requirement under 35 U.S.C. § 121. Such a divisional application must be directed to the subject matter carved out by the restriction requirement, but the applicant may amend existing claims or add new claims in the divisional so long as those claims are directed to the same subject matter carved out by the restriction requirement.

Fourth, Tafas alleges that Final Rule 78(a) prevents him from filing a divisional application in a reissue application under 35 U.S.C. § 251. Tafas Am. Compl. ¶ 56(k). Again, Tafas misapprehends the rule. Final Rule 78(a) does not prohibit Tafas from filing a divisional application in a reissue application provided he received a restriction requirement under 35 U.S.C. § 121.[19] In fact, Final Rule 78(d) does not single out reissue applications in any way; it treats them exactly like all other kinds of applications.

Fifth, Tafas complains that Final Rule 78(d)(1)(ii) prevents an applicant from filing "voluntary divisionals." Tafas Am. Compl. ¶ 56 (e). The term "voluntary divisional" is a

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[19] See 37 C.F.R. § 1.176 (2006) (restriction may be required in a reissue application); see also MPEP § 1450 (explaining that a divisional application may be filed in response to a restriction in a reissue application).

misnomer; it is not based in Title 35, the corresponding regulations, or agency guidance. As already explained, 35 U.S.C. § 121 permits a "divisional" application to be filed in response to a restriction requirement. See also MPEP § 804.01. If an applicant chooses to file a child application claiming priority to a parent application, then that application is simply a continuation application. This is, and always has been, the law. Hence, the definition of divisional application found in Final Rule 78(d)(1)(ii) is consistent with 35 U.S.C. § 121.

Sixth, Tafas argues that Final Rule 78(d) thwarts participation in federally supported research and development and impedes federal "march-in" rights available under 35 U.S.C. §§ 200 and 203. Tafas Am. Compl. ¶¶ 56(l) & (m). None of the Final Rules contravene the "Policy and Objectives" of federally-funded research, 35 U.S.C. § 200, or the patent rights of the federal government in the research and development it funds, id. at § 203. The Final Rules simply do not speak to these issues.

Finally, Tafas alleges that the requirement to identify "patentably indistinct claims" in Final Rule 78(f) will force applicants to disclose subject matter that they want to maintain in confidence. Tafas Am. Compl. ¶ 56(h). Tafas has waived this argument because it was not raised to the USPTO during the notice and comment period. See Ohio v. U.S.E.P.A., 997 F.2d 1520, 1528-29 (1993); see generally Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 529, 553-54 (1978). In any event, a patent application is published eighteen months after its earliest priority date unless a patent applicant files a non-publication request, averring that it has not and will not file a corresponding application in foreign patent offices. 35 U.S.C. § 122. Absent such a request, by law, the USPTO must publish all applications promptly at eighteen months from the earliest effective filing date. See id. Consequently, Final Rule 78(f) does not erode any confidentiality protections owed to applicants.

In sum, each and every one of the challenged rules is consistent with the Patent Act, and they should all be upheld as reasonable regulations.

II. THE USPTO DID NOT ACT IN AN ARBITRARY OR CAPRICIOUS MANNER IN PROMULGATING RULES THAT AIM TO IMPROVE QUALITY AND EFFICIENCY OF PATENT APPLICATION EXAMINATION

Judicial review of an agency's rulemaking under the APA's "arbitrary" or "capricious" standard, 5 U.S.C. § 706(2)(A), is guided by the highly deferential standard of Motor Vehicle Manufacturers. Ass'n of the United States, Inc. v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29 (1983). Under State Farm, "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." Id. at 43; see also Lacavera, 441 F.3d at 1383. To satisfy judicial review, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." State Farm, 463 U.S. at 43 (internal quotation marks omitted). If the agency's decision was "based on a consideration of the relevant factors," and there has not been a "clear error of judgment," the agency action must be upheld. Id. (internal quotation marks omitted).

As this Court indicated at the preliminary injunction stage, the USPTO has amply satisfied the State Farm standard. See Tafas v. Dudas, 511 F. Supp. 2d 652, 666 (E.D.Va. 2007) ("[T]he PTO's rationale appears to be sufficient to satisfy arbitrary and capricious review, and the Court will find that GSK has not shown a real likelihood of success on the merits."). The more than 4,000 pages of data in the administrative record demonstrate that the USPTO "examine[d] the relevant data" over more than two years of rulemaking. Id.; see generally A03200-A07202. After examining this data and reviewing more than 500 public comments, among other materials, the USPTO published a 127-page Federal Register notice, in which it "articulate[d] a satisfactory explanation for its rules including a rational connection between the facts found and the decisions

made." State Farm, 463 U.S. at 43. The USPTO explained that the rules are aimed to "[l]ead to more focused and efficient examination, improve the quality of issued patents, result in patents that issue faster, and give the public earlier notice of what the patent claims cover." 72 Fed. Reg. at 46719. Focusing on data showing increasing continuations, id. at 46718, a massive backlog of applications, id. at 46790, and long pendency periods, id. at 46576, the USPTO addressed how each of the Final Rules would satisfy the stated objectives, see, e.g., id. at 46718-23.

By encouraging applicants to claim their inventions in an initial application, two continuation applications, and one RCE, the USPTO explained, Final Rules 78 and 114 will "permit the Office to apply the patent examining resources otherwise consumed by [continuing applications and RCEs] to the examination of new applications and thereby reduce the backlog of unexamined applications." Id. at 46719. Final Rules 78 and 114 will also improve the quality and efficiency of patent examination by curbing applicants who delay the prosecution of their applications and engage in "unfocused practices" because of the availability of unlimited continuations.[20] Id. at 46720. The Final Rules will cause such applicants to prosecute their applications with greater diligence, using a cohesive patent strategy. Id. at 46754.

With respect to claims, the USPTO explained that applications that contain a large number of claims absorb an inordinate amount of patent examining resources because they are difficult to

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[20] The USPTO is not alone in commenting on the problems caused by unlimited continuations practice. See U.S. Patent and Trademark Office: Transforming To Meet the Challenges of the 21st Century, at 50 (National Academy of Public Administration 2005) (A03826, A03897); To Promote Innovation: The Proper Balance of Competition and Intellectual Property Law and Policy, Ch. 4 at 26-31 (Federal Trade Commission 2003) (A03202, A03393-98); To Promote the Progress of Useful Arts, Report of the President's Commission on the Patent System, at 17-19 (1966) (A04913, A04937-39); see also Mark A. Lemley & Kimberly A. Moore, Ending Abuse of Patent Continuations, 84 B.U. L. Rev. 63, 64 (2004) (cited at 72 Fed. Reg. at 46718-19). The USPTO also received numerous public comments remarking on the need to address this problem and supporting the USPTO's rulemaking. See, e.g., A01357 (Apple Computer, Inc.), A02360-61 (Clarcor Inc.), A02139-42 (Microsoft Corp.), A02242-51 (Micron Technology Inc.), A02715-16 (CCIA), A02749-61 (Intel), A02972-75 (BSA).

process and examine. 72 Fed. Reg. at 46720-721; A03860, A03885-86. Such applications also cause more examiner errors. A05059. Final Rules 75 and 265 will lead to more efficient and effective examination by requiring an applicant who exceeds the 5/25 threshold to submit an ESD. 72 Fed. Reg. at 46721. The ESD will provide the most relevant prior art and other useful information to the Office, thereby assisting the examiner in determining the patentability of a claimed invention and expediting examination. Id. Freeing Office time to examine a higher percentage of new applications will help reduce the backlog of unexamined applications. See id. at 46717-19.

In view of the Office's careful rulemaking, Plaintiffs' complaints that the USPTO acted in an arbitrary or capricious manner ring hollow. GSK first alleges that the USPTO did not adequately explain its "administrative efficiency rationale" or "backlog rationale" for the Final Rules. GSK Am. Compl. ¶¶ 115-16, 126-128. As outlined above, however, the USPTO explained in detail how the Final Rules would improve efficiency and reduce the backlog.[21] The Office's explanation amply demonstrates that there is a reasonable relation between the articulated problems and the Office's choices, as required to satisfy APA review. Baltimore Gas & Elec. Co. v. Nat'l Res. Def. Council, Inc., 462 U.S. 87, 105-06 (1983) (explaining that court's "only task is to determine whether the Commission has considered the relevant factors and articulated a rational connection between the facts found and the choice made").

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[21] As the USPTO also explained, the Final Rules are not the only way that the agency is seeking to improve the quality and efficiency of examinations. See 72 Fed. Reg. at 46819-820. These rules are only one among many initiatives aimed at these goals. See Changes to Practice for Petitions in Patent Applications to Make Special and for Accelerated Examination, 71 Fed. Reg. 36323 (June 26, 2006); Changes to Information Disclosure Requirements and Other Related Matters, 71 Fed. Reg. 38808 (July 10, 2006); Examination of Patent Applications That Include Claims Containing Alternative Language, 72 Fed. Reg. 44992 (Aug. 10, 2007); see also Patent Reform: The Future of American Innovation, Hearing Before the Senate Comm. on the Judiciary, 110th Cong. at 265-68 (2007) (testimony of Jon W. Dudas).

