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

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

CONSOLIDATED WITH

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

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF TRIANTAFYLLOS TAFAS'S MOTION FOR SUMMARY JUDGMENT

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MISCELLANEOUS

Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively "USPTO" or "Office") respectfully oppose Plaintiff Triantafyllos Tafas's ("Tafas") cross-motion for summary judgment. This memorandum addresses only those claims that Tafas raises but that the GlaxoSmithKline Plaintiffs ("GSK") do not. To the extent that Tafas's arguments overlap with those of GSK, the USPTO addresses those arguments in its memorandum opposing GSK's cross-motion for summary judgment. The USPTO respectfully recommends that the Court first read the memorandum that responds to GSK's cross-motion for summary judgment before turning to this brief.

ARGUMENT

I. TAFAS'S ANCILLARY ARGUMENTS FAIL TO ESTABLISH THAT THE FINAL RULES CONFLICT WITH THE PATENT ACT

Tafas challenges the Final Rules on a variety of grounds beyond those already addressed in the USPTO's opposition to GSK's summary judgment motion.[1] These arguments are largely distractions from the core issues in this case and are uniformly without merit. They must, of course, be considered within the framework of Chevron deference elaborated in the USPTO's opening brief and in its opposition to GSK's summary judgment motion. Chevron USA, Inc. v. NRDC, Inc., 467 U.S. 837 (1984); Mem. in Supp. of Defs. Mots. for Summ. J. ("USPTO Mem."), Dkt. No. 127, at 13-17; Defs. Mem. in Opp. to the GlaxoSmithKline Pls. Mot. for Summ. J. ("USPTO GSK Opp."), at Part I.A.

A. Final Rules 75 and 265 Do Not Impermissibly Alter Burdens of Proof

Tafas's approach to attacking Final Rules 75 and 265, is different, but no more persuasive

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

than GSK's approach. Tafas argues that Final Rules 75 and 265 ("the 5/25 Rule") violate the Patent Act by "impermissibly shift[ing] the burden of proving when an application should issue to the applicant." Pl. Triantafyllos Tafas' Mem. of Law in Supp. of Summ. J. Mot. ("Tafas Mem."), Dkt. No. 141, at 13. This is incorrect both as a matter of fact and law.

As a factual matter, by requiring an examination support document ("ESD") when applicants present more than 5/25 claims for examination, the Office is not transferring to applicants its own duty under 35 U.S.C. §§ 131 and 151 to examine an application and determine whether the claimed invention is patentable. Nor is the Office asking applicants to come forward with a prima facie case of patentability, diverging from current practice where the examiner makes a prima facie case of unpatentability. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Instead, Final Rules 75 and 265 merely require an applicant who files a large number of claims to assist the examiner by providing additional information about the claims, which the examiner will use in examining the application. The applicant is not required to prove that any material is patentable or conduct the examination for the examiner. See 72 Fed. Reg. at 46805.

Furthermore, notwithstanding the USPTO's adoption of the prima facie case mechanism, it is well-established that the USPTO may promulgate rules that place on the applicant the burden of coming forward with information to assist in examination. It is well-settled, for example, that the USPTO has authority under 37 C.F.R. § 1.56 (2006) to require applicants to present information known to them that is material to examination. See, e.g., Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1352 (Fed. Cir. 2005). Likewise, under 37 C.F.R. § 1.105 (2006), an examiner may require an applicant to produce "such information as may be reasonably necessary to properly examine or treat the matter." As the Federal Circuit held in Star Fruits S.N.C. v. United States, 393 F.3d 1277 (Fed. Cir. 2005), an examiner may properly

declare an application abandoned for failure to comply with a request under § 1.105, even though the applicant contended the requested information could not provide the basis for an unpatentability rejection on the merits. This is because the USPTO has "inherent authority . . . to require information from an applicant," which extends beyond what would be material under § 1.56. Id. at 1282.

Even if the Court were to find that Final Rules 75 and 265 shift the burden of proof to the applicant, however, Tafas fails to cite any section of the Patent Act unambiguously establishing that the USPTO must bear the burden of coming forward with prima facie evidence of unpatentability. The sections he cites – 35 U.S.C. §§ 101, 111, 112, 131, and 151 – say nothing of the sort, and as the Federal Circuit has acknowledged, the origin of the current burden-shifting practice is "uncertain." In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Moreover, the only case Tafas cites, Oetiker, does not purport to interpret the Patent Act, but simply describes the USPTO's current practice of having the examiner come forward with a prima facie case of unpatentability. In the absence of unambiguous language requiring the USPTO to bear the burden to come forward with a prima facie case, the USPTO may enact reasonable regulations altering this practice, provided it has the power to do so under 35 U.S.C. § 2(b)(2).[2] See United States v. Mead Corp., 533 U.S. 218, 229 (2001); Chevron, 467 U.S. at 842-431. Oetiker establishes that the USPTO has such authority, for it makes clear that "the prima facie case is a procedural tool," id. – precisely the type of tool that even Tafas would admit the USPTO has authority to alter. See also Piasecki, 745 F.2d at 1472. Thus, in Stevens v. Tamai, 366 F.3d 1325 (Fed. Cir. 2004), the Federal Circuit affirmed the USPTO's authority to set burdens of

[2] At least two judges of the Federal Circuit have noted the anomaly of a regime that does not place the burden of proof on the party seeking a government grant of exclusive rights and implied that the statute may not require that outcome. See In re Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, Cowen, J.J. *concurring*).

proof in interference proceedings. See id. at 1333 ("[T]he Office can allocate the burdens associated with this goal in a reasonable manner not inconsistent with the existing statutory scheme.") (citing Merck & Co, Inc. v. Kessler, 80 F.3d 1543, 1549 (Fed. Cir. 1996)).

Finally, contrary to Tafas's suggestion, there is no loss of substantive rights because the Final Rules do not alter the substantive criteria for allowing and rejecting applications. See 35 U.S.C. § 101, 102, 103 & 112. The USPTO will still only reject applications on the merits if the evidence of record establishes a prima facie case of unpatentability.[3]

B. Final Rule 78(f)(2) Does Not Alter Burdens of Proof

Tafas also challenges the legality of Rule 78(f)(2), which sets forth a rebuttable presumption that applications that meet certain narrow conditions contain patentably indistinct claims. 72 Fed. Reg. at 46840; 37 C.F.R. § 1.78(f)(2). Final Rule 78(f)(2) helps ensure that applicants will not evade the 2 + 1 and 5/25 Rules by seeking to patent the same invention using multiple initial applications. Final Rule 78(f)(2), like the 5/25 Rule, is fundamentally an information-producing regulation, for in order to rebut the presumption, an applicant must "explain[] how the application contains only claims that are patentably distinct from the claims in each of such other pending nonprovisional applications or patents." 72 Fed. Reg. at 46840; 37

[3] Tafas concocts a rather far-fetched example wherein the agency would instruct an applicant that certain claims were allowable if rewritten and then prevent the applicant, by operation of rule, from receiving a patent with the rewritten claims. Tafas Mem. at 14. The USPTO suggests that such esoteric examples are not appropriately considered on this facial challenge and are best handled if and when they arise in the real world. Cf. Abbott Labs. v. Gardner, 387 U.S. 136, 148-49 (1967), overruled on other grounds, Califano v. Sanders, 430 U.S. 99 (1977). Certainly Tafas has not alleged that he is currently facing anything like the hypothetical problem he posits. Of course, even if he were, there are avenues of relief available for applicants unjustly caught by USPTO rules, including an examiner's amendment, wherein the examiner and not the applicant amends the claims, see U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure ("MPEP") § 1302.04 (8th ed. 2001, rev. Aug. 2006), or a petition by the applicant under 37 C.F.R. § 1.183 (2006) to waive a particular rule.

C.F.R. § 1.78(f)(2). This information, like the ESD, helps an examiner determine whether the application meets the conditions of patentability and ensures against double-patenting.

The arguments that refute Tafas's ESD-related burden-shifting claim thus apply with equal force to Final Rule 78(f)(2). See supra Part I.A. First, Final Rule 78(f)(2) does not, as a factual matter, shift burdens of proof, but merely is an information-producing regulation that aids the USPTO in examining an application. Furthermore, the Federal Circuit has made clear that the USPTO can require the submission of information in aid of its meeting its burden under current practice to come forward with a prima facie case of patentability. See Bruno Indep. Living Aids, 394 F.3d at 1352; Star Fruits S.N.C., 393 F.3d at 1282. Regardless, even if Final Rule 78(f) shifts any burden of proof, Tafas can point to no statutory language prohibiting the USPTO from doing so. Burdens of proof are "procedural" tools lying within the agency's authority under § 2(b)(2). Stevens, 366 F.3d at 1333; Oetiker, 977 F.2d at 1445. Accordingly, Final Rule 78(f)(2) does not run afoul of the Patent Act.[4]

C. Final Rule 78(f) Comports with Section 122

Tafas also argues that the requirement to identify patentably indistinct claims and the requirement to rebut a presumption of patentably indistinct claims in related applications in Final Rule 78(f) will force applicants to disclose subject matter that they want to maintain in confidence. Tafas Mem. at 16-18; see also Tafas Am. Compl. at ¶ 56(h). Such forced disclosure, Tafas complains, contravenes 35 U.S.C. § 122. Id.

