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

TRIANTAFYLLOS TAFAS, **Plaintiff,** **v.** **JON W. DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the UNITED STATES PATENT AND TRADEMARK OFFICE,** **Defendants.**	**CIVIL ACTION: 1:07cv846 (JCC/TRJ) and Consolidated Case (below)**
SMITHKLINE BEECHAM CORPORATION, **Plaintiff,** **v.** **JON W. DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and the UNITED STATES PATENT AND TRADEMARK OFFICE,** **Defendants.**	

PLAINTIFF TRIANTAYLLOS TAFAS' MEMORANDUM OF LAW IN SUPPORT OF SUMMARY JUDGMENT MOTION

Steven Moore, Esq. (*Pro Hac Vice*) James E. Nealon, Esq. (*Pro Hac Vice*) William R. Golden Jr., Esq. (Of Counsel) KELLEY DRYE & WARREN LLP 101 Park Avenue New York, New York 10178-0002 Telephone: (212) 808-7992 Facsimile: (212) 808-7897 E-mail: wgolden@kelleydrye.com smoore@kelleydrye.com jnealon@kelleydrye.com	Joseph D. Wilson, III, Esq. (VSB#43973) Joanna Baden-Mayer, Esq. (VSB#67920) Shaun Gehan, Esq. (*Pro Hac Vice*) KELLEY DRYE & WARREN LLP Washington Harbor, Suite 400 3050 K Street, NW Washington, DC 20007 Telephone: (202) 342-8400 Facsimile: (202) 342-8451 E-mail: jwilson@kelleydrye.com sgehan@kelleydrye.com

Counsel for Plaintiff Triantafyllos Tafas

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PRELIMINARY STATEMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 56, the Plaintiff, Dr. Triantafyllos Tafas ("Tafas"), by and through his attorneys, KELLEY DRYE & WARREN LLP, hereby moves for summary judgment on all claims in his First Amended Complaint dated September 7, 2007 (the "Amended Complaint").

As set forth more particularly below and in the supporting Declarations of Tafas (the "Tafas Decl.") (Appendix A), Robert Fenili, Ph.D (the "Fenili Decl.") (Appendix B) and Michael Rueda, Esq. (the "Rueda Decl.") (Appendix C), and based on the administrative record[1] filed by Defendants Jon W. Dudas ("Dudas") and the United States Patent and Trademark Office ("USPTO")(sometimes collectively referred to herein as "Defendants"), there are no genuine issues as to any material fact, and Tafas is entitled to judgment as a matter of law.

Tafas brings this action for declaratory judgment pursuant to 28 U.S.C. § 2201 et seq., and for judicial review under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, and the Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 611. Tafas seeks the seeks the entry of summary judgment, inter alia, to:

(1) permanently enjoin Defendants from implementing sections 1.75, 1.78, 1.104, 1.105, 1.110, 1.114, 1.142, 1.265 and 1.704 of certain new federal regulations promulgated by the USPTO, with an effective date of November 1, 2007, which were published at 72 Fed. Reg. 46716, 46835-43 (Aug. 21, 2007) and are to be codified at 37 C.F.R. Part 1 (the "Revised Rules" or "Final Rules"); and,

(2) declaring the Final Rules, in toto, null, void and without legal effect, inter alia, as beyond the rule USPTO's rule-making power and inconsistent

[1] Tafas has challenged the sufficiency and completeness of the USPTO's administrative record and Tafas' Objection to Magistrate Thomas Rawles Jones, Jr. Order denying discovery is still sub judice with the Court. In the event that the Court should subsequently overrule Magistrate Jones and permit discovery, Tafas reserves the right to move to re-open and/or supplement his present summary judgment motion.

with various federal statutes and the United States Constitution, including Article I, Section 8, Cl. 8 and the Due Process and Takings Clauses of the Fifth Amendment; and,

(3) vacating and remanding the Final Rules, including requiring Defendants to comply with the requirements of the APA, 5 U.S.C. § 553, and the RFA, 5 U.S.C. § 601 et seq., in promulgating any future regulations concerning the subject matter of the Revised Rules.

As set forth more particularly below, the Final Rules should be permanently enjoined and declared null and void, among other reasons, because they:

(1) violate and conflict, in whole or in part, with Sections 2, 41, 101, 102, 111, 112, 120, 121, 122, 131, 132 and 151 of the Patent Act and Sections 200-203 of the Bayh-Dole Act (35 U.S.C. §§ 1 et seq.) and exceed the USPTO's rule making authority delegated by Congress and under the U.S. Constitution;

(2) violate Tafas' statutory and constitutional rights;

(3) violate and conflict with Sections 553(b)-(c) and 706(2) of the APA (5 U.S.C. §§ 553(b)-(c) and 706(2)), among other ways, due to the Final Rules' retroactive application; because the public was denied of a meaningful ability to be informed of and comment on the "the terms or substance of the proposed rule"; because they are not in accordance with the law or treaties, and, because Defendants rulemaking was arbitrary, capricious and an abuse of discretion; and,

(4) violate and conflict with the RFA, 5 U.S.C. §§ 601-612, because the USPTO erroneously certified under RFA Section 605(b) that the Final Rules would not have a significant impact on a substantial number of small businesses and, in reliance on this flawed certification failed to prepare a Final Regulatory Flexibility Analysis.