GSK also mistakenly objects that the USPTO's own statistics fail to support the "backlog" rationale of the Final Rules because only 2.7% of applications filed in Fiscal Year 2006 were a third or subsequent continuing application. GSK Am. Compl. ¶116. As the USPTO explained in the Federal Register, the application filing rate and backlog of unexamined applications are at historic highs. See 72 Fed. Reg. at 46790 (noting that in 2006, the Office had a backlog of 701,147 applications); A07478-79 (showing increase in application filings since 1986). Not only is the number of continuing applications growing, the proportion of multiple continuing applications and RCEs as a percentage of overall filings is also increasing. A05015.

Viewed against this background, even modest progress achieved under the Final Rules will vastly improve the problems now facing the patent system. The 2.7% of applications represents approximately 11,000 continuation applications and RCEs, which equates to a year's worth of work for 275 new patent examiners.[22] A05022, A05646. The Final Rules also seek to contain the 2.7% from growing even larger. A05015. The USPTO has modeled the impacts of the Final Rules (and other changes under consideration) on patent pendency. A05641-A05721. The models demonstrate that the changes in the Final Rules will have an appreciable impact on the backlog. A05645. It is for the USPTO, not the Plaintiffs, to balance the efficiency gains anticipated from the Final Rules against any burden claimed by applicants and decide whether they are worth pursuing. See Bicycle Trails Council of Marin v. Babbitt, 82 F.3d 1445, 1468 (9th Cir. 1996) ("To call such agency action arbitrary and capricious simply because one disapproves of the outcome reached would be to distort the purposes of the APA."). Using its particular

[22] The USPTO explained that it plans to hire 1,200 examiners each year for the next five fiscal years, but that "[e]ven with this increase in the size of the Patent Examining Corps, the Office anticipates that average pendency to first Office action will increase from 22.6 months in fiscal year 2006 to 28.9 months in fiscal year 2012, and that average total pendency will increase from 31.1 months in fiscal year 2006 to 38.6 months in fiscal year 2012." 72 Fed. Reg. at 46817.

expertise, the USPTO has reasonably balanced competing interests.

Finally, after arguing that the Final Rules do too little, GSK turns around and complains that they do too much. GSK alleges that the Final Rules are arbitrary and capricious because the USPTO ignored "less-drastic and less-damaging alternatives to eliminating abusive continuation applications" and "failed to consider the dynamic effects"[23] of the claims rules on patent applicants, and because the Final Rules will preclude "some perfectly meritorious claims to invention." GSK Am. Compl. ¶¶ 116, 126-127. The USPTO squarely addressed these concerns in several ways. First, the USPTO modified the Proposed Rules by, among other things, increasing the number of continuing applications and RCEs an applicant may file before filing a petition and making a showing. See 72 Fed. Reg. at 47662. The USPTO also considered weaker alternatives but ultimately concluded that lesser measures, standing alone, would not adequately address the Office's concerns. See id. at 46816-22, 46824-26, 46833-34.

Furthermore, the USPTO adopted Final Rules that would prevent applicants from circumventing the ESD requirement by filing multiple parallel applications to a single invention.[24] 72 Fed. Reg. at 46761, 46788, 46797-98. The USPTO also considered that additional claims are sometimes necessary to protect certain inventions. The Final Rules thus permit an applicant to receive up to fifteen independent claims and seventy-five total claims to a single invention in an application family without a petition or ESD as a matter of right. They also allow an applicant to file an unlimited number of claims if the applicant provides an ESD. 72 Fed. Reg. at 46795, 46788. The USPTO's reasonable consideration of these concerns satisfies the arbitrary and

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[23] The USPTO understands GSK's reference to "dynamic effects" to refer to the filing strategies applicants may employ to circumvent the 5/25 Rule.

[24] For example, the USPTO enacted Final Rule 75(b)(4) and 78(f)(1) and (f)(2) to preclude applicants from evading the claims rule by simply filing multiple applications to the same invention contemporaneously. 72 Fed. Reg. at 46797-798; see supra Background, II.C.

capricious standard of review. See, e.g., Aaipharma, Inc. v. Thompson, 296 F.3d 227, 242 (4th Cir. 2002) (holding that agency did not act arbitrarily and capriciously where it sufficiently considered comments); Maritel Inc. v. Collins, 422 F. Supp. 2d. 188, 201 (D.D.C. 2006) (same).

In the end, the Final Rules strike a careful and logical balance between providing applicants an adequate number of claims and opportunities to present claims to protect their inventions and the need to reduce the large and growing backlog of unexamined patent applications, improve the quality of issued patents, and make the patent examination process more effective. 72 Fed. Reg. at 46717, 46757, 467966, 46825-26. The Final Rules satisfy the APA.

III. THE FINAL RULES ARE NOT RETROACTIVE

Plaintiffs also cannot prevail on their allegations that the Final Rules are retroactive. Regardless of whether Congress has conferred retroactive rulemaking authority on the USPTO, see Bowen v. Georgetown Univ. Hosp., 488 U.S. 204 (1988), the Final Rules simply are not retroactive. The Final Rules have purely "future effect," 5 U.S.C. § 551(4), and thus do not exceed the USPTO's rulemaking authority on retroactivity grounds.

As a threshold matter, the Final Rules do not seriously implicate retroactivity concerns because "[c]hanges in procedural rules may often be applied in suits arising before their enactment without raising concerns about retroactivity." Landgraf v. USI Film Prods., 511 U.S. 244, 275 (1994); see Combs v. Comm'r of Soc. Sec., 459 F.3d 640, 647 (6th Cir. 2006) (en banc) ("[C]hanges to procedural rules generally do not have retroactive effect because procedural rules regulate secondary as opposed to primary conduct."). Final Rules 78 and 114 merely add a new procedural requirement – the "petition and showing" requirement – to certain future-filed continuing applications and RCEs. Final Rules 75 and 265 simply require applicants to submit information to assist the examiner in considering large numbers of claims. As explained above, see infra Part I.B, these rules do not affect the substantive eligibility requirements for obtaining a

patent, which are contained in 35 U.S.C. §§ 101, 102, 103, and 112. Thus, like the new rules in Combs, 459 F.3d at 647, the Final Rules are procedural in nature and do not implicate retroactivity concerns.

Even if the Final Rules were substantive, however, they still are not retroactive. A regulation "does not operative retrospectively merely because it is applied in a case arising from conduct antedating the statute's enactment or upsets expectations based in prior law." Landgraf, 511 U.S. at 269 (internal citation and quotation marks omitted). Nor is a regulation "'made retroactive merely because it draws upon antecedent facts for its operation.'" Id. at 270 n. 24. Rather, a regulation is impermissibly retroactive only if it "would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed." Id. at 280 (emphases added).

Plaintiffs erroneously proceed on the first and third Landgraf theories – that the Final Rules allegedly impair vested rights and impose new duties on transactions already completed. These theories fail, however, because the Final Rules are prospective in nature.[25]

A. The Final Rules Do Not Implicate Vested Rights

Plaintiffs' retroactivity claims rest on the mistaken assumption that patent applicants have vested rights in their pending applications. GSK Am. Compl. ¶ 122, Tafas Am. Compl. ¶ 68. It is well-settled, however, that the mere filing of an application for a government benefit does not confer a cognizable right that can be impaired by the enactment of a new regulation while the application is pending. See Bellsouth Telecomms., Inc. v. Southeast Telephone, Inc., 462 F.3d

[25] Because the Final Rules are not unlawful under Landgraf, Tafas cannot prevail on his claim that the Final Rules contravene the APA's definition of a "rule" as an agency statement having "future effect." 5 U.S.C. § 551(4); see Celtronix Telemetry, Inc. v. FCC, 272 F.3d 585, 588 (D.C. Cir. 2001) (employing Landgraf standard to determine whether allegedly retroactive rule violated the APA's definition of rule); Tafas Am. Compl. ¶ 62.

650, 660-661 (6th Cir. 2006) ("[F]iling an application with an agency does not generally confer upon the applicant an inviolable right to have the agency rule on the application pursuant to the regulations in effect at the time of the filing."); Pine Tree Med. Assocs. v. Sec. of Health & Human Servs., 127 F.3d 118, 121 (1st Cir. 1997) (rejecting "the proposition that filing an application with an agency essentially fixes an entitlement to the application of those substantive regulations in force on the filing date"); Chadmore Commc'n v. FCC, 113 F.3d 235, 240-41 (D.C. Cir. 1997) (holding that a new FCC rule could be applied to a pending application because the filing of an application did not complete a transaction and did not give rise to a vested right); Bergerco Canada v. U.S. Treasury Dep't, 129 F.3d 189, 195 (D.C. Cir. 1997) (rejecting broad view that applicant's expectation in filing application for a license is a "right"). This is because an applicant's "rights" do not vest until the benefit the applicant seeks is granted. See Bellsouth, 462 F.3d at 662.