[4] Because Final Rule 78(f)(1) and (2), like the ESD requirement, are both fundamentally information-producing measures, *Amicus* Cantor Fitzgerald Property Holdings, LLC ("CFPH") errs in suggesting that this rule is substantive rather than procedural in nature. Br. of *Amicus Curiae* CFPH, LLC in Supp. of Pls. Summ. J. Mots., Dkt. No. 119. Final Rule 78(f) is procedural, and within the USPTO's rulemaking authority under 35 U.S.C. § 2(b)(2), for many of the same reasons as Final Rules 75 and 265. See USPTO GSK Opp. at Part I.A.

The USPTO addressed this claim in its opening brief, including explaining that the issue has been waived. USPTO Mem. at 33. The USPTO responds further only to address an unlikely hypothetical Tafas poses. Tafas speculates that the situation could arise in which an applicant files one application on track for publication and later files a second, related application with a non-publication request. While the Office is unaware of any such situation, such an applicant could use existing Office procedure to keep certain information about the second application out of the publicly-available file by filing a "petition to expunge." See MPEP § 724 (addressing submission of trade secret, proprietary, and protective order materials and expungement procedures for information not material to patentability). Under those procedures, the Office would maintain such information under seal and expunge the information if it was found not to be important to a reasonable examiner in deciding whether to allow the application to issue as a patent. MPEP § 724.04(a). Thus, the process would lead only to the disclosure of information that an applicant would otherwise be required to disclose to obtain a patent. Alternatively, such a hypothetical applicant could petition for a waiver of Final Rule 78(f) under 37 C.F.R. § 1.183 (2006) if he believes compliance with Final Rule 78(f) will cause a disclosure of information that he thinks should be protected under § 122. Thus, Final Rule 78(f) would not automatically require the disclosure of unpublished information in Tafas's unique hypothetical.

D. Final Rule 78(d) Is Consistent with Section 121, Which Permits a "Divisional Application" in Response to a Restriction Requirement

Tafas appears to assert that Final Rule 78(d) prohibits the filing of so-called "voluntary divisional" applications. Tafas Mem. at 15-16. Tafas's argument proceeds from the flawed premise that 35 U.S.C. § 121 permits an applicant to file a divisional application drawn to subject matter that was described, but not claimed, in a parent application where no restriction ever issued. Id. As the USPTO's opening brief explains, the Final Rules simply follow the Patent

Act's requirement that a "divisional" application may be drawn to subject matter that was: (i) disclosed; (ii) claimed; and (iii) subject to a restriction requirement in an earlier application. USPTO Mem. at 31-32. Section 121 states:

> If two or more independent and distinct inventions **are claimed** in one application, the **Director may require the application to be restricted** to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application **with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement**, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application . . . .

35 U.S.C. § 121 (emphases added). Section 121 thus explains that only "claimed" subject matter may be restricted. In addition, § 121 explains that the estoppel effect against double patenting will not arise unless the Office issues a restriction requirement. See Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1347-48 (Fed. Cir. 2004) ("As section 121 has been interpreted by this court, Bristol-Myers is entitled to invoke the statutory prohibition against the use of the '707 patent 'as a reference' against the divisional application that resulted in the '927 patent only if the divisional application was filed as a result of restriction requirement.") (emphasis added); Studiengesellschaft Kohl mbh v. N. Petrochemical Co., 784 F.2d 351, 360 (Fed. Cir. 1986) (Newman, J., concurring) ("[T]he safeguard of §121[3] does not apply if the divisional application was voluntarily filed by the applicant and not in response to a PTO restriction requirement . . . [n]or does it apply if the restriction requirement was withdrawn by the examiner.").

A so-called "voluntary divisional" lacks the necessary restriction requirement and therefore cannot qualify as a true "divisional" application under § 121. While Tafas or any

applicant may voluntarily file a child application drawn to subject matter disclosed (but unclaimed) in a parent application, that filing is simply a continuation application under 35 U.S.C. § 120.[5]

The cases Tafas cites are not to the contrary. Tafas Mem. at 16. Tafas selectively quotes from In re Schneller, 397 F.2d 350 (C.C.P.A. 1968), but there, the C.C.P.A. merely expressed bafflement over why the applicant did not wait for a restriction requirement. Id. at 353 ("There is, therefore, no direct indication before us of why appellant chose this voluntary division method . . . except for his present contention that under the rules he thinks he should not have done so. He certainly could have tried it. At worst he would have had a requirement for restriction."). Moreover, In re Van Ornum, 686 F.2d 937 (Fed. Cir. 1982), simply clarifies that the so-called "voluntary divisional application" in Schneller was actually nothing more than a "continuation" application. Id. at 943.

Tafas also asserts – with no explanation – that Final Rule 78(d)(1)(iii) improperly prohibits filing continuation-in-part applications off of divisional applications. Tafas Mem. at 16. As the USPTO explained in its opening brief, the law has never permitted such a practice. USPTO Mem. at 31.

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[5] The allegation by *Amicus* "FICPI" that the definition of a "divisional application" in the Final Rules violates the Paris Convention for the Protection of Industrial Property ("Paris Convention"), July 14, 1967, 21 U.S.T. 1583, is flawed. See Br. of *Amicus Curiae* Federation Internationale des Conseils en Propriete Industrielle ("FICPI") in Supp. of the Pls. Anticipated Mots. for Summ. J., Dkt. No. 140, at 3-4. In fact, to the extent that the Paris Convention permits an applicant to divide a patent application "on his own initiative," Article 4G (2) expressly provides that "each country of the Union shall have the right to determine the conditions under which such division shall be authorized." Paris Convention, Article 4G (2), 21 U.S.T. 1583. Here, the United States has exercised such right by enacting 35 U.S.C. § 121, which conditions the filing of divisional applications upon issuance of a restriction by the Director. See also infra Part VIII (explaining why no cause of action for violation of the Paris Convention may be pursued under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A)).

E. Final Rule 78(d)(ii)(B) Does Not Implicate, Let Alone Conflict with, the "Objectives" of the Bayh-Dole Act (35 U.S.C. § 200)

Tafas argues that Final Rule 78(d)(ii)(B) frustrates the objectives of the Bayh-Dole Act as set out in 35 U.S.C. § 200 (titled "Policy and objective"). Tafas Mem. at 19-20. Focusing on a prefatory statement of policy, Tafas does not allege that the Final Rules violate any actual rights, requirements, or obligations of the Bayh-Dole Act. Indeed, they do not. The Bayh-Dole Act simply creates funding agreements between the Government and small businesses or non-profit organizations and, under certain circumstances, confers on the Government rights to license inventions whose research and development it has funded. See 35 U.S.C. §§ 202-10. None of the Final Rules remotely relate to – much less conflict with – these substantive provisions, which is enough to dispose of Tafas's claim.

To the extent the Court goes further, Tafas's specific argument is that requiring applicants to prosecute generic claims[6] to exhaustion before filing a divisional application to any non-elected species[7] "significantly delays the commercial utilization of non-elected species later found by contractors under the Bayh-Dole Act to be valuable." Tafas Mem. at 20; Tafas Am. Compl. at ¶ 56 (l) & (m). In fact, the Final Rules treat generic claims exactly like the pre-existing rules, and Tafas fails to show otherwise.[8] The Final Rules thus have no bearing on the

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[6] A generic claim is a claim that covers multiple species that may also be separately claimed in the same application. See MPEP § 806.04(d).

[7] When the Office examines a generic claim, it may ask the applicant to choose (i.e., "elect") one of the species covered by the generic claim for initial examination. The species not chosen for initial examination are referred to as "non-elected species." See MPEP § 809.02(a).

[8] For example, if an application contains a generic claim covering multiple species as well as separate species claims, the only action the USPTO can take is to issue a "provisional" restriction. See MPEP § 809.02. That is, if the generic claim is ultimately found allowable, then the Office cannot issue a restriction requirement under 35 U.S.C. § 121, dividing the species claims, because the allowable generic claim covers all the species. If, however, the generic claim

objectives of the Bayh-Dole Act.

F. Final Rule 75 Tracks Statutory Definitions Set Forth in Sections 41 and 112

Tafas incorrectly argues that Final Rules 75(b)(2) and 75(c) impermissibly alter the definition of "dependent" and "multiple dependent" claims in violation of 35 U.S.C. § 112 and allegedly reset fees in violation of 35 U.S.C. § 41.[9] Tafas Mem. at 12-13; Tafas Am. Compl. at ¶ 56(a). He is incorrect on both counts. See USPTO Mem. at 30-31.

Final Rule 75(b)(2) states that: (i) a "claim that refers to another claim but does not incorporate by reference all the limitations of the claim to which it refers will be treated as an independent claim for fee calculation purposes" and (ii) "a claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for fee calculation purposes." 72 Fed. Reg. at 46836. By treating such claims as independent, Final Rule 75(b)(2) tracks the statutory definitions of "dependent" and "multiple dependent" claims set forth in the Patent Act.

A dependent claim refers to an earlier claim and further limits the subject matter of that claim. See 35 U.S.C. § 112, ¶ 4. A multiple dependent claims refers to more than one earlier claim and also further limits the subject matter of those claims. See id., ¶ 5. A claim that refers to another claim but does not incorporate the limitations of that claim, as set forth in 75(b)(2), is in no way dependent on the referenced claim. Similarly, a claim that references another claim of

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is ultimately not found allowable and the applicant chooses to cancel the rejected generic claim, then the Office would be free to issue a restriction requirement dividing the independent and distinct species claims. Once the restriction requirement issues, the applicant could file claims to the non-elected species claims in divisional applications under § 121.