STATEMENT OF UNDISPUTED FACTS

Under the applicable legal standard, judicial review of this APA rule-making is largely confined to the administrative record. Since the issues for decision are primarily purely legal in nature and the Final Rules apply across the board to all patent applicants, a determination as to their validity should not turn on facts unique or peculiar to a particular plaintiff or, for that matter, any disputes that might subsequently become apparent as to such background facts.

Thus, unlike a typical federal case in the summary judgment context, a statement of material facts in dispute is of little utility or bearing here. In any event, in addition to his Amended Complaint, Tafas has submitted a supporting Declaration (Appendix A) setting forth his standing to sue, as well as enumerating some of the different types of substantial harm and economic injury Tafas and the patent community at large are faced with as a direct result of the Final Rules. In the interest of brevity, Tafas begs leave to incorporate the factual statements made in the appendices herein by reference, to the extent the USPTO should subsequently elect to challenge as "material" any of the factual matter contained therein.

STANDARD OF REVIEW

Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Shenandoah Ecosystems Defense Group v. United States Forest Serv., 144 F.Supp.2d 542, 547 (W.D.Va. 2001). "Rule 56 mandates entry of summary judgment against a party who 'after adequate time for discovery and upon motion … fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.'" [2] Bender v. Gutierrez, 2006 WL 4877550 *4-5 (E.D.V.A. 2006), quoting Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

In a case involving the review of a decision of an administrative agency, a motion "stands in a somewhat unusual light, in that the administrative record provides the complete factual predicate for the court's review." Krichbaum v. Kelley, 844 F.Supp. 1107, 1110

[2] In Bender, the E.D.V.A. Court was deciding a motion for summary judgment in the context of a plaintiff challenging administrative rules that the NMFS (National Marine Fisheries Service) had enacted. Bender, at *3. The plaintiff in Bender claimed that the issued Rules violated the Administrative Procedure Act (APA) as "arbitrary and capricious" because they were based on insufficient data. Id. at *3.

(W.D.Va. 1994), aff'd, 61 F.3d 900 (4th Cir. 1995). Due to the Court's restricted review of only the administrative record and limited supplements thereto, the movant's "burden on summary judgment is not materially different than his ultimate burden on the merits." Id. In order, therefore, to prevail by summary judgment, the parties in an APA case, "must point to facts in the administrative record or to factual failings in that record which can support [their] claims under the governing legal standard." Id.; See generally, Shenandoah Ecosystems Def. Group v. United States Forest Serv., 144 F.Supp.2d 542, 547 (W.D.Va. 2001).

The APA provides parties "suffering a legal wrong because of agency action" the right of judicial review. 5 U.S.C. § 702. Under the APA, the Court shall set aside agency action if it is "arbitrary, capricious …; contrary to constitutional right …; [or] in excess of statutory authority …." 5 U.S.C. § 706(2)(A). APA's standard of review, while deferential, "in no way requires the Court to 'rubber stamp' an agency action …. On the contrary, the Court must 'immerse' itself in the evidence in order to 'determine whether the agency decision was rational and based on consideration of the relevant factors.'" Ohio Valley Envtl Coalition v. U.S. Army Corps of Eng'rs, 479 F.Supp.2d 607, 621 (S.D. W.Va. 2007), quoting Ethyl Corp. v. EPA, 541 F.2d 1, 36 (D.C. Cir. 1976). Although the Court's review is based on "the entire administrative record[,] it may, when necessary, consider evidence outside the record to determine whether the agency has considered all relevant factors or to explain technical terms or complex subject matter." Id. (footnote omitted).

ARGUMENT

POINT I

THE REVISED RULES ARE CONTRARY TO THE PATENT ACT

a. The Final Rules Violate 35 U.S.C. § 120 which Mandates Unfettered Continuation Practice

Neither the general grant of rulemaking authority to the USPTO in 35 U.S.C. § 2(b)(2), nor any other statutory provision expressly authorizes the USPTO to substantively regulate or limit long established continued examination practice. More than 150 years ago, in Godfrey v. Eames, the U.S. Supreme Court recognized the ability of an applicant to file a revised version of a patent application and withdraw the original while still retaining the original filing date. Godfrey, 68 U.S. 317, 323-325 (1863). Section 120 of the Patent Act codifies this principle as follows:

> An application for patent for an invention . . . 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.
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> * * * *

35 U.S.C. § 120 (Emphasis added).

Thus, so long as all other statutory conditions of patent eligibility are met, a patent application "shall have" or "shall be" entitled to the benefit of the filing date of previously filed patent applications. 35 U.S.C. § 120. The mandatory "shall have" and "shall be" language is similarly utilized in 35 U.S.C. § 365(c), which also mandates that the benefit of the filing date of an earlier filed application is mandatory -- not optional.