This is particularly true in the context of patent applications, where the Supreme Court has long held that a patent application does not confer any property rights on the applicant. See Marsh v. Nichols, Shepherd & Co., 128 U.S. 605, 612 (1888) ("Until the patent is issued, there is no property right in it; that is, no such right as the inventor can enforce. Until then there is no power over its use, which is one of the elements of a right of property in anything capable of ownership."); see also Exxon Chem. Patents, Inc. v. Lubrizol Corp., 935 F.2d 1263, 1266 (Fed. Cir. 1991) ("[A]n inventor has no enforceable rights under the patent laws until the patent securing those rights has issued."); Mullins Mfg. Co. v. Booth, 125 F.2d 660, 664 (6th Cir. 1942); De Ferranti v. Lyndmark, 30 App. D.C. 417, at *5 (1908); Brenner v. Ebbert, 398 F.2d 762, 764-65 (D.C. Cir. 1968).[26] Instead, an applicant accrues cognizable patent rights only when the patent

[26] Winchester v. Comm'r of Internal Revenue, 27 B.T.A. 783, 1933 WL 231 (Bd. Tax. App. 1933), cited by GSK, has no precedential value in this Court and is clearly outweighed

is granted, for there is no "right" to a patent unless the applicant meets the relevant eligibility criteria. 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 which Congress has imposed.") (internal citation omitted). Accordingly, in Bruno Independent Living Aids, the Federal Circuit applied an amended USPTO rule to an application that was pending at the time of its enactment without raising any concerns about retroactivity. 394 F.3d at 1352-53.

Further, GSK's allegations prove too much. GSK alleges that the USPTO may not amend the patent regulations because "changes to the rules on patent applications mid-stream – while such applications are pending – are inherently retroactive." GSK Am. Compl. ¶ 122. If this were correct, the USPTO would never be able to amend its rules because some patent applications would always be "mid-stream." The Supreme Court has thus made clear that a regulation is not retroactive merely because it "upsets expectations based in prior law." Landgraf, 511 U.S. at 249; see also Chem. Waste Mgmt. v. EPA, 869 F.2d 1526, 1536 (D.C. Cir. 1989) ("It is often the case that a business will undertake a certain course of conduct based on the current law, and will then find its expectations frustrated when the law changes. This has never been thought to constitute retroactive lawmaking[.]"); Bellsouth, 462 F.3d at 662 ("The fact that parties engaged in conduct on the assumption that the law will allow them to act or to benefit in a certain manner is not sufficient reason to refuse to apply a new law that renders that assumption misplaced.").

Unable to point to any vested rights in pending patent applications, GSK argued at the preliminary injunction stage that the USPTO has impaired its reliance interests, asserting that

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by Supreme Court precedent. In any event, the Board of Tax Appeals simply held there that, as a matter of statutory interpretation of the provisions of Title 26, patent applications could be considered property under the Revenue Act. See id. at *3.

GSK relied upon a bargain with the USPTO to surrender its trade secrets in exchange for filing a patent application. GSK Am. Compl. ¶¶ 66, 106, & 148. Nothing could be further from the truth. As the Supreme Court explained in Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984), "[i]f 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." Here, GSK has extinguished its own trade secret rights by failing to ask the USPTO to maintain its applications in confidence. The USPTO will maintain an application in confidence if the applicant makes a nonpublication request certifying that the application has not been and will not be filed in a country requiring eighteen-month publication. 35 U.S.C. § 122(b)(2)(B)(i); 37 C.F.R. § 1.213 (2006). If the applicant so elects, it need never disclose trade secrets. Here, GSK has chosen to surrender its trade secrets in order to file for patent protection abroad, not because the USPTO required it and not because of any guarantee of protection in the United States. Thus, the USPTO did not break its end of any bargain or induce GSK to surrender any trade secrets. Plaintiffs lack any vested rights that could be impaired by application of the Final Rules to their pending and future patent applications.

B. The Final Rules Impose No New Duties With Respect To Completed Transactions

Filing a patent application is not a "transaction already completed." Landgraf, 511 U.S. at 280. In ordinary usage, a "transaction" is "an exchange of transfer of goods, services, or funds," or a "communicative act activity involving two parties or things that reciprocally affect or influence each other." Webster's Collegiate Dictionary 1327 (11th ed. 2003) (emphases added). Accordingly, as the courts have recognized, the mere filing of an application – without receiving any reciprocal benefit from the application – does not constitute a "transaction," much less a "completed" transaction. See Pine Tree Med. Assocs. v. Health & Human Serv., 127 F.3d at 121

("[M]ere filing of an application is not the kind of completed transaction in which a party could fairly expect stability in the relevant laws as of the transaction date."); Chadmore Commc'n, 113 F.3d at 240-41(holding that a new FCC rule could be applied to a pending application because the filing of an application did not complete a transaction). This is particularly true in the context of patent prosecution, which involves an iterative exchange between the applicant and examiner. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 618 (Fed. Cir. 2000) (Michel, J. dissenting) ("Patent prosecution is an iterative process in which the applicant typically submits claims that are thought allowable, the examiner rejects the claims in view of the prior art, and the applicant then amends the claims to traverse the examiner's patentability rejections."). The relevant "transaction" is not completed until the application is granted, becomes abandoned, or is finally rejected. See 35 U.S.C. § 151.

Even if the initial filing of an application were deemed to be a completed transaction, which it is not, the Final Rules do not render invalid any action taken by applicants before the effective date of the rules. Cf. Durr v. Nicholson, 400 F.3d 1375, 1380 (Fed. Cir. 2005) (new rule altering content of Veterans' Administration appeals could not be retroactively applied to pending appeals because it would render them invalid as filed). Final Rules 78 and 114 do not threaten any continuing applications or RCEs that applicants have already filed. They merely put conditions on the number of continuing applications and RCEs that applicants may file going forward. Likewise, Final Rules 75 and 265 do not require any applicant to have already filed an ESD. Rather, an applicant whose application has claimed more than 5/25 claims and who has not received a first Office action on the merits in that application before the Final Rules' effective date will receive a notice and have an opportunity to either amend its claims to bring them under that threshold or to submit an ESD. Because the Final Rules do not change the legal consequences for patent applications filed in the past, they are not retroactive.

For all of these reasons, the Final Rules must be upheld in their current application.[27]

IV. THE FINAL RULES ARE CONSTITUTIONAL UNDER THE FIFTH AMENDMENT

Plaintiffs allege that the Final Rules violate the Fifth Amendment on two different theories: Tafas contends that they violate the Due Process Clause, Tafas Am. Compl. ¶ 61, while GSK alleges that they violate the Takings Clause, GSK Am. Compl. ¶¶ 150, 153.[28] See U.S. Const. amend. V. Both theories fail because both depend on the existence of a cognizable property right that Plaintiffs do not have. Even if Plaintiffs could identify a cognizable property right, the Final Rules do not violate substantive due process or constitute a regulatory taking.

A. Plaintiffs Cannot Prevail Under the Fifth Amendment Claim in the Absence of a Cognizable Property Right

Plaintiffs' Fifth Amendment claims fail at the outset because the Final Rules affect no cognizable property interest. The Takings Clause is only implicated where "private property" is taken for a public use without just compensation, and the Due Process Clause proscribes the deprivation of "life, liberty, or property" without due process of law. U.S. Const. amend. V. Thus, both theories depend on the existence of a cognizable property right.

Plaintiffs cannot identify any such right because the Final Rules merely affect patent applications, which may or may not yield a patent. As explained above, patent applications do not confer cognizable property interests. See, e.g., Marsh, 128 U.S. at 612; Exxon Chem. Patents, 935 F.2d at 1266. Plaintiffs likewise have no property interest in their expectations of possibly

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[27] If the Court were to find that any of the Final Rules are retroactive, the proper remedy would be to construe the regulations as applying only to future-filed applications, not to invalidate the regulations entirely. See Fernandez-Vargas v. Gonzales, 126 S.Ct. 2422, 2428 (2006) (explaining that if a statute is found to be retroactive under Landraf, the court construes the statute "as inapplicable to the event or act in question").

[28] Lingle v. Chevron U.S.A., Inc., 544 U.S. 528 (2005), makes clear that these are separate and distinct theories that take into account different considerations.

receiving patents from their patent applications – even when those expectations might be backed by capital investments. See Bd. of Regents of State Colleges v. Roth, 408 U.S. 564, 577 (1972) ("To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it.").