[9] Tafas incorrectly cites Final Rule 75(b)(4) rather than Final Rule 75(c) regarding the definition of multiple dependent claims. Tafas Mem. at 30. In the USPTO's opening memorandum, the Office incorrectly identified Final Rule 75(c) as Final Rule 75(b)(5)(C). USPTO Mem. at 30. The USPTO apologizes for any confusion this error may have caused.

a different statutory class of invention,[10] as set forth in 75(b)(2), cannot be a dependent claim either because it does not further limit the referenced claim in any way; it merely refers to it. See USPTO Mem. at 30 (citing IPXL Holdings, 430 F.3d at 1384 (single claim directed to multiple statutory classes of invention is improper under 35 U.S.C. § 112)).[11] Thus, both kinds of claims set forth in Final Rule 75(b)(2) stand alone and are properly treated as independent claims.

Further, as is evident from the quoted text of Final Rule 75(b)(2), the rule says nothing about changing the fees an applicant must pay for independent claims. A claim classified as "independent" costs the same under the Final Rules as it does under pre-existing rules. Although such claims have been treated as dependent in the past for fee purposes, substantively such claims have always been treated as independent for patentability purposes. Hence, contrary to Tafas's argument, Final Rule 75(b)(2) comports with both 35 U.S.C. § 112 and 35 U.S.C. § 41.

The same is true of Final Rule 75(c). This rule states: "For fee calculation purposes . . . 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. Notably, this is the same definition for "multiple dependent" claim found in pre-existing Rule 75(c). See USPTO Mem. at 30 (citing 37

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[10] Under 35 U.S.C. § 101, there are four types of inventions: (i) process; (ii) machine; (iii) manufacture; and (iv) composition of matter. A claim must be directed to one of these statutory kinds of invention to be eligible for patenting. If a claim is directed to more than one kind, it is said to be a "claim of different statutory classes."

[11] Tafas specifically mentions "product-by-process" claims to argue that Final Rule 75(b)(2) changes the definition of a dependent claim. Tafas Mem. at 12. A "product-by-process" claim is a specialized type of product claim where the product is defined in terms of process or method of making. See MPEP § 2113. In such a claim, the process steps are not considered to be limitations of the claims for patentability purposes, i.e., the patentability of the product does not depend upon its process of making. Id.; In re Thorpe, 777 F.2d 695 (Fed. Cir. 1985). Where a "product-by-process" claim is written in dependent form – incorporating the process steps by reference to a process claim – it nevertheless must be substantively treated as an independent claim since incorporated process steps are not given patentable weight.

C.F.R. § 1.75(c) (2006)). Final Rule 75(b)(5)(c) thus does not change the definition of "multiple dependent claim" in any way. Moreover, in treating a multiple dependent claim to be that number of claims to which it refers, Final Rule 75(c) and pre-existing Rule 75(c) adopt the statutory definition for a "multiple dependent" claim set forth in 35 U.S.C. § 112, ¶ 5. As explained above, the Patent Act defines a "multiple dependent" claim as making "reference, in the alternative only, to more than one claim previously set forth." 35 U.S.C. § 112, ¶ 5. Lastly, the text in Final Rule 75(c) regarding the fees to be charged for a multiple dependent claim matches the fee language in 35 U.S.C. § 41. See 35 U.S.C. § 41(a) (providing that a multiple dependent claims "for purposes of computing fees" "shall be considered as separate dependent claims in accordance with the number of claims to which reference is made") (unnumbered ¶). Accordingly, like Final Rule 75(b)(2), Final Rule 75(c) is consistent with the Patent Act.

G. Tafas May Not Challenge the Final Rules's Retention of First Action Final Rejection Practice

Tafas alleges for the first time in his cross-motion for summary judgment that the Final Rules' maintenance of "first action final rejection" ("FAFR") practice violates 35 U.S.C. § 132(a).[12] Tafas Mem. at 18-19. Because Tafas failed to present this claim in his complaint, it should not be considered. See New Motor Vehicle Bd. of Ca. v. Orrin W. Fox Co., 439 U.S. 96, 125 n.29 (1978) ("Although the Court has endorsed the modern relaxation of pleading rules, it has never receded from the requirement that civil complaints provide parties defendant with "fair

[12] FAFR allows the USPTO to finally reject on the merits the claims in a continuation application in a first Office action in certain circumstances. See MPEP § 706.07(b) ("The claims of a new application may be finally rejected in the first Office action in those situations where (A) the new application is a continuing application of, or a substitute for, an earlier application, and (B) all claims of the new application (1) are drawn to the same invention claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application.").

notice" of the claims against them."); Ribis v. Mike Barnard Chevrolet-Cadillac, Inc., 468 F. Supp. 2d 489, 495 (W.D.N.Y. 2007) ("[A] plaintiff may not use a memorandum of law or similar paper to assert a claim that is not contained in the complaint."); Anderson v. Aset Corp., 329 F. Supp. 2d. 380, 383 (W.D.N.Y. 2004) ("[A] memorandum of law is not a proper vehicle for rewriting or amending the complaint.").

Moreover, the Federal Circuit has already held that a facial challenge to FAFR practice under 35 U.S.C. § 132, like Tafas's, is unripe, as a challenge to such a long-standing policy must first be brought in the context of a specific application. See Molins PLC v. Quigg, 837 F.2d 1064 (Fed. Cir. 1988) (declining to review USPTO's longstanding "FAFR" policy until it was presented to the court in context of specific application, "concluding that validity of MPEP 706.07(b) in vew of 35 U.S.C. § 132 is not ripe for judicial review"). Accordingly, this claim is not justiciable.

Regardless, nothing in § 132(a) prohibits the FAFR practice, which has existed since 1923 and serves the important purpose of preventing delay tactics by applicants. See, e.g., In re Bogese, 22 U.S.P.Q. 2d 1821, 1827 (Comm'r Pat. 1991) (FAFR practice "is in accordance with the statutory objective of reducing delay in prosecution . . . [and] is traceable as far back as 1923 and has existed on a continuous basis until the present date . . . [and] was crystallized in Office practice in MPEP Section 706.07(b) at the time the present 35 U.S.C. Section 120 was enacted in 1952; it must be assumed that legislators were aware of the practice . . ."). Section 132(a) simply requires the Office to "notify" an applicant of any rejection or objection to a claim and allow the applicant to respond so that the application can be reexamined. 35 U.S.C. § 132(a). Since FAFR practice simply permits the Office to reject a claim in a continuation application in a first Office action – where that claim has been previously rejected on the same grounds in the

prior parent application and the applicant has not amended that claim or presented any new evidence – FAFR practice comports with 35 U.S.C. § 132(a). See Bogese, 22 USPQ2d at 1825 (holding that FAFR practice is consistent with 35 U.S.C. § 132(a)).

In sum, despite his many attempts, Tafas fails to establish that the Final Rules violate the Patent Act.

II. THE FINAL RULES ARE NOT ARBITRARY OR CAPRICIOUS

Tafas argues on three erroneous and unsupported grounds that the Final Rules are arbitrary or capricious. See 5 U.S.C. § 706(2)(A). Like GSK, he fails to show that the Court should not defer to the Final Rules under the highly deferential State Farm standard. Motor Vehicle Mfrs. Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 43 (1983); see Tafas v. Dudas, — F. Supp. 2d —, 2008 WL 112043, at *3 (E.D. Va. Jan. 9, 2008) ("Tafas II").

First, Tafas disagrees with one of the USPTO's stated reason for the Final Rules, calling the "backlog" rationale arbitrary and capricious.[13] Tafas Mem. at 33. The USPTO's articulated goal of improving efficiency is neither arbitrary nor capricious. See, e.g., Nat'l Ass'n of State Utility Consumer Advocates v. FCC, 372 F.3d 454, 460 (D.C. Cir. 2004) (finding agency's efficiency rationale for increasing subscriber line charge cap proper and supported by the evidence). As the USPTO explained in its opening brief and its opposition to GSK's summary judgment motion, the administrative record amply establishes that the Final Rules will enable the USPTO to help reduce its backlog of pending applications. See A05641-A05721 (computer modeling of efficiency gains)[14]; see also USPTO Mem. at 35-36 (articulating a rational

[13] By focusing solely on the backlog rationale, Tafas (like GSK) ignores the USPTO's additional purposes for the Final Rules (e.g., to improve patent quality).

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

connection between each rule and expected efficiency gains); USPTO GSK Opp. at Part II.

Rather than pointing to contrary record evidence to support his claim, Tafas resorts to bald assertions and citations to extra-record evidence (without any explanation of what he believes is probative in that evidence). Tafas Mem. at 33-34. Use of such extra-record evidence is improper and must be disregarded.[15] As this Court has already observed, "'the focal point for judicial review should be the administrative record already in existence.'" Tafas II, 2008 WL 112043, at *3 (quoting Camp v. Pitts, 411 U.S. 138, 142 (1973)). Despite extraordinary efforts to prove that the USPTO's record is incomplete or inadequate, Tafas failed to make a "sufficiently strong or substantial showing of incompleteness to overcome the presumption that the USPTO properly designated the administrative record." Id. at 18. Accordingly, this Court's review is confined to the administrative record, and Tafas's "same arguments," relying on "most of the same exhibits" as in his discovery-related briefs, must be disregarded.[16] Tafas Mem. at 34 n.12.

Second, Tafas suggests that there are inconsistencies between materials that the USPTO submitted to the Office of Management Budget (OMB), primarily pursuant to the Paperwork Reduction Act ("PRA"), 44 U.S.C. § 3501 et seq, and other materials that he fails to clearly

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[15] The USPTO has contemporaneously filed a motion to strike, *inter alia,* Tafas's extra-record evidence and the parts of his brief that rely on them. The USPTO also moves to strike the vast majority of the exhibits to and text of the *Amici* Polestar Capital and Norseman Group's brief, which likewise uses extra-record evidence to argue that the Final Rules are arbitrary or capricious. See Br. of *Amici Curiae* Polestar Capital & Norseman Group in Supp. of Pls. ("Polestar Br."), Dkt. No. 173.