Nor do Plaintiffs have any constitutionally-protected interest in the procedures by which their patent applications are adjudicated. Olim v. Wakinekona, 461 U.S. 238, 250 (1983) ("Process is not an end in itself. Its constitutional purpose is to protect a substantive interest to which the individual has a legitimate claim of entitlement."); Fleury v. Clayton, 847 F.2d 1229, 1231 (7th Cir.1988) ("There is neither a 'liberty' nor a 'property' interest in procedures themselves . . . ."); see also United of Omaha Life Ins. Co. v. Solomon, 960 F.2d 31, 34 (6th Cir. 1992) (holding that a "disappointed bidder" to a state contract did not have a property interest in the State's purchasing guidelines, and so suffered no due process violation when the State failed to comply with its own procedure in awarding the bid), or, by extension, in the continuation of a particular regulatory scheme, see Prometheus Radio Project v. F.C.C., 373 F.3d 372, 430 (3d Cir. 2004); see also Folden v. United States, 56 Fed. Cl. 43, 61-62 (2003) (citing cases). Finally, although trade secrets may implicate property rights when they are maintained in confidence, Plaintiffs have voluntarily foregone those rights by choosing to make their patent applications public in order to pursue patent protection in others countries. See supra, Part III.A.

In the absence of a cognizable property right, Plaintiffs' Fifth Amendment claims fail.

B. The Final Rules Satisfy Due Process Because They Are Not Arbitrary or Irrational

Even if Tafas could establish the existence of a cognizable property right, the Final Rules are not so "arbitrary or irrational" as to run afoul of the Due Process Clause. Lingle, 544 U.S. at

542 (citing County of Sacramento v. Lewis, 523 U.S. 833, 846 (1998)); see also id. at 549 (Kennedy, J. concurring); see also Kelley v. Johnson, 425 U.S. 238, 248 (1976) ("The constitutional issue to be decided . . . is whether petitioner's determination that such regulations should be enacted is so irrational that it may be branded 'arbitrary'. . . ."). For the reasons discussed supra Part II, the USPTO did not act an arbitrary or irrational manner when it enacted Final Rules that advance legitimate government interests, including allowing the Office to more efficiently process the many applications it receives and providing the Office and the public with prompt notice of what applicants regard as their invention. Nothing more is required to show that these economic regulations comport with the Due Process Clause.

C. The Final Rules Do Not Effect an Unconstitutional Taking

Even if GSK could establish that it had a cognizable property right, the Final Rules do not effect a regulatory taking. "Given the propriety of the governmental power to regulate, it cannot be said that the Taking Clause is violated whenever legislation requires one person to use his or her assets for the benefit of another." Connolly v. Pension Benefit Guaranty Corp., 475 U.S. 211, 223 (1986). The overriding question is whether "'justice and fairness' require that economic injuries caused by public action be compensated by the government, rather than remain disproportionately concentrated on a few persons." Penn Central Trans. Co. v. City of New York, 438 U.S. 104, 124 (1978); see also Lingle, 544 U.S. at 537. Here, even assuming *arguendo* that the Final Rules cause economic injuries, the Final Rules do not disproportionately concentrate any burden on a few persons, but rather implement regulatory changes that affect the public generally.

Furthermore, "'where an owner possesses a full 'bundle' of property rights, the destruction of one 'strand' of the bundle is not a taking.'" Tahoe-Sierra Preservation Council, Inc. v. Tahoe Regional Planning Agency, 535 U.S. 302, 327 (2002) (quoting Andrus v. Allard, 444 U.S. 51, 66 (1979)). Here, applicants have many options available to them to claim and obtain patents for

their inventions. See, e.g., supra Background, II.D, II.E. Even if the Final Rules are less than optimal from any particular applicant's perspective, their "bundle" of rights remains intact.

Beyond these broad principles, Plaintiffs also cannot satisfy the three-factor test for establishing a regulatory taking set forth in Penn Central.[29] Under Penn Central, the court must consider: (1) the character of the governmental action; (2) the economic impact on the regulated parties; and (3) whether the regulated parties had reasonable investment-backed expectations that they would not be subjected to regulation. See Cienega Gardens v. United States, 503 F.3d 1266, 1279 (Fed. Cir. 2007) (citing Penn Central, 438 U.S. at 124).

With respect to the first factor, "[a] 'taking may more readily be found when the interference with property can be characterized as a physical invasion by government, than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good." Penn Central, 438 U.S. at 124 (internal citations omitted). The enactment of the Final Rules certainly qualifies as the latter, as the Final Rules aim to improve the efficiency and quality of patent examination. As in Connolly, therefore, the USPTO has not effected an unconstitutional taking under the first factor. See 475 U.S. at 225.

Second, the economic impact on regulated parties is not significant because the rules do "not interfere with what must be regarded as [patent applicants'] primary expectation": obtaining patents on their inventions. Penn Central, 438 U.S. at 136 (emphasis added); see also Cienega Gardens, 503 F.3d at 1289. Although the Final Rules may require Plaintiffs to cease delaying claiming their inventions and to submit an ESD when they have large numbers of claims, they will

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[29] The Supreme Court has identified three categories of takings: (1) physical invasions of property; (2) takings of property that deprive owners of "all economically beneficial us[e]" of theirs property; and (3) other regulatory takings, which require application of the Penn Central factors. Lingle, 544 U.S. at 538 (internal quotation marks omitted). Because the first two categories clearly do not apply, the USPTO will proceed using the Penn Central analysis.

not stop Plaintiffs from applying for and receiving patents to the extent they are eligible to do so. Furthermore, "there are a significant number of provisions in the [Final Rules] that moderate and mitigate the economic impact" on the regulated parties. Connolly, 475 U.S. at 225-26; see also Cienega Gardens, 503 F.3d at 1282 (criticizing the court below for failing to consider benefits "which were specifically signed to ameliorate the impact" of the new regulations). The USPTO specifically designed the Final Rules to ensure that applicants would still be able to claim all of their inventions. See supra Background, Part II.E. Such mitigating factors prevent Plaintiffs from satisfying the second Penn Central factor.

Third, in contrast to takings cases in which plaintiffs find their investments decimated by a government action, see, e.g. Lucas v. South Carolina Coastal Council, 505 U.S. 1003 (1992), GSK's "investment-backed expectations" remain largely intact after the Final Rules due to the many measures the USPTO has taken to ensure that applicants may obtain patent protection for their disclosed, but as yet unclaimed, inventions. See supra Background, II.E.

Furthermore, to the extent Plaintiffs assumed that the USPTO would never seek to curb their delay tactics or require them to assist examiners by submitting additional information, their expectations were not "reasonable." Penn Central, 438 U.S. at 124. Prior to the Final Rules, 37 C.F.R. § 10.18 (2006) already prohibited filings that intentionally delay prosecution, and 37 C.F.R. §§ 1.56 and 1.105 (2006) already required applicants to submit additional documentation to the USPTO in support of their applications beyond the application itself. The Final Rules expand on and strengthen these preexisting duties but do not regulate on a blank slate.[30]

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[30] Because the Final Rules do not effect an unconstitutional taking, GSK's allegation that the USPTO lacks the power to effect a taking through "substantive" rules is irrelevant, and, in any event, in error. See GSK Am. Compl. ¶¶ 152-153. For reasons already discussed supra Part I.B, the USPTO disputes GSK's characterization of the Final Rules as "substantive," as well as the proposition that the USPTO lacks substantive rulemaking authority. See id. GSK's conclusory assertion the USPTO acted in an arbitrary and capricious manner by not addressing

Accordingly, even if Plaintiffs could show that they have some property right that the Final Rules implicate – which they cannot – the Final Rules do not violate the Fifth Amendment.

V. TAFAS CANNOT PREVAIL ON HIS PATENT CLAUSE CLAIM

Tafas also alleges that the Final Rules violate the Patent Clause because the USPTO "fail[ed] to appropriately weigh the effect of its regulations on the promotion of the progress of science and the useful arts." Tafas Am. Compl. ¶ 60. The Patent Clause provides: "Congress shall have power . . . [t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const., art. I., § 8, cl. 8. Tafas's claim fails for at least four reasons.

First, the Patent Clause does not exist as a factor that an executive agency must "weigh." Rather, the plain language of Article I, Section 8 ("Congress shall have power . . .") makes clear that the Patent Clause simply confers on the Federal Government, through Congress, the power to create a system to protect intellectual property. See Eldred v. Ashcroft, 537 U.S. 186, 212 (2003) ("The 'constitutional command' we have recognized, is that Congress, to the extent it enacts copyright laws at all, create a 'system' that 'promote[s]' the Progress of Science.") (emphases added); Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 5 (1966) (explaining that the Clause is a "grant . . . and limitation" on Congress's power); S. Rep. No. 82-1979 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2396 ("This provision was unanimously adopted by the Constitutional Convention following suggestions for Federal jurisdiction over both patents and copyrights . . . ."). Unless Tafas wishes to challenge Congress's authority to establish a patent

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the takings issue in its August 21, 2007 Federal Register notice is similarly irrelevant because no taking occurred. GSK Am. Compl. ¶ 151. In any event, the allegation is false. See 72 Fed. Reg. at 46827-28, 46834 (addressing takings issue).

system, the Patent Clause is irrelevant.[31]

Second, the preamble of the Clause –"To promote the Progress of Science and useful Arts" – does not create an enforceable limitation even on Congress's power. In Schnapper v. Foley, 667 F.2d 102 (D.C. Cir. 1981), the D.C. Circuit held that it "cannot accept appellants' argument that the introductory language of the Copyright Clause constitutes a limitation on Congress's power." Id. at 112; see also Hutchinson Tel. Co. v. Fronteer Directory Co. of Minn., Inc., 770 F.2d 128, 130 (8th Cir. 1985) ("[A]lthough the promotion of artistic and scientific creativity and the benefits flowing therefrom to the public are purposes of the Copyright Clause, those purposes do not limit Congress' power to legislate in the field of [patent and] copyright."). In Eldred, the Supreme Court declined to decide whether the Clause's preamble was "an independently enforceable limit on Congress's power" because the petitioner conceded that it was not. 537 U.S. at 211; see also Figueroa v. United States, 466 F.3d 1023, 1030 & n. 9 (Fed. Cir. 2006) (declining to decide whether the Clause's preamble limits congressional power).

Third, even if one could use the Clause's preambular language to challenge the USPTO's rulemaking, all that is required is a "rational basis" for the conclusion that the USPTO's Final Rules "'promot[e] the progress of science.'" Eldred, 537 U.S. at 213 (quoting art. I, § 8, cl. 8); see also Figueroa, 466 F.3d at 1031-32 ("As the Court reiterated in Eldred, judicial review . . . is limited to determining whether Congress's actions were a rationale exercise of the legislative authoriy conferred by the [Patent] Act.") (internal quotation marks omitted). The USPTO has already established that a rational basis exists for the Final Rules. See supra, Part II; see also

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[31] In opposing the USPTO's now-withdrawn Partial Motion to Dismiss, Tafas argued – contrary to what is pled in his Complaint, see Tafas Am. Compl. ¶ 60 – that his Patent Clause allegation really intends to assert that the USPTO exceeded its authority by enacting substantive rules. To the extent that this is Tafas's real argument, it is duplicative of the Patent Act claims discussed supra Part I, and the USPTO relies on its discussion in that Part to rebut it.

Tafas, 511 F. Supp. 2d at 666 ("[T]he PTO's rationale appears to be sufficient to satisfy arbitrary and capricious review, and the Court will find that GSK has not shown a real likelihood of success on the merits").[32]

Finally, as a purely factual matter, concern over promoting the interests set out in the Patent Clause pervaded the USPTO's decision to enact the Final Rules. As the USPTO explained, the fundamental aim of the Final Rules was to "[l]ead to more focused and efficient examination, improve the quality of issued patents, result in patents that issue faster, and give the public earlier notice of what the patent claims cover." 72 Fed. Reg. at 46719. All of these ends help promote the progress of science and the useful arts. See U.S. Const. art. I, § 8, cl. 8.

For all of these reasons, Tafas's constitutional claim under the Patent Clause must fail.

VI. GSK DOES NOT RAISE AN ACTIONABLE CONSTITUTIONAL VAGUENESS CHALLENGE

GSK asserts that the Final Rules should be held void-for-vagueness because they do not sufficiently put applicants on notice of how to comply with: (1) Rule 265's ESD requirement; and (2) Rule 75's prohibition on presenting "unduly multiplied" claims. GSK Am. Compl. ¶¶ 140-144. GSK fails to assert a cognizable claim because the void-for-vagueness doctrine relates only to regulations or statutes defining prohibited conduct. In any event, the Final Rules are sufficiently clear to meet the constitutional standards for Due Process.

A. The Void-For-Vagueness Doctrine Is Inapplicable

The Supreme Court has established the general standard to apply in assessing void-for-vagueness challenges to federal statutes and regulations. See Grayned v. City of Rockford, 408

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[32] Although the final Federal Register notice amply demonstrates the Final Rules' rational basis, the Court need not limit itself to the USPTO's stated policy reasons to find that there is a rational basis for the rules. See Figueroa, 466 F.3d at 1032 ("The question, rather, is whether there is a rational basis on which Congress could conclude that the level of fees served legitimate congressional objectives. . . . In Eldred, the Supreme Court, in conducting its rational basis review, did not limit itself to the policy justifications that Congress articulated.").

U.S. 104, 108 (1972) ("It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined.") (emphasis added). The Court in Grayned explained the basic policies underlying that doctrine as follows:

> First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. . . . Second, if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them.

Id. at 108-09 (emphasis added). The void-for-vagueness doctrine is, therefore, fundamentally aimed at regulations or statutes that leave individuals unable to determine what constitutes prohibited conduct, and that permit law enforcement officials to engage in arbitrary enforcement. See e.g., id.; United States v. Lanier, 520 U.S. 259, 264-65 (1997); Kolender v. Lawson, 461 U.S. 352, 357-58 (1983) (challenging a statute that required individuals to present "credible and reliable" information when requested by a police officer). For that reason, the Federal Circuit has expressly held that the void-for-vagueness doctrine applies only to prohibitions of conduct and not to applications for government benefits or entitlements such as those at issue here. Nyeholt v. Sec'y of the Veterans Affairs, 298 F.3d 1350, 1356 (Fed. Cir. 2002) (holding that the vagueness doctrine "relate[s] to prohibitions, not to entitlements").

The Federal Circuit's limited application of the void-for-vagueness doctrine is consistent with the Supreme Court's approach of applying the doctrine only to statutes or regulations that purport to define the lawfulness of conduct or a First Amendment right such as free speech. See, e.g., Kolender, 461 U.S. at 357-58; Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498-99 (1982) (applying the doctrine to regulation requiring a license to sell items "designed or marketed for use with illegal drugs"); Papachristou v. City of Jacksonville, 405 U.S. 156 (1972) (applying the doctrine to a vagrancy ordinance); Kunz v. New York, 340 U.S. 290 (1951) (applying the doctrine to an ordinance prohibiting public worship on public streets without

first obtaining a permit); Herndon v. Lowry, 301 U.S. 242 (1937) (applying the doctrine to a Georgia statute defining criminal offense of attempting to incite an insurrection). Significantly, the Federal Circuit noted that it could find no other Circuit Court of Appeals decision supporting the proposition that a statute or regulation that is not aimed at defining the lawfulness of conduct or speech can be challenged as impermissibly vague. Nyeholt, 298 F.3d at 1356.

Here, the Final Rules do not define the lawfulness or unlawfulness of conduct or speech. They instead regulate the process by which an applicant seeks a patent – a government benefit. Specifically, Final Rule 75 merely requires an applicant who wants to present more than 5/25 claims to provide information about those claims gleaned through a preexamination search to the Office. Accordingly, the void-for-vagueness doctrine is inapplicable to these regulations. See Nyeholt, 298 F.3d at 1356; cf. Woodruff v. U.S. Dep't of Labor, 954 F.2d 634, 642 (11th Cir. 1992) (concluding that the void-for-vagueness doctrine was not applicable to manual provision that does not regulate conduct but merely establishes standards for determining whether injury is covered by Federal Employees' Compensation Act).

B. The Final Rules Are Sufficiently Clear

Even if the void-for-vagueness doctrine were applicable here, GSK's vagueness challenge fails because the Final Rules are sufficiently clear. As a preliminary matter, because the Final Rules do not reach any constitutionally protected interests, see supra Part IV.A, GSK must demonstrate that the Final Rules are impermissibly vague in all of its applications, see Village of Hoffman Estates, 455 U.S. at 494 (holding that where constitutional rights are not involved, a court "should uphold the challenge only if the enactment is impermissibly vague in all of its applications"). Further, the Supreme Court has held that the Due Process Clause does not require that a statute or regulation describe with "mathematical certainty" the specific facts or circumstances to which it may apply. Grayned, 408 U.S. at 110. As the Supreme Court stated in

Colten v. Kentucky, 407 U.S. 104 (1972):

> The root of the vagueness doctrine is a rough idea of fairness. It is not a principle designed to convert into a constitutional dilemma the practical difficulties in drawing . . . statutes both general enough to take into account a variety of human conduct and sufficiently specific to provide fair warning that certain kinds of conduct are prohibited.

Id. at 110. At bottom, courts simply require that the challenged regulation be sufficiently clear such that a "reasonably prudent person," familiar with the circumstances motivating the regulation and the goal of the regulation, would have "fair warning" of what the regulation prescribes. Freeman United Coal Mining Co. v. Fed. Mine Safety & Health Rev. Comm., 108 F.3d 358, 362 (D.C. Cir. 1997).

1. *The Preexamination Search Requirement of Rule 265's ESD Provision is Sufficiently Clear to Meet Due Process Standards*

A reasonably prudent patent applicant (or, more likely, patent attorney) would have fair warning of what Final Rule 265 requires. Rule 265(b) provides, in relevant part:

> The preexamination search . . . must involve U.S. patents and patent application publications, foreign patent documents, and non-patent literature, unless the applicant justifies with reasonable certainty that no references more pertinent than those already identified are likely to be found in the eliminated source and includes such a justification with the statement required by paragraph (a)(1) of this section. The preexamination search . . . must be directed to the claimed invention and encompass all of the limitations of each of the claims (whether in independent or dependent form), giving the claims the broadest reasonable interpretation.