[16] Notably, even if this Court were to consider the extra-record statement of Commissioner John Doll that both Tafas and *Amici* Polestar Capital and Norseman Group excerpt (without providing a full transcript of the remarks), the administrative record shows that the USPTO did, in fact, consider whether rework applications were caused by examiner error or by applicant error and the impact of that rework upon the backlog. A04705-A04718.

identify. Here again, Tafas relies on extra-record materials, including a document that was submitted to OMB on September 26, 2007, more than a month after the USPTO promulgated the Final Rules. See Tafas Mem. at 35 (citing Ex. 25 to Reuda Declaration). Such materials are not properly before the Court, and his arguments should not be considered.

Tafas's OMB-related arguments are improper for another threshold reason. Even assuming (contrary to fact) that the USPTO's submissions to OMB contain information at odds with other USPTO statements, any such difference is irrelevant to the question of whether the Final Rules are arbitrary or capricious. To the extent any discrepancies exist, an assertion the USPTO contests, Tafas's recourse is to inform the Director of OMB. Cf. Ass'n of Am. Physicians & Surgeons, Inc. v. U.S. Dept. of Health & Human Servs., 224 F. Supp.2d 1115, 1129 (S.D. Tex. 2002) ("The PRA does not create a private right of action."); Tozzi v. EPA, 148 F. Supp. 2d 35, 43, 47 (D.D.C. 2001) (same); Exec. Order No. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993) (stating that Order "is intended only to improve the internal management of the Federal Government" and "does not create any right or benefit, substantive or procedural, enforceable at law or equity"). This lawsuit is not about whether the USPTO properly complied with the PRA or Executive Order 12,866, which is all that his claims implicate.[17] See Tafas Mem. at 35.

In any event, Tafas's claims are meritless and do not remotely suggest that the USPTO acted in an arbitrary or capricious manner:

(a) Tafas contends that the USPTO made "comments" that the rules would have

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[17] *Amici* Polestar Capital and Norseman Group similarly add a challenge under the Information Quality Act ("IQA"), 44 U.S.C. § 3516 Note, which is not properly considered by the Court because it is not raised by the parties. Polestar Br. at 15-17. In any event, like Executive Order 12,866 and the PRA, the IQA "creates no legal rights in any third parties" and simply "orders the [OMB] to draft guidelines concerning information quality and specifies what those guidelines should contain." Salt Inst. v. Leavitt, 440 F.3d 156, 159 (4th Cir. 2006).

"little impact" on applicants, but "suggested" to OMB that 5,000 applicants would avail themselves of the ESD procedure, while stating in unspecified "other forums" that most applicants would not file an ESD. Tafas Mem. at 35 ¶(a). Tafas fails to specify any such comments or statements in his extra-record exhibits, nor can the USPTO find any. Id. Moreover, while the USPTO has stated that the Final Rules will not have a "significant economic impact on a substantial number of small entities[,]" 72 Fed. Reg. at 46830-31 – a term of art under the RFA – it has not stated that they would have "little impact." Tafas Mem. at 35 ¶(a). The number of small entity applicants who will file an ESD bears no correlation to whether such filing will have a "significant economic impact" on those applicants.

(b) Tafas accuses the USPTO of misstating that it received "no comments" in response to the Information Collection Review ("ICR") that it submitted to OMB on September 26, 2007. Tafas Mem. at 35 ¶(b) (citing Ex. 25). The USPTO's statement is true. The USPTO published notice of its proposed ICR in the Federal Register on May 30, 2006 and opened a sixty-day comment period. See Notice, 71 Fed. Reg. 30,662 (May 30, 2006). Just as Tafas's exhibit states, "[n]o public comments were received" in response to that notice. The statement does not refer to public comments on the Proposed Rules.

(c) Tafas argues that the USPTO asserted to the public that the Final Rules place no limit on the number of continuing applications, but estimated to OMB that it expected 1,000 petitions for third or subsequent continuation applications to be filed. Tafas Mem. at 35 ¶(c). Here again, Tafas fails to identify any specific statements. Regardless, the USPTO's estimate was just that – an estimate – based on public comments it received during the rulemaking process concerning applicants' expected behavior. There is no inconsistency.

(d) Tafas claims that USPTO told the public the effect of the Final Rules would be

"offset by a rapidly decreasing inventory in the appeal process" while at the same time promulgating other proposed rules that "would increase workload in appeal by approximately one-third." Tafas Mem. at 35 ¶(d). Tafas again cites nothing for the USPTO's purported "assertions to the public." Id. In any event, the USPTO's analysis of pre-appeal brief conference effects speaks for itself. A05018.

(a)[18] Tafas asserts that the USPTO told OMB the rules were not economically significant, while internal data in the administrative record at A04553 indicates a substantial economic effect. Tafas Mem. at 35 second ¶(a). A04553 compares projected costs to applicants of the Proposed Rules, not the Final Rules. See A04553 (showing the cost to applicants of the "10 Representative Claims" to be $158.3 million). A04553 is not inconsistent with any representations the USPTO made to OMB about the cost of the Final Rules actually adopted.

(b) Tafas likewise makes much of the USPTO's decreased estimate to OMB of the paperwork burden imposed by the ESD requirements. Tafas Mem. at 35 second ¶(b). Yet again, the Agency's estimates are simply that – estimates – which are always subject to change, and which the OMB will have an opportunity to review in conducting its PRA review.

(c) Tafas's argument that Under Secretary Dudas failed to cite specific numbers in his Congressional speech is plainly irrelevant. Moreover, as with the OMB issues, his recourse is to alert his member of Congress, not to have the Final Rules invalidated. Tafas Mem. at 35 second ¶(c).

Finally, Tafas disagrees with portions of the USPTO's calculations relating to the ESD requirement, but his objection is irrelevant. Tafas Mem. at 36. As Tafas's own brief makes clear, the numbers he cites relate only to the agency's certification of the Proposed Rules under

[18] The USPTO echoes Tafas's paragraph numbering on page 35 of his brief, which restarts (a)-(c).

the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-12. Id. (citing 71 Fed. Reg. 61, 66 (Jan. 3, 2006)). These numbers, which were later refined in the Agency's final RFA certification, did not form the basis for the Final Rules. See 72 Fed. Reg. at 46830-46834. As only "final agency action" is reviewable under the APA, 5 U.S.C. § 704, Tafas's objection is irrelevant. In any event, the data he cites was necessarily an estimation, as the ESD requirement had never existed before.

For all of these reasons, Tafas, like GSK, has not shown that the Final Rules are arbitrary or capricious, and the USPTO is entitled to summary judgment in its favor on this issue.

III. THE FINAL RULES DO NOT IMPLICATE "SECONDARY RETROACTIVITY" CONCERNS

Tafas argues that the Final Rules raise "secondary retroactivity" concerns, a theory that neither the full Supreme Court nor the Federal Circuit has ever expressly embraced. Tafas Mem. at 28. That theory originates in Justice Scalia's solo concurrence to Bowen v. Georgetown University Hospital, 488 U.S. 204 (1988). Justice Scalia stated that even when a regulation does not alter "past legal consequences" under Landgraf v. USI Film Products, 511 U.S. 244 (1994), "a rule that has unreasonable secondary retroactivity – for example, altering future regulation in a manner that makes worthless substantial past investment incurred in reliance upon the prior rule – may for that reason be 'arbitrary or capricious,' see 5 U.S.C. § 706, and thus invalid." Bowen, 488 U.S. at 219-20 (Scalia, J. concurring).

Tafas initially fails to show how the new procedural rules render "worthless" past investment. In view of the many avenues that the USPTO created for applicants to claim inventions disclosed in pending inventions, it is clear they do not. Id. Furthermore, for reasons already explained, the Final Rules are anything but arbitrary or capricious. See supra Part II; USPTO Mem. at 39-43. In particular, it was not unreasonable for the USPTO to conclude that

the Final Rules needed to apply to pending applications in order for the rules to make any appreciable impact on the backlog in the near future. 72 Fed. Reg. at 46833 ("Given the current backlog of over 700,000 unexamined applications, a decision to not apply the changes to the backlog of unexamined applications would mean that it would be calendar year 2010 before the Office would see any benefit from the change, and that the Office (and applicants) would be in a transition state until late calendar year 2011."). Nor was it unreasonable for the USPTO not to adopt two sets of rules – one set for pending applications and the other set for brand new applications. Doing so would create an extended transition period for both the agency and applicants and would cause a significant administrative burden. Id. Plaintiffs now ask the Court to impose that burden on the USPTO by declaring the Final Rules retroactive in their present application. The Final Rules are neither "primarily" nor "secondarily" retroactive.

IV. TAFAS'S PATENT CLAUSE CLAIMS FAIL

Tafas contends that the Final Rules run afoul of the Patent Clause, U.S. Const. art. I, § 8, cl. 8, on two grounds, both of which fail for multiple reasons.

Tafas first argues that the Patent Clause prohibits the USPTO from enacting the Final Rules because it only confers on Congress "substantive" rulemaking authority. Tafas Mem. at 21. The Court need not consider this argument because it is not in Tafas's complaint. See Tafas Am. Compl. ¶ 60 (alleging only that the USPTO violated the Patent Clause because it "fail[e]d to weigh the effect of its regulations on the promotion of the progress of science and the useful arts"); see New Motor Vehicle Bd. of Cal., 439 U.S. at 125 n.29 (1978); Ribis, 468 F. Supp. 2d at 495. Even if the Court considers the allegation, it fails on numerous grounds. Tafas provides no authority for striking down USPTO regulations on the ground that the Patent Clause gives only Congress substantive authority to regulate patent law. The only case he cites, Graham v.

John Deere Co. of Kansas City, 383 U.S. 1 (1966), concerned whether a statutory provision ran afoul of the Patent Clause for wholly different reasons. Furthermore, for the reasons already provided, the Final Rules are procedural, not "substantive." See USPTO Mem. at 18-20, 59-60; supra Part I.A. Even if they were substantive, however, the USPTO disputes that the *dicta* of Merck, 80 F.3d at 1550-51, prohibits the USPTO from promulgating substantive rules. See USPTO Mem. at 17-18. Moreover, Congress has expressly authorized the USPTO to promulgate rules using APA notice and comment procedures– a type of rulemaking that the APA requires only when an agency is enacting substantive rules. See 35 U.S.C. § 2(b)(2)(B) (citing 5 U.S.C. § 553); USPTO Mem. at 20. Here, the USPTO voluntarily used notice and comment rulemaking to give the public an opportunity to provide input, not because the agency was required to do so.

Tafas next contends that the Final Rules violate the preamble of the Patent Clause because the USPTO allegedly failed to "advance the promotion of science and the useful arts." Tafas Mem. at 22. As the USPTO has explained, the Patent Clause's preambular language is not an enforceable limitation. USPTO Mem. at 51. Tafas disagrees, citing three cases. Figueroa v. United States, 57 Fed. Cl. 488, 498-99 (2003); Graham, 383 U.S. at 5-6; and A.F. Stoddard & Co. v. Dann, 564 F.2d 556, 563-64 (D.C. Cir. 1977). Tafas fails to note, however, that on appeal of Figueroa, the Federal Circuit expressly declined to decide whether the Patent Clause's preamble creates an enforceable limitation and disagreed with the Court of Federal Claims's basis for holding that it was. Figueroa v. United States, 466 F.3d 1023, 1030 & n.9 (Fed. Cir. 2006). The Federal Circuit also noted that in Eldred v. Ashcroft, 537 U.S. 186 (2002), the Supreme Court "rejected the notion that such a limitation was established in Graham."[19]

[19] The Eldred Court did not ultimately have to decide whether the preamble created an enforceable limitation because the petitioner conceded that it did not. Eldred, 537 U.S. at 211.

Figueroa, 466 F.3d at 1030 (citing Eldred, 537 U.S. at 211-12). Tafas's last case, A.F. Stoddard, did not concern whether USPTO regulations violated the Patent Clause or expressly consider whether the clause created an enforceable limitation.

Even if Tafas could state a claim under the Patent Clause, however, this Court has held that "[t]o survive a constitutional challenge under the Patent Clause, the USPTO need only show that there is a rational basis for the conclusion that the Final Rules 'promote the progress of science and the useful arts.'" Tafas II, 2008 WL 112043, at *12 (quoting U.S. Const. art. I, § 8, cl. 8). As the 127-page Federal Register notice explains, the USPTO promulgated the Final Rules primarily to improve administrative efficiency and the quality of issued patents. See USPTO Mem. at 34-36 (citing 72 Fed. Reg. at 46716-21). The USPTO could rationally conclude that examining more new patent applications and issuing better patents would achieve these goals and thereby "promote the progress of science and the useful arts." U.S. Const. art. I, § 8, cl. 8; 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.") (emphasis original).

Tafas's arguments to the contrary either reflect his disagreement with the policies the USPTO adopted or rehash arguments that this Court has already rejected. For example, Tafas complains that the USPTO did not simply hire more examiners to contend with its backlog. Tafas Mem. at 24. The USPTO expressly considered this possibility but concluded that it would not make a sufficient impact on patent pendency. 72 Fed. Reg. at 46817. Tafas also suggests that the USPTO's administrative record should include deliberative documents showing that in debating the Final Rules, agency officials explicitly talked about promoting the progress of science and the useful arts. Tafas Mem. at 23-24. This Court properly rejected that argument

when it held that "[a] complete administrative record . . . does not include privileged materials, such as documents that fall within the deliberative process privilege." Tafas II, 2008 WL 112043, at *4. Tafas's claims under the Patent Clause are thus without merit.

V. ALTHOUGH THEY ARE PROCEDURAL, THE FINAL RULES COMPLY WITH THE APA'S NOTICE AND COMMENT PROVISIONS

A. The Proposed Rules Provided Sufficient Notice of the Additional Final Rules Identified by Tafas

As the USPTO explained in its opening brief and in opposition to GSK's summary judgment motion, the notice and comment requirements of the APA – and thus the logical outgrowth doctrine – are inapplicable here because the Final Rules are procedural rather than substantive. Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 927 (Fed. Cir. 1991) ("ALDF") (explaining that the APA's notice requirements apply only to substantive rules). Even if the Court were to apply this doctrine, however, Tafas's logical outgrowth claims fail because the Proposed Rules provided reasonable notice of the Final Rules. See Long Island Care at Home, Ltd. v. Coke, 127 S. Ct. 2339, 2351 (2007) (explaining that notice is sufficient when the final rule was reasonably foreseeable).

Tafas identifies several "differences" between the Final Rules and Proposed Rules, the majority of which are merely ramifications of the same "5/25" Rule that is the subject of GSK's challenge. See Tafas Mem. at 30 ¶¶ (a), (b), (d), & (e). Tafas contends, without any substantive analysis, that Final Rules 78(d)(1)(iii) and 265(a)(4) are impermissibly distinct from the Proposed Rules. See Tafas Mem. at 30 ¶¶ (c), (f). As explained in the USPTO's opening brief, neither of those provisions differ in actual scope from the Proposed Rules, and therefore, the logical outgrowth inquiry is not even applicable. USPTO Mem. at 63-64.

Tafas also asserts, for the first time, that Final Rule 104 is "new" and causes "significant

and substantive impacts on the patent community." See Tafas Mem. at 30 ¶ (g). *Amici* Polestar Capital and Norseman Group ("Polestar") also raise logical outgrowth arguments in connection with the same rule. See Polestar Br. at 20. The Court should not consider this new claim. See New Motor Vehicle Bd., 439 U.S. at 125 n.29 (1978); Ribis, 468 F. Supp. 2d at 495.

Regardless, the claim is without merit. Although Tafas fails to specifically articulate his objection to this rule, Polestar objects that the USPTO's addition of the phrase "and other requirements" gives examiners additional authority not contemplated by the Proposed Rules. Id.; see 72 Fed. Reg. at 46841; 37 C.F.R. § 1.104 (emphasis added).[20] Polestar, and presumably Tafas, misread Final Rule 104. The identified language does not expand an examiner's authority beyond what already exists; it merely clarifies that in order to conduct a complete examination, an examiner should consider not only what is required by "statutes" and "rules," but also what case law and the MPEP require. See 72 Fed. Reg. at 46737 (explaining that the added language is aimed "to address situations in which the requirement is based upon Office practice as set forth in the MPEP or in the case law," and citing Fressola v. Manbeck, 1995 WL 656874, at *1 (D.D.C. 1995), in which the court upheld the examiner's application of a requirement found in MPEP § 608.01(n) that a claim be written in single sentence format). Because the USPTO

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[20] Final Rule 104 states, in relevant part:

> (a) Examiner's action. (1) On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes, rules, and other requirements, and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

72 Fed. Reg. at 46841; 37 C.F.R. § 1.104(a) (emphasis added).

merely modified Rule 104 to state more explicitly what an examiner is already expected to do, the logical outgrowth doctrine has no application. See MPEP § 702 (explaining that an examiner "should be careful to see that the application meets all the requisites set forth in MPEP Chapter 600 both as to formal matters and as to the completeness and clarity of the disclosure").

B. The Information Provided by the USPTO Was Sufficiently Complete

Tafas further contends that additional information should have been made available to the public during the rulemaking process. According to Tafas, "an agency must identify and provide all information to the public during its notice and comment period that it had employed in making its proposed rules." Tafas Mem. at 32 (emphasis omitted). As noted above, the USPTO was not required to engage in notice and comment rulemaking. Even if it was, there is no requirement that an agency must stuff its proposed rulemaking with "all information" it used. Instead, an agency must disclose the "critical factual material" used to support its position. Chamber of Commerce of U.S. v. SEC, 443 F.3d 890, 900 (D.C. Cir. 2006) (citing Ass'n of Data Processing Serv. Org., Inc. v. Bd. of Governors of the Fed. Reserve Sys., 745 F.2d 677 (D.C. Cir. 1984)). For example, internal agency studies used to confirm the basis for the proposed rulemaking need not be made available for comment unless they provide "entirely new information 'critical' to the [Agency's] determination." Cmty. Nutrition Inst. v. Block, 749 F.2d 50, 58 (D.C. Cir. 1984); see also Air Transport Ass'n of Am. v. Civil Aeronautics Bd., 732 F.2d 219, 224 (D.C. Cir. 1984). Likewise, the requirement to publish data or studies during rulemaking does not apply when an agency relies on its own expertise and knowledge rather than particular studies or data when promulgating rules. Conference of State Bank Supervisors v. Office of Thrift Supervision, 792 F. Supp. 837, 843 (D.D.C. 1992). Finally, a litigant challenging the failure to disclose information during rulemaking must identify what part of the

information it objects to and how it would have responded during the rulemaking. See Air Transport Ass'n of Am., 732 F.2d at 224, n.11 (citing Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 540-41 (D.C. Cir. 1983)).