72 Fed. Reg. at 46842; 37 C.F.R. § 1.265(b). The rule cannot, however, be read in isolation. To ensure that applicants had ample information regarding how to comply with the Rules, the USPTO provided significant guidance regarding how to conduct the required searches both in the Federal Register publication of the Final Rules and in subsequently issued guidance.

The Court must consider such guidance in evaluating this vagueness challenge. As the D.C. Circuit has said, "[i]f, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable

certainty,' the standards with which the agency expects parties to conform, then the agency has fairly notified a petitioner of the agency's interpretation." Gen. Elec. Co. v. EPA, 53 F.3d 1324, 1329 (D.C. Cir. 1995) (emphasis added); cf. Kolender, 461 U.S. at 355 ("In evaluating a facial challenge to a state law, a federal court must, of course, consider any limiting construction that a state court or enforcement agency has proffered."). Similarly, in Hyatt v. Town of Lake Lure, 114 Fed. Appx. 72 (4th Cir. 2004) (unpublished), the Fourth Circuit found, in denying a vagueness claim, that it was "hardly insignificant" that the challenged regulation expressly invited the public to contact the relevant agency for clarification of certain terms. Id. at *3.

Here, the rule-by-rule analysis section of the Federal Register notice refers applicants to the Office's accelerated examination procedure, which requires applicants to conduct a search similar to that required under Final Rule 265. See 72 Fed. Reg. at 46741. The Office previously published information about searches for that procedure in several detailed documents. See Ex. 4a, "Guidelines for Applicants under the New Accelerated Examination Procedure," (ii) Ex. 4b, "Basic Search Strategy" slide show consisting of 43 slides; and (iii) Ex. 4c, "Frequently Asked Questions" document featuring four questions about searching.

The Office also discussed the preexamination search requirement in responding to public comments in the final Federal Register notice. See generally 72 Fed. Reg. at 46800-01. In particular, the Office stated:

> The standard for the preexamination search that is required is the same standard that the Office uses to examine patent applications, which is set forth in MPEP §§ 904-904.03. . . . If an applicant follows the search guidelines set forth in the MPEP, then the preexamination search should be sufficient.

Id. (emphasis added). The MPEP "is well known to those registered to practice in the PTO and reflects the presumptions under which the PTO operates." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997).

The Office also published a sixteen-page document on its website entitled,"Examination Support Document Guidelines (ESD) under 37 Fed. Reg.1.265" ("ESD Guidelines"), explaining:

> A search that includes the following three items should generally be sufficient: (1) [a] classification search of U.S. patents and published patent applications ...; (2) [a] text search of the U.S. patents and published patent applications, foreign patent documents, and non-patent literature (NPL) . . . ; and (3) [a] search employing any special tools . . . .

Ex. 4d. Moreover, the USPTO has provided search templates – 1,300 of them covering more than 600 classes and subclasses of inventions. See Ex. 4e, showing samples.

Because applicants claim a wide range of inventions and because technologies are ever-evolving, the Office drafted Final Rule 265 "with as much exactitude as possible in light of the myriad conceivable situations which could arise." See Ryder Truck Lines, Inc. v. Brennan, 497 F.2d 230, 233 (5th Cir. 1974). It would be unreasonable, if not impossible, for the Office to give exact direction for how to search every possible invention ever to be claimed in a patent application. Such micro-management in a regulation, which is certainly not required by Due Process, would be fundamentally unfair to applicants and nearly impossible to follow.

Finally, failure to initially comply with Final Rule 265 will not result in the forfeiture of the application. Final Rule 265(e) expressly provides notice and an opportunity to cure an ESD's deficiencies. See 72 Fed. Reg. at 46843; 37 C.F.R. § 265(e) ("If an [ESD] . . . is deemed to be insufficient, . . . applicant will be notified and given a two-month time period . . . within which, to avoid abandonment of the application, the application must: (1) file a corrected or supplemental [ESD] . . . ; or (2) amend the application such that it contains no more than five independent claims and no more than twenty-five total claims"). Because of the reasonable opportunity to comply, this is simply not the kind of enactment that can be held impermissibly vague.

2. ***Final Rule 75(b) Provides Sufficient Notice of What the Phrase "Not Unduly Multiplied" Means***

Final Rule 75(b) permits an applicant to file more than one claim provided that the claims "differ substantially from each other and are not unduly multiplied." 37 C.F.R. § 1.75(b). This is not a vague requirement; it is not even new. The same requirement using the same terms – "not unduly multiplied" – has been part of 37 C.F.R. § 1.75 since at least 1949. See 37 C.F.R. § 1.75(b) (1949) ("More than one claim may be presented: Provided, They differ substantially from each other and are not unduly multiplied.") (emphasis added).

Moreover, courts have addressed the "not unduly multiplied" language in cases dating back more than a hundred years, treating it as meaning "repetitive," and sanctioning its usage. See, e.g., Carlton v. Bokee, 84 U.S. 463, 472 (1873) ("Without deciding that a repetition of substantially the same claim in different words will vitiate a patent, we hold that where a specification by ambiguity and a needless multiplication of nebulous claims is calculated to deceive and mislead the public, the patent is void.") (emphasis added); In re Barnett, 155 F.2d 540, 546 (CCPA 1946) ("If by so doing he more clearly defines his invention and does not by undue multiplicity obscure the same, he is acting within the rights granted and the duties required by the patent laws.") (emphasis added).

Finally, the MPEP has discussed claim multiplicity since the first edition in 1949. See MPEP § 706.03(l) (1st ed. Nov. 15, 1949) ("An unreasonable number of claims; that is unreasonable in view of the relative simplicity of applicant's invention and the state of the art, affords a basis for a rejection on the ground of multiplicity.") (citing 37 C.F.R. § 1.75(b) (1949). Under these circumstances, GSK cannot feign confusion as to this term.

GSK's vagueness challenge to both Final Rules 265 and 75(b) must fail.

VII. THE FINAL RULES DID NOT REQUIRE NOTICE UNDER THE APA, BUT EVEN IF THEY DID, THEY ARE A LOGICAL OUTGROWTH OF THE PROPOSED RULES

Plaintiffs improperly assert that the USPTO erred in failing to provide notice and another

opportunity for comment after the Proposed Rules were amended. GSK Am. Compl., Count VI; Tafas Am. Compl. ¶ 71. Because the Final Rules are procedural in nature, the USPTO was not required to provide any opportunity for notice and comment; the "logical outgrowth" doctrine is thus inapplicable. Even if the doctrine does apply, however, the USPTO met its obligations.

A. The Logical Outgrowth Doctrine Is Inapplicable

Under the APA, notice and comment provisions do not apply "to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). Only substantive, or "legislative," rules require notice and comment. See, e.g. Tunik v. Merit Sys. Prot. Bd., 407 F.3d 1326, 1344 (Fed. Cir. 2005); ALDF, 932 F.2d at 927.

The Final Rules are clearly "procedural" and not "substantive" under the relevant APA jurisprudence. See also supra Part I.B (explaining why Final Rules are procedural). They 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 Broad. Co. v. Fed. Commun. Comm'n ("FCC"), 22 F.3d 320, 326-27 (D.C. Cir. 1994) (concluding that a regulation was "procedural" because it did not change the substantive standards by which the agency evaluated applications was "procedural," and accordingly, was exempt under § 553(b)(A) from notice and comment); Combs, 459 F.3d at 647 (holding that a rule changing the presumption of whether obesity was a disability was "procedural" because the "substantive requirements for disability eligibility have not changed, only the way in which the agency goes about determining whether they are present"). Final Rules 78 and 114 simply add new procedural requirements to a patent application – requiring a petition and showing if an applicant files more than two continuation applications or more than one RCE. Final Rule 75 simply requires the applicant to submit an extra document and perform a preexamination search to assist the examiner in considering applications that exceed the 5/25 threshold. In other words, the Final Rules require an applicant to

provide additional information to the Office in connection with certain patent applications, which the Office will examine using the same criteria that existed prior to implementation of the new rules. A rule that merely requires further information from an applicant is not a substantive rule. See, e.g., Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp., 589 F.2d 658, 665-66 (D.C. Cir. 1978) (holding that a rule that required an audit to be performed by outside accountants, rather than agency staff, was procedural).

Because the Final Rules fall within the "procedure" exception to § 553(b), the USPTO was under no obligation to provide any notice and comment period. Tunik, 407 F.3d at 1344. To the extent the USPTO did not have to make proposed rules available for comment, the "logical outgrowth" doctrine has no application.