The cases cited by Tafas are entirely consistent with these principles, and moreover, do not support his (or Polestar's) assertion that the USPTO improperly withheld information that it was obligated to disclose. See Hanover Potato Prods., Inc. v. Shalala, 989 F.2d 123 (3d Cir. 1992); Conn. Light & Power Co. v. NRC, 673 F.2d 525, 530 (D.C. Cir. 1982). Both Hanover Potato and Conn. Light & Power merely stand for the proposition that an agency must disclose during the notice and comment period the information upon which it expressly relied in reaching its decision to propose certain rules.

In this case, the Proposed Rules did not implement the results of any particular technical study or set of data that was not made publically available. Rather, the Proposed Rules were based on the USPTO's clearly explained assumptions that: (i) putting reasonable conditions on the filing of continuations would reduce the number of pending continuation applications; and (ii) requiring assistance from applicants with more than a threshold number of claims would ease the examination burden placed on the system by those applications. See Changes to Practice for Continuing Applications, Requests for Continuing Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48, 49-51 (Jan. 3, 2006); Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61, 62-63 (Jan. 3, 2006). The USPTO did not keep from the public any critical technical information upon which the rules were based, and Tafas has not identified any such information. Instead, Tafas identifies an internal chart at A07096, which he says "portrays 'key model assumptions' underlying . . . computer generated data." Tafas Mem. at 32. In fact, this internal chart merely shows how

additional approaches or conditions, like hiring or attrition, might affect pendency with or without any change in the rules. Tafas also cites a single page from a 1000-page spreadsheet identifying the number of pending applications in various Technology Centers around the Office in 2004. A06725. The data that Tafas references, however, does not form the basis of the Proposed Rules because the rules are not specific to a particular Technology Center, but rather to the Office as a whole.

Finally, Tafas cites A04524-25, an internal email communication from July 2006 – after the comment period had closed – directed to the number of various types of applications filed since 1982. Id. At most, this document amounts to the type of internal, confirmatory data that need not be made public. See Cmty. Nutrition Inst. 749 F.2d at 58; Air Transport Ass'n of Am., 732 F.2d at 224. Moreover, Tafas is wrong that the email failed to contemplate File Wrapper Continuations ("FWCs"). Tafas Mem. at 33. Because they used to exist as a type of continuing application, see 37 C.F.R. § 1.62 (1996), FWCs were included in the accounting of "continuation" applications, even if not specifically identified.

In sum, to the extent the Final Rules differ from the Proposed Rules, those differences evince the expected improvements achieved through proper notice-and-comment rulemaking. As the USPTO established in its motion for summary judgment, the APA's rulemaking scheme operated exactly as Congress intended: the Office modified its proposed rules in response to public concerns while keeping the overall scheme intact. The Court should therefore reject Tafas's arguments because the Final Rules are a logical outgrowth of the Proposed Rules.

VI. THE FINAL RULES COMPLY WITH THE REGULATORY FLEXIBILITY ACT

Recognizing that the USPTO fully complied with its strictly procedural obligations under the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-12, Tafas has resorted to proffering a

flawed, extra-record, and biased economic analysis in a futile attempt to challenge the USPTO's RFA certification. The Court should not consider Dr. Robert Fenili's declaration, or Tafas's discussion of his declaration, for the reasons set out in the accompanying motion to strike. Even if the Court considers it, Tafas fails to provide any evidence that the Office's certification constitutes an abuse of discretion. 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). Because the USPTO has not abused its discretion, and in fact has provided an extensive, sophisticated RFA analysis that reflects the Office's efforts to minimize the cost impact the Final Rules impose on small entities, this Court should reject Tafas's RFA challenge. Id.

By challenging what he erroneously concludes is inappropriate economic modeling used by the Office, Tafas largely ignores what this Court and others around the country have repeatedly made clear: that the RFA is merely a procedural statute and imposes no substantive requirements on a federal agency. See Tafas II, 2008 WL 112043, at *9 (recognizing that the RFA imposes no substantive requirements on an agency); see also Envtl. Def. Ctr., Inc. v. EPA, 344 F.3d 832, 879 (9th Cir. 2003) ("Like the Notice and Comment process required in administrative rulemaking by the APA, the analyses required by the RFA are essentially procedural hurdles; after considering the relevant impacts and alternatives, an administrative agency remains free to regulate as it sees fit."). In other words, "section 604 does not command an agency to take specific substantive measures, but, rather, only to give explicit consideration to less onerous options." Assoc. Fisheries, Inc. v. Daley, 127 F.3d 104, 114 (1st Cir. 1997); U.S. Cellular Corp. v. FCC, 254 F.3d 78, 88 (D.C. Cir. 2001).

Most importantly, the RFA only requires agencies to consider alternatives that lessen the economic impact regulations will impose on small entities and explain why significant

alternatives were not selected. Alenco Comm'n Inc. v. FCC, 201 F.3d 608, 625 (5th Cir. 2000); see also N.C. Fisheries Ass'n, Inc. v. Gutierrez, 2007 WL 2331048, *24 (D.D.C. Aug. 17, 2007) ("a court reviewing a RFA-based challenge does not evaluate whether the agency got the required analysis right, but instead examines whether the agency has followed the procedural steps laid out in the statute"); Grocery Serv., Inc. v. USDA Food & Nutrition Serv., 2007 WL 2872876, *11 (S.D. Tex. Sept. 27, 2007) ("Plaintiff's complaints are substantive, not procedural, and this Court does not review the factual substance of an agency's RFA determination."); Ass'n of Am. Physicians & Surgeons v. HHS, 224 F. Supp. 2d 1115, 1128 (S.D. Tex. 2002) (holding that plaintiffs' claim that agency did not account for burden of compliance on small entities "failed to articulate any specific procedural flaws in HHS's promulgation of the Privacy Rule.").

Here, the USPTO's RFA certification demonstrates, among many other things, that the Office analyzed the potential economic effect its Rules would have on small entities, considered specific alternatives to its proposed Rules, implemented certain modifications to the rules in light of comments received, and explained why it chose not to implement other modifications. These are the procedural "hurdles" mandated by the RFA, and the Office's certification analysis demonstrates that the Office satisfied its obligations. Tafas's complaints that the Office used improper economic modeling, underestimated certain economic variables, and improperly concluded that its Rules would not impose substantial economic impacts on small entities – each of which, as explained below, lack merit – constitute substantive challenges and are, therefore, inappropriate under the RFA. See, e.g., Alenco Comm'n, 201 F.3d at 625. The USPTO responds to them only out of an abundance of caution.

A. The USPTO Considered Significant Alternatives and Took Efforts to Minimize Cost Impacts on Small Entities.

As set forth above, an agency principally complies with the procedural mandate of the

RFA by analyzing the economic impact of its proposed regulations, considering "significant alternatives" that minimize economic impact, and explaining why significant alternatives were not selected. See U.S. Cellular, 254 F.3d at 88; Alenco Comm'n, 201 F.3d at 608, 625; Assoc. Fisheries, 127 F.3d at 114. Here, the USPTO satisfied these obligations. Indeed, the Office implemented five alternatives in the Final Rule to lessen the impact on small entities. A08301.

The first two alternatives are associated with the claims requirement and the remaining three relate to the continuations practice. Id. First, the USPTO changed the ESD requirement threshold from more than ten representative claims in an application family to more than five independent claims/twenty-five total claims per application, thereby reducing the number of small entities affected by the Final Rules. Id. Second, the Office exempted small entities from the requirement to identify, for each reference cited in an ESD, all the limitations of each of the claims that are disclosed by the reference. Id. The costs associated with complying with this rule will therefore be greatly reduced for small entities.

Third, the USPTO increased the threshold for filing a petition and showing from one continuation or continuation-in-part ("CIP") or one RCE to two continuations or CIPs and one RCE. Id. The Office found that this change would reduce the number of small entities effected by the Final Rules. Fourth, the USPTO expanded the permissible period for filing a divisional application from solely the pendency of the initial application to the pendency of both the initial application *and* any of its continuing applications. A08302. This allows applicants to spread out the associated cost of filing divisional applications over time, thereby easing the financial burden on small entities. Id. Fifth, the USPTO implemented the Final Rules more leniently than initially proposed, allowing an applicant to file "one more" continuation or CIP after the effective date, irrespective of the number of previous filings, as long as the applicant did not file a continuation or CIP between the publication date of the Final Rules and the effective date. Id.

The Office also considered a number of alternatives that it expressly chose not to implement. The Office considered, for example, changing the claims rule to provide for expedited examination of applications containing less than a set number of claims. Id. Because the Office has an accelerated examination program for certain applications, however, it decided not to pursue this alternative. Id. The Office also considered not applying the ESD requirement to pending applications. Id. In light of the significant backlog, however, the Office determined that it would not realize any appreciable benefits from this alternative until calendar year 2010, and that the Office would be in a transition state until 2011. Id. The Office also considered imposing additional fees for continued examination filings and/or a graduated fee schedule. Id. The Office recalled that in 2002 it proposed a fee structure that included additional fees for continuations and a graduated fee schedule, but that it could not garner support for the proposal from patent user groups. The Office therefore opted not to implement this proposal. Id. Finally, the Office considered expanding its deferred examination program to allow for longer deferrals. A08303. The USPTO noted, however, that this program is rarely used by applicants. 72 Fed. Reg. at 46829. It also noted that it continues to study whether changes to the program would be appropriate, but that patent user groups have historically not favored increases in the deferral of examinations. A08303. Accordingly, the Office did not pursue this alternative.[21]

In light of the USPTO's substantial analysis regarding the economic impact imposed by the rules, consideration of significant alternatives, implementation of certain alternatives, and explanation of its decision to reject other alternatives, the Office unquestionably complied with

[21] *Amicus* Katznelson therefore erroneously asserts that the USPTO "silently rejected" his "examination-on-request" alternative. See Mem. of *Amicus Curiae* Ron D. Katznelson in Supp. of Pls. Mots. for Summ. J. ("Katznelson Br."), Dkt. No. 198, at 10-11. His alternative would be similar in effect to the expanded deferred examination program, which the Office expressly considered but did not adopt. Katznelson's disagreement with the Office's decision is an inappropriate substantive challenge to the Office's RFA certification, and must be rejected.

its procedural obligations under the RFA.

B. The Assumptions Underlying the USPTO's RFA Certification are Reasonable and Supported by the Administrative Record

To the extent that the Court entertains Tafas's substantive arguments notwithstanding that the RFA imposes only procedural obligations, the USPTO did not abuse its discretion in certifying that the Final Rules would not have a significant impact on a substantial number of small entities. Carpenter, 343 F.3d at 1357. The Office expressly stated the factual basis for each assumption supporting its RFA certification and articulated the rationale underlying those assumptions. See generally A08270-306.

Tafas asserts that the Office arbitrarily assumed that the average small inventor earns $75,000 yearly. Tafas Mem. at 41-42. To the contrary, the Office reasonably concluded that the minimum annual income an individual filer would need in order to afford normal living expenses, as well the financial burden of the costs and fees associated with preparing the complicated patent applications affected by this rule, is $75,000. A08295. If anything, the Office's estimate is overly conservative because many filers certainly have income above $75,000, whereas even if some have lower levels of income, the number of such entities would be negligible. Tafas fails to articulate how this estimate is unreasonable.

Unlike the agency in South Offshore Fishing Association v. Daley, 995 F. Supp. 1411 (M.D. Fla. 1998), that estimated "average gross revenue from shark fishing was only $26,426" without any basis whatsoever, USPTO here used existing data – supported by the record – to make a reasonable assumption concerning income for the smallest of entities.[22] In light of the absence of any other data about the income of small entity inventors, and the reasonableness of

[22] Further undermining his RFA challenge, neither Tafas nor his expert even suggest an alternate income level. Grand Canyon Air Tour Coal. v. FAA, 154 F.3d 455, 471 (D.C. Cir. 1998) (rejecting plaintiff's RFA claim where he could not show why agency's response was inadequate or point to any alternative the agency irrationally rejected).

the USPTO's supported assumption, Tafas's challenge must be rejected.

Tafas next asserts that USPTO's assumption that there are no costs associated with rebutting the presumption regarding "patentably indistinct claims" is unfounded. Tafas Mem. at 42. On the contrary, the Office noted that if an applicant filed two or more applications containing patentably indistinct claims for the sole purpose of avoiding an ESD, then the Final Rules need not account for the cost of preparing a terminal disclaimer because the mere submission of a terminal disclaimer would not relieve the applicant of his obligation to file the ESD.[23] A08291. To the extent an applicant filed the applications for purposes other than to avoid an ESD, the Final Rules impose no new costs because existing rules already provide that applicants may be required to eliminate patentably indistinct claims from all but one application. See 37 C.F.R. § 1.78(b) (2006). Additionally, the double patenting doctrine requires a terminal disclaimer if the patentably indistinct claims are not so eliminated. A08291. Thus, any additional legal costs are not properly attributed to the Final Rules.

Tafas next complains that the USPTO improperly amortized the cost of obtaining a patent over a period of twenty years, a decision Tafas characterizes as an "egregious" error that "shockingly misunderstands" the life of a patent.[24] Tafas Mem. at 42-43. He further complains that the Office failed to recognize that small entities do not have "ready access to cheap credit" and that they generally account for costs at the time incurred. Id. As the Office explained in its certification, however, it is entirely appropriate to allocate the cost of obtaining a patent over its

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[23] A terminal disclaimer is a written document filed by an applicant with the USPTO in which the applicant disclaims or dedicates to the public the entire term, or any terminal part of the term, of a patent. See 35 U.S.C. § 156(b)(2)(B); 37 C.F.R. § 1.321; MPEP § 1490.

[24] *Amicus* Katznelson misapprehends the USPTO's assumption on this score by contending that the Office improperly assumed that small entities file only one patent application per twenty years. Katznelson Br. at 4-5. Nowhere in the record does the Office make this assumption.

life span because – like many capital investments – the patent will ostensibly contribute to income over an extended period. A08292. In fact, generally accepted accounting principles ("GAAP") for intangible assets require patents, like other intangible assets, to be amortized over the asset's useful life (i.e. the period over which the asset is expected to contribute to future cash flows), which in this case is twenty years. Id. (citing GOODWILL AND OTHER INTANGIBLE ASSETS, Statement of Fin. Accounting Standards No. 142 (Fin. Accounting Standards Bd. 2001)). The analysis simply assumes that when valuing the cost of preparing the ESD (either the cost of an inventor's own time or the cost of a professionally-prepared ESD), the applicant views the effort relative to the expected twenty-year period. In other words, applicants will view the cost as a capitalized investment rather than an ordinary expense. A08292.

The Office's decision to amortize costs over the life span of a patent is reasonable and consistent with the requirements of the RFA. Little Bay Lobster Co., Inc. v. Evans, 352 F.3d 462, 471 (1st Cir. 2003) (applying the "rule of reason" in deciding whether agency complied with the RFA); Env'l Def. Ctr., Inc., 344 F.3d at 878-89 (rejecting plaintiff's argument to use different measures of economic impact because agency's measure was consistent with the Section 605 statutory language). The cases cited by Tafas do not suggest otherwise. Tafas Mem. at 43, n.19. In South Offshore Fishing Association, for example, the Court found the agency's explanation of the manner in which it calculated average gross revenue from shark fishing wholly lacking, calling the seemingly manufactured numbers a "transparent and unbecoming effort to demonstrate limited economic dependence." S. Offshore Fishing Ass'n, 995 F. Supp. at 1435. Here, by sharp contrast, the USPTO expressly documented the data, methods, assumptions, and economic impact of the Final Rules. A08270-A8306. Indeed, the USPTO relied on sophisticated economic modeling of costs over the life of a patent based entirely on data from the administrative record – not funny numbers as in South Offshore Fishing Association. Likewise,

in North Carolina Fisheries Ass'n v. Daley, 27 F. Supp. 2d 650, 660-61 (E.D. Va. 1998), the Court rejected the agency's attempt to offset present economic losses caused by the challenged regulation against past revenues earned by over-fishing. Id. Here, the USPTO makes no attempt to "offset" any economic impact. The Office explicitly acknowledges the costs associated with compliance of the Final Rules, and assesses those economic impacts using a reasonable and conservative methodology.

C. The USPTO's RFA Certification Properly Accounted for all Costs of Filing an ESD

Tafas asserts that in considering the economic impact of the ESD requirement, the USPTO improperly limited its certification analysis to initial applications even though the ESD requirement applies both to continuation or continuation-in-part ("CIP") applications. Tafas Mem. at 43. The Office considered all applications. The analysis indicates that 325 small entity filings and 924 of all filings are affected by both the claims and continuations rules. A08285. Because initial applications are not affected by the continued examination filing requirements, it follows that these applications are continuations or CIPs that exceed the threshold. Similarly, Exhibits 3-2, 5-3 and 5-4 of the RFA certification, among others, also consider continuation or CIP filings. A08286. Likewise, the purpose of Exhibit 3-1 is to distinguish continuations and CIPs that also are affected by the claims requirement. A08285. Tafas's claim that the analysis did not consider the claims requirement with respect to continuations of CIP applications lacks merit.

Tafas also complains that the USPTO failed to consider the additional costs of preparing and filing three applications in order to stay within 15/75 claims when, under existing rules, one would suffice. Tafas Mem. at 43. Tafas's argument, however, fails to appreciate that applicants who file excess claims also file numerous applications (i.e., generally, applicants will not need to

file additional applications; rather, the applicant will evenly distribute claims among existing applications). See A04767-83. The USPTO's analysis also took into account the opportunity costs now raised by Tafas. Indeed, the Office specifically considered applicants who would need to file an ESD (because their application families exceeded 15/75 claims through the use of continuing applications) to assert additional claims from those prosecuted in the initial application. Even if all applicants exceeding the 5/25 claim threshold were to prepare ESDs, the results in Exhibits 5-3 and 5-4 of the certification report, see A08299, remain accurate, as does the conclusion that the rule will not result in significant economic impacts on a substantial number of small entities. A08300.