B. The Final Rules Are a Logical Outgrowth of the Proposed Rules.

Even if the notice and comment provisions apply to the Final Rules, the notice given in the Proposed Rules was sufficient. The APA requires an agency to provide "general notice of proposed rulemaking" including "either the terms or substance of the proposed rule." 5 U.S.C. §§ 553(b), 553(b)(3). As the Supreme Court stated in Long Island Care at Home, Ltd. v. Coke, — U.S. —, 127 S. Ct. 2339, 2351 (2007), "Courts of Appeals have generally interpreted [§ 553(b)(3)] to mean that the final rule the agency adopts must be 'a logical outgrowth' of the rule proposed." The Long Island Care Court holds such a standard met when a final rule is "reasonably foreseeable" in light of the proposed rule. Id.

Generally, when final rules are consistent with the overall approach of proposed rules, courts have found that the logical outgrowth requirement is satisfied. See Am. Coke and Coal Chems. Inst. v. EPA, 452 F.3d 930, 939-40 (D.C. Cir. 2006) (concluding that a final rule that resulted in more stringent regulations than those proposed was a logical outgrowth because overall methodology remained the same); Ariz. Pub. Serv. Co. v. EPA, 211 F.3d 1280, 1299-1300 (D.C.

Cir. 2000) (holding that the logical outgrowth requirement was satisfied where "the final rule was not wholly unrelated or surprisingly distant from what the [agency] initially suggested"); Omnipoint Corp. v. FCC, 78 F.3d 620, 632 (D.C. Cir. 1996) (concluding that the FCC's final rule that defined eligibility preferences in a manner that excluded more participants than under proposed rule was a logical outgrowth because it is consistent with the FCC's overall approach in its proposed rules). The initial notice and comment is adequate if the changes to the proposed plans "are in character with the original scheme." Chocolate Mfrs. Assoc. v. Block, 755 F.2d 1098, 1105 (4th Cir. 1985). Only if the final rule "materially alters" the issues involved in the rulemaking or if it "substantially departs from the terms or substance of the proposed rule," is the notice inadequate. Id.

The USPTO's overall approach throughout the rulemaking process for the continuing applications and claims practices has not changed. As to continuations practice, the Final Rules, like the Proposed Rules, set a threshold for the number of continuing applications that could be filed as a matter of right. The Final Rules differ from the Proposed Rules only by relaxing that threshold and allowing applicants to file more continuing applications and RCEs before having to petition and make a showing, thus inuring to the benefit of applicants.

The Proposed and Final Rules also include the same general approach to claims – to set a threshold number of claims in an application beyond which an applicant must submit an ESD. In fact, 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." 71 Fed. Reg. at 62 (citing Changes to Implement the Patent Business Goals, 63 Fed. Reg. 53497, 53506-508 (Oct. 5, 1998)). In light of that earlier proposal, interested parties were well aware that limiting total claims was an equally viable option for relieving the burden on examination caused by high numbers of claims. Thus, although a change in the threshold used, i.e., representative

claims vs. total claims, emerged (in response to public comments and in order to reduce applicant burdens), the essential framework of specifying the number of claims to be examined without submitting an ESD remained the same. The differences between the Proposed and Final Rules are consistent with circumstances approved by the courts and not "a surprise switcheroo on regulated entities." Envt'l Integrity Project v. Envt'l Prot. Agency, 425 F.3d 992, 996 (D.C. Cir. 2005).

The actual comments received in response to the proposed rulemaking underscore that the Final Rules were reasonably foreseeable. In response to the proposal that only ten representative claims would be examined without the submission of an ESD, several comments criticized the representative claim approach, explaining that it might lead to piecemeal examination or adversely affect the treatment given to dependent claims in court. 72 Fed. Reg. at 46787. Further, comments criticized the representative claim approach because it would affect "the vast majority" of applications rather than targeting only those with an unusually large number of claims. Id. at 46795. Some comments suggested a hard limit that could never be exceeded, e.g., A01835, while others suggested setting a limit on the number of claims that could be exceeded if an applicant submitted an ESD. 72 Fed. Reg. at 46787. The rationale given by the commentor for that last suggestion, which was ultimately adopted in the Final Rules, was that it relieves most applicants of the burden of selecting representative claims. Id. As for the specific number of claims, various suggestions were made, e.g., 6 independent and 30 total, A00673 (AIPLA suggesting more claims could be added for a "very high per claim cost") and 2-3 independent and 20-30 total, A01835. Thus, the comments demonstrate that interested parties not only anticipated the full potential scope of the Final Rules, but also that they supported the alternative approach that the USPTO took to relieve burdens of the original proposal. Because the USPTO's Final Rules are consistent with the concerns and overall approach raised in the Proposed Rules, they are unquestionably a "logical outgrowth," requiring no new notice and comment period.

Turning to the specific additional provisions of the Final Rules that Tafas asserts are different from the Proposed Rules, Tafas Am. Compl., ¶ 71(e), (f), & (i), Tafas either misstates the difference between the Proposed and Final Rules or ignores the logic of the outgrowth.[33] First, Tafas contends that Final Rule 78(d)(1)(iii), which prohibits the filing of a continuation-in-part application from a divisional application, differs from the Proposed Rules. Id. In fact, the prohibition to which Tafas refers was implicitly within the scope of the Proposed Rules, which defined "divisional application" in a way that excluded so-called "voluntary" applications," i.e., applications not filed in response to a restriction requirement. See 71 Fed. Reg. at 58 (Proposed Rule 78(a)(3), requiring that a restriction, or unity-of-invention, requirement is a prerequisite to filing a divisional application) (Ex. 3). Because continuation-in-part applications have never been allowed following a "divisional application," as that term was defined in the proposed rule, the Final Rules do not differ from the Proposed Rules.

Second, contrary to Tafas's claim, Final Rule 78(d)(1)(iv) does not create a "penalty" for filing a demand in an international application designating the United States.[34] Tafas Am. Compl. ¶ 71(f). To the contrary, this rule relaxes the 2+1 Rule by permitting an applicant an additional continuing application ("3+1") when an application claims the benefit of an international application for which a demand has not been filed, while making the general 2+1 Rule (Final Rule 78(d)(1)(i)) applicable if a demand has been filed in an international application. See Small

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[33] Although Tafas lists nine separate "provisions" allegedly promulgated without notice, six of those are nothing more than ramifications of the same "5/25" aspect of the Final Rules about which GSK complains. See Tafas Am. Compl. at ¶ 71(a)-(d), (g), & (h). In other words, the allegations Tafas seems to be making in parts (a)-(d), (g), and (h) of paragraph 71 of his Amended Complaint all seem to turn on the shift from representative claims to total claims, and not some other aspect of the Final Rules.

[34] A "demand" is a request made in an international application for a preliminary examination at the international level before an application enters the United States or other designated states. See MPEP § 1865.

Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 548 (D.C. Cir. 1983) (EPA's request for comments on how to prevent increases in the number of refineries that qualify as small also encompassed loopholes permitting large refineries to qualify as small).

Finally, contrary to Tafas's assertion that Final Rule 265(a)(4) added an ESD requirement not present in the Proposed Rules, see id. at ¶ 71(i), Proposed Rule 261(a)(4) contained the same ESD requirement. See 71 Fed. Reg. at 68-69 (Ex. 3). The only difference between the two requirements was a reference in the Proposed Rule to an existing regulation, 37 C.F.R. § 1.111. The deletion of that reference in the final rule does not change its scope.

In short, where the Final Rules differ from the Proposed Rules, those differences are the result of the notice-and-comment process working, not its violation. The APA's rulemaking scheme operated exactly as Congress designed: An agency modified proposed rules to address public concerns while keeping the overall scheme intact. The Court should reject Plaintiffs' arguments because the Final Rules are a logical outgrowth of the Proposed Rules.

VIII. THE USPTO COMPLIED WITH THE REGULATORY FLEXIBILITY ACT

The Court should uphold the USPTO's Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-612, certification that the Final Rules will not have a significant economic impact on a substantial number of small entities. Although the USPTO did not have to abide by the RFA because its rules were procedural in nature, it nevertheless published a certification that complies with 5 U.S.C. § 605(b). See 72 Fed. Reg. at 46830-34; A08307-08315. It also published a report analyzing in the detail required of a full RFA analysis the impact of the Final Rules on small entities. See 72 Fed. Reg. at 46831; A08270-306. Accordingly, even if this Court were to find the certification deficient, the Office has alternatively complied with the RFA by performing an analysis that would pass muster as a final regulatory flexibility analysis under 5 U.S.C. § 604.

"The RFA imposes no substantive requirements on an agency; rather, its requirements are

'purely procedural' in nature." Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric., 415 F.3d 1078, 1100 (9th Cir. 2005) (quoting U.S. Cellular Corp. v. FCC, 254 F.3d 78, 88 (D.C. Cir. 2001)); Alenco Commc'ns Inc. v. FCC, 201 F.3d 608, 625 (5th Cir. 2000) ("The RFA is a procedural rather than substantive agency mandate"). For any regulation required to be published through notice and comment rule-making,[35] the RFA requires federal agencies to consider the effect that the rule will have on small entities, analyze alternatives that may minimize a regulation's impact on such entities, and make the initial and final analyses available for public comment. 5 U.S.C. §§ 601-604. As the Fifth Circuit has explained, the agency typically must include a final regulatory flexibility analysis, encompassing:

> a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

Alenco Commc'ns., 201 F.3d at 624-25.

A full regulatory flexibility analysis is not required, however, where, as here, the agency "certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities," and provides a factual basis for that certification. 5 U.S.C. § 605(b); Transmission Access Policy Study Grp. v. Fed. Eng. Reg. Comm'n, 225 F.3d 667, 737-38 (D.C. Cir. 2000). Only a limited judicial review of agency compliance with the RFA is permitted. 5 U.S.C. § 611(a)(5). The Federal Circuit has held that so long as the agency did not abuse its

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[35] As previously discussed, because the Final Rules are merely procedural, the Office was not required to comply with the notice and comment provisions of Section 553 of the APA. Accordingly, the impact analysis requirements of the RFA are equally inapplicable. See Central Texas Tel. Coop. v. FCC, 402 F.3d 205, 214 (D.C. Cir. 2005) (holding that the impact analysis requirements of the RFA apply only to legislative, i.e., substantive, rules). For this reason alone, Tafas's RFA claim must be dismissed.

discretion, RFA certifications must be upheld. Carpenter v. Sec'y of Veterans Affairs, 343 F.3d 1347, 1357 (Fed. Cir. 2003) (applying an "abuse of discretion" standard in reviewing an RFA certification).

A. The USPTO Provided a Factual Basis For Its Certification and Reasonably Concluded that the Final Rules Would Not Have a Significant Impact on Small Entities

The Office concluded that the Final Rules would not have a "significant" economic impact on a "substantial" number of small entities. 72 Fed. Reg. at 46832. As to economic impact, the USPTO explained that the Final Rules would cost applicants between $2,563 and $13,131 to file an ESD, a petition for continued examination, or both. Id. Presuming that an economic impact of greater than 3% of annualized incremental cost as a percentage of revenue was a "significant" impact, the USPTO determined that no small entities would fall into this category. Id. Also presuming that an economic impact of greater than 1% would cause a more moderate impact, the Office determined that fewer than 1% of small entities fell into this category. Id. The Office's analysis considered that the number of small entities affected would be "substantial" if more than 20% were affected. Id. The Office concluded that 1.0% of small entities would be required to submit an ESD, that 2.7% would be affected by the requirement to submit a petition for an additional continued examination filing, and that 0.3% would be affected by both requirements. Id. Thus, the Office reasonably concluded that the Final Rules did not impact a substantial number of small entities.

Despite Tafas's allegations to the contrary, see Tafas Am. Compl. ¶¶ 82-84, the USPTO considered each of the issues he now raises and was reasonable in certifying the Final Rules. 72 Fed. Reg. at 46831-834. First, the USPTO used a reliable methodology to calculate the ESD costs. A08287-90, A08304. Taking into account the six elements that an ESD must contain, the USPTO calculated the cost to applicants to perform each element separately. A08288-90.

Further, the USPTO broke down the cost analysis into two additional categories, one for applicants who had previously conducted a patent search report and the other category for applicants who had not. Id. The USPTO meticulously detailed all sources it used for every cost element. A08304. Ultimately, using this methodology, the USPTO estimated that the incremental cost to prepare and file an ESD for applicants in the first category (search report already conducted) was $2,563 - $10,136, and for applicants in the second category (no search report conducted yet) was $5,170 - $13,121. A08290.

Second, Tafas's argument that the USPTO did not consider the "economic impact" of the Final Rules on an inventor's ability to defend its patents lacks a factual basis. See Tafas Am. Compl. ¶ 82. The Office specifically considered the effect the Final Rules might have on an inventor's ability to defend its patents. 72 Fed. Reg. at 46768, 46779, 46801-882 (discussing why the Final Rules would not increase a patentee's inequitable conduct exposure). That Tafas disagrees with the Office's conclusions does not demonstrate that the USPTO violated the RFA.

Third, the Office specifically assumed, for purposes of a sensitivity analysis, that all patent applicants qualified as small entities. 72 Fed. Reg. at 46833; A08283. Thus, the Office accounted (actually, over-accounted) for the entire universe of affected small entities, as well as all entities.

Finally, the USPTO did, in fact, consider all of the public's comments, as well as studies concerning the commercial value of patents, and responded to them in the Federal Register. 72 Fed. Reg. at 46831-834; A08301-03. The Office not only considered and responded to public comments, but also changed numerous provisions as a direct result of those comments. 72 Fed. Reg. at 46831-834. Clearly, in this situation, the USPTO acted reasonably. Cement Kiln Recycling Coal. v. EPA, 493 F.3d 207, 225-26 (D.C. Cir. 2007) (upholding agency's rule where it considered all comments); Aeronautical Repair Station Ass'n v. Fed. Aviation Admin., 494 F.3d 161, 173 (D.C. Cir. 2007) (finding agency's succinct response to comments adequate).

The final Federal Register notice contains the factual basis for the Office's certification, and its decision to certify is fully supported by the administrative record. Carpenter, 343 F.3d at 1357 (dismissing RFA claim where administrative record did not support plaintiff's contention that certification was improper). Indeed, upon review of the Office's certification of the Final Rules, an Assistant Chief Counsel at the Small Business Administration (SBA) Office of Advocacy remarked that "this is one of the best responses to Section 3(c) of E.O. 13272 that I have seen." A08505. The Federal Circuit has upheld a far less comprehensive certification than the one the USPTO prepared for the Final Rule. See, e.g., Carpenter, 343 F.3d at 1357.[36] In the end, Plaintiff's mere disagreement with the USPTO's ultimate conclusions about the economic impact of the Final Rules does not render the USPTO's certification an abuse of discretion. Nat'l Coal. For Marine Conservation v. Evans, 231 F. Supp.2d 119, 143 (D.D.C. 2002) (RFA does not give plaintiff the authority to determine which alternatives best meet the agency's goals).

B. The USPTO Substantially Provided a Full Regulatory Flexibility Analysis

Even if the Court concluded that the certification was deficient in some respect, Tafas cannot prevail because the USPTO has otherwise substantially complied with the RFA. See Envt'l Defense Center v. EPA, 344 F.3d 832, 879 (9th Cir. 2003) (finding any hypothetical noncompliance with RFA harmless). Indeed, the USPTO has already met the requirements for initial and final analyses under §§ 603 and 604(a) by issuing thorough initial and final certifications, along with a comprehensive final analysis. See A07325-27; A08307-08318;

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[36] A full statement of the certification and analysis in Carpenter is as follows: "The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. §§ 601-602. This rule will affect only the processing of claims by VA and will not affect small businesses. Therefore, pursuant to 5 U.S.C. § 605(b), this final rule is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604." Board of Veterans' Appeals: Rules of Practice-Attorney Fee Matters, 67 Fed. Reg. 36102, 36104 (May 23, 2002).

A08270-306. Specifically, the USPTO has: (1) stated the need for and objective of the Final Rules, 72 Fed. Reg. at 46717-22; A08275-79; (2) summarized significant issues raised by public comments about the Office' s initial certification, 72 Fed. Reg. at 46831-34; (3) assessed all public comments, including comments submitted by the Small Business Administration's Office of Advocacy, id.; (4) stated the changes adopted in the Final Rules as a result of these comments, 72 Fed. Reg. at 46831; (5) described and estimated the number of small entities to which the rule applies, id.; A08281-82; (6) described the projected reporting, record keeping and other compliance requirements of the Final Rules, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for preparation of the report or record, 72 Fed. Reg. at 46831, A08287-91; and (7) described the steps the Office has taken to minimize any impact on small entities consistent with the stated objectives, including a statement of the factual, policy and legal reasons for selecting the alternative adopted and why each one of the other significant alternatives was rejected, A08291-302. See 5 U.S.C. § 604(a).

Accordingly, the USPTO's certification constituted a reasonable, good faith analysis consistent with the full requirements of a regulatory flexibility analysis. U.S. Cellular Corp., 254 F.3d at 89; Associated Fisheries of Me., Inc. v. Daley, 127 F.3d 104, 116 (1st Cir. 1997) ("The point is not whether the Secretary's judgments are beyond reproach, but whether he made a reasonable, good faith effort to canvass major options and weigh their probable effects."). The USPTO's analysis meets every requisite component for a final regulatory flexibility analysis. Id. at 115 (agency can satisfy § 604 of RFA by making the end product, in whatever form it reasonably may take, readily available to the public). Accordingly, there has been no RFA violation.

CONCLUSION

For the foregoing reasons, the Court should grant the USPTO's motions for summary judgment. The Final Rules are careful and lawful provisions that seek to effect critical reforms. They should be permitted to take effect without further delay.

Respectfully submitted,

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