D. The Agency Properly Certified that the Rules Do Not Impose a Significant Economic Impact on a Substantial Number of Small Entities

Contrary to Tafas's assertions, the Offices's certification accurately captures the universe of affected entities. Tafas Mem. at 44. Tafas complains that USPTO's stated limitation equating each application with a separate or individual small entity filer understates the cost impact of the Final Rules. Id. As the USPTO explained, "[a]lthough the assumption certainly does not hold true for many large firms, these firms have sufficient revenue to avoid significant impacts under the final rule. The assumption is much more reasonable, however, for the smallest firms, such as the sole proprietorship described above, which might face significant impacts under the rule." A09296. Thus, the Office did not "dilute" the universe of applicants or "shrink" the percentage of affected entities.[25]

Likewise, the certification accurately captures the economic impact the Final Rules potentially impose on small entities. Unable to directly attack the Offices's impact data, Tafas's

[25] Katznelson challenges – without any evidentiary support – the Office's conclusion that only one percent of small entities would be affected by the ESD requirement associated with the claims rule. The USPTO supported its certification with specific facts contained in the record. A08284.

expert uses his own economic model in order to opine that the Office erroneously certified the Final Rules. Tafas Mem. at 43; Fenili Decl. ¶17 (using incremental costs as a percent of revenue, as opposed to annualized incremental costs as a percent of revenue, the measure used by the USPTO). The Office expressly considered, but found less appropriate, the economic model now touted by Tafas (along with five other measures). A08292-94. Tafas's requested approach grossly overstates economic impact because it does not account for the long-lived nature of a patent asset and because it does not consider the potential returns on patent investment. A08292 (citing GOODWILL AND OTHER INTANGIBLE ASSETS, Statement of Fin. Accounting Standards No. 142 (Fin. Accounting Standards Bd. 2001).

Furthermore, the Office expressly stated the reasons why it chose its economic approach – annualized incremental costs as a percent of revenue – over the other possible methodologies: (1) it considers costs on an annualized basis, which is consistent with the generally accepted recognition that a patent is an asset conveying a multi-year earning potential, (2) it evaluates impacts relative to revenue, which is useful and relevant measure of the size of an entity, (3) it can be applied readily across many industries and entity types, (4) data availability typically is not an impediment to analysis, and (5) most people understand it without difficulty. A08292-94. Tafas's dislike of USPTO's chosen analytical method does not – as a matter of law – call into question the validity of the comprehensive certification analysis, nor does it render the Office's report an elaborate ruse to obfuscate economic impact data. See Washington v. Daley, 173 F.3d 1158, 1171 (9th Cir. 1999) (rejecting plaintiff's argument that revenue earned from a particular harvest should be the measure for RFA certification); Nat'l Coal. for Marine Conserv. v. Evans, 231 F. Supp.2d 119, 143 (D.D.C. 2002) (despite plaintiff's suggested alternatives, RFA does not give plaintiff the authority to determine which alternatives best meet agency's goals).

Tafas next urges that the difference between the impact of the Final Rules on small

entities and all entities actually shows disproportion. Tafas Mem. at 45; Fenili Decl. ¶¶ 24, 25. As support for that proposition, Tafas and his declarant proffer their own wild assumptions to create out of whole cloth new numbers purporting to show a large disproportionate economic impact. Tafas Mem. at 45. To obtain such large percentages, they subtracted numbers out of the numerator of their calculation, but left the denominator the same, in an effort to overstate impact. Id. Fenili neglects to identify what he claims the denominator should be, and he failed to include a total universe column (such as those presented in the Agency's certification analysis) in his chart. Even the presentation of Fenili's chart is misleading since a reader would assume, mistakenly, that both the numerator and the denominator have been adjusted to remove small entities. Fenili Decl. ¶ 24. It takes only elementary logic, not an expert witness, to realize Tafas's math does not add up. There is no evidence in Tafas's motion, Fenili's "expert" declaration, or the Office's thorough administrative record that the Final Rules will impact a far greater proportion of small entities than large entities. U.S. Cellular Corp., 254 F.3d at 88 (holding that the FCC was entitled to conclude no disproportionate impact where plaintiff's claims of higher costs were not supported by evidence); Cactus Corner v. USDA, 346 F. Supp. 2d 1075, 1116-17 (E.D. Cal. 2004) (upholding agency's certification where plaintiff's prediction was hyperbole, based on incorrect hypothesis).

In sum, the Court need not reach the vast majority of issues that Tafas raises because the RFA is a procedural statute, and Tafas's arguments are predominantly substantive. Even if it does, however, the USPTO clearly did not abuse its discretion in certifying that the Final Rules do not have a significant economic impact on a substantial number of small entities.

VIII. THE FINAL RULES COMPORT WITH INTERNATIONAL TREATIES, BUT THE ISSUE IS NOT PROPERLY BEFORE THIS COURT.

Finally, Tafas alleges for the first time in his summary judgment motion that Final Rules

75(b) and 265 violate international treaties, and thus are "contrary to law" under the APA. See 5 U.S.C. § 706(2)(A). Tafas Mem. at 11. Specifically, Tafas asserts that these rules violate Article 27 of the Patent Cooperation Treaty ("PCT"), Jan. 24, 1978, 28 U.S.T. 7645, because PCT Rule 6.1(a) prohibits the imposition of "arbitrary limits" on the number of claims in an application and because PCT Rule 51*bis*.1 does not expressly provide for the ESD requirement.[26] Tafas Mem. at 11-12. Article 27 of the PCT provides that "[n]o national law shall require compliance with requirements relating to the form or contents of an international application different from or in addition to those which are provided for in this Treaty and the Regulations." Id.

The Court should not reach this issue for several reasons. First, Tafas's amended complaint does not raise this claim, much less even mention the PCT. See New Motor Vehicle Bd., 439 U.S. at 125 n.29 (1978); Ribis, 468 F. Supp. 2d at 495. Second, in Suramerica de Aleaciones Laminadas, C.A. v. United States, 966 F.2d 660, 667-668 (Fed. Cir. 1992), the Federal Circuit held that because a treaty "does not trump domestic legislation," it would not find an agency regulation that was consistent with domestic law to be inconsistent with a treaty. The USPTO has already shown that the Final Rules are consistent with the Patent Act. See supra, Part I.B. Third, when Congress enacted legislation to implement the PCT, it specifically noted that the PCT did not change the "substantive requirements for obtaining a patent" or "replace present domestic filing procedures." H.R. Rep. 94-592 (1975), reprinted at 1975 U.S.C.C.A.N. 1220, 1223; see also 4A Chisum on Patents § 14.02[4] (2004). Accordingly, it is improper for Tafas to suggest that the PCT could prevent the USPTO from altering its procedures.

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[26] *Amicus* FICPI alleges that the Final Rules violate the Paris Convention, a different treaty. See FICPI Br. at 3-4. In addition to this claim not being raised by a party, it fails because the Paris Convention is not self-executing and does not constitute binding domestic "law" under 5 U.S.C. § 706(2)(A), except to the extent it is implemented by domestic legislation. See, e.g., In re Rath, 402 F.3d 1207, 1209 (Fed. Cir. 2005); Novo Hydro Can, Inc. v. United States, 472 F.3d 1347, 1360 n. 21 (Fed. Cir. 2006). FICPI fails to identify any such legislation.

In any event, the Final Rules do not conflict with the specific PCT provisions that Tafas cites. PCT Rule 6.1(a) states that "the number of claims shall be reasonable in consideration of the nature of the invention claimed." See PCT Rule 6.1(a), 28 U.S.T. 7645. This rule is simply a command to the applicant not to pursue an unreasonable number of claims, not a limitation on the Office. Moreover, contrary to Tafas's contention, Final Rules 75(b) and 265 do not set an arbitrary "limit" on the number of claims an applicant may file, but rather reasonably require an applicant to provide additional information if the number of claims in a particular application exceeds the 5/25 claim threshold. See USPTO GSK Opp. at Part I.D. Such a requirement for additional information is not inconsistent with PCT Rule 6.1(a).

The ESD requirement of Final Rule 265 also is not inconsistent with PCT Rule 51*bis*.1. Rule 51*bis*.1 states that "the national law applicable by the designated Office may, in accordance with Article 27, require the applicant to furnish, in particular," certain items. See PCT Rule 51*bis*.1, 28 U.S.T. 7645 (emphasis added). The words "in particular" in PCT Rule 51*bis*.1 show that the list of items recited in the rule is not exhaustive.[27] Furthermore, the purpose of PCT Rule 51*bis*.1 is not to limit the types of items that a national Office, like the USPTO, may require an applicant to submit. Instead, the express purpose is to "provide[] clarity for both applicants and designated Offices that such items may be required to be furnished by the applicant under the national law applicable by the designated Office." See WIPO PCT Committee document PCT/CAL7/2, ¶10, supra n. 27. The USPTO has made its expectations clear through the

[27] The World Intellectual Property Organization (WIPO) has recognized that the list is in not exhaustive. WIPO PCT Committee document PCT/CAL/7/2, ¶10, Proposed Amendments of the PCT Regulations and Modifications of the PCT Administrative Instructions, Relating to the Draft Patent Law Treaty (Oct. 18, 1999), available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=3933; WIPO Assembly document PCT/A/28/2, ¶10, Proposed Amendments of the PCT Regulations and Modifications of the PCT Administrative Instructions, Relating to the Draft Patent Law Treaty (Jan. 28, 2000), available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=4001.

promulgation of Final Rules 75(b) and 265.

Finally, Article 27 of the PCT, specifically referenced in Rule 51*bis*.1, expressly states that "national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law." PCT Art. 27(6).[28] Here, the ESD requirement in the Final Rules is precisely that: a requirement for additional evidence to assist the USPTO with the substantive examination of a patent application. Thus, contrary to Tafas's assertion, the Final Rules fully comport with the PCT.

CONCLUSION

For the foregoing reasons, as well as those set out in the USPTO's opening brief and in its opposition to GSK's summary judgment motion, the Court should grant the USPTO's motion for summary judgment and deny Tafas's cross-motion for summary judgment.

Respectfully submitted,

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[28] Notably, articles of the PCT control regulations promulgated to implement them. See, e.g., PCT Article 58(5) ("In the case of a conflict between the provisions of the Treaty and those of the Regulations, the provisions of the Treaty shall prevail.").

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