Under the Final Rules, the USPTO will "refuse to enter, or will delete if present" the benefit of priority claimed to prior applications in all third or subsequent voluntary-divisional divisional and continuation-in-part applications if a showing is not made to the satisfaction of the Director that such claimed subject matter could not have been pursued earlier. Final Rule 37 C.F.R. § 1.78(d)(1). The Final Rules imply that the USPTO has some inherent authority to constrict long-standing continuation practice by setting an arbitrary fixed limit on the number of continuations that may be filed as at right. However, as noted in In re Hogan, 559 F.2d 595 (CCPA 1977), "a limit upon continuation applications is a matter of policy for the Congress." Id. at 604 n.13.

Pointing to the doctrine of patent prosecution laches recently recognized by several Federal Circuit panels, Defendants assert that the USPTO has inherent authority under 35 U.S.C. § 2 to ensure that laches does not occur with respect to any patent application. The USPTO extrapolates from these cases that it is empowered to limit the number of continuing applications an applicant may file. 71 Fed. Reg. 48, 50 (Jan. 3. 2006). The USPTO asserts that In re Bogese II, 303 F.3d 1362 (Fed. Cir. 2002) ("Bogese II"), "stood for the broad proposition that 35 U.S.C. § 120 does not give applicants carte blanche to prosecute continuing applications in any desired manner." 71 Fed. Reg. at 50.

Contrary to the USPTO's position, a careful reading of Bogese II indicates that the majority of the three (3) member panel did not suggest any unfettered power by the USPTO to limit continuation practice under 35 U.S.C. § 120. Instead, the Bogese II panel merely found that the USPTO has the power to reject the application in a case of unreasonable and extreme delay in prosecution (i.e., prosecution laches) as long as the applicant is afforded notice and an opportunity to correct the delay. Bogese II, 303 F.3d at 1369. The panel specifically

distinguished the applicant in Bogese II from an applicant who "maintain[s] pendency of an application . . .while competitor's products appear on the market. . .", implicitly accepting the later practice as being sanctioned under the law. Id. at 1369. In Bogese II, the applicant had acted egregiously by repeatedly filing continuations as a procedural ruse to circumvent the need to respond to USPTO actions without ever amending his claims in any substantive manner. Significantly, the dissenting judge argued against even the limited power urged by the majority stating, "nowhere however, has an agency been authorized to impose, in its discretion, restrictions contrary to the statute that governs agency action." Id. at 1371 (Newman, J., dissenting). Here, the USPTO has essentially taken a very limited exception (i.e., prosecution laches) -- intended to apply only in very narrow and extraordinary fact specific circumstances -- and bootstrapped off it to presume in its Final Rules that an applicant seeking to file more than two (2) continuations is guilty of such laches. The USPTO shifts the burden of proof to the applicant to prove otherwise under the Final Rules. In sum, the USPTO's Final Rules would result in a very narrow exception (i.e., prosecution laches) totally swallowing the rule.[3]

As noted in the case of Ricoh Company Ltd. v. Nashua Corp., "[S]ection 120, governing continuation applications, does not contain any time limit on an applicant seeking broadened claims." 185 F.3d 884, 1999 WL 88969, *3 (Fed.Cir. Feb. 18, 1999). The court in this case approvingly cited to In re Hogan, "[A] limit upon continuing applications … is a matter of policy for Congress, not for us." Id. (citing 559 F.2d 595, 604 n.13 (CCPA 1977)).

[3] The USPTO asserts that the Final Rules serve to remedy abuses of unlimited continuation practice. 71 Fed. Reg. at 49. Continuing application filings are, however, already limited by statute. Applicants may not file an unlimited number of continuing applications. For example, utility patents are limited to a term "beginning on the date on which the patent issues and ending 20 years [or sooner] from the date on which the application for the patent was filed in the United States…." 36 U.S.C. § 154(a)(2).

Section 120 imposes no restrictions on the number of continuation statements that may be filed and the USPTO's attempt to essentially re-work Section 120 to impose such an arbitrary limitation is ultra vires and plainly contrary to the statute.

b. The Final Rules Are Impermissible Substantive Rules That Exceed the Scope of the USPTO's Authority Under 35 U.S.C. § 2.

Under section § 2(b)(2)(A) of the Patent Act, the USPTO has the power to "[E]stablish regulations, not inconsistent with law, which -- (A) shall govern the conduct of proceedings in the Office…. "35 U.S.C. § 2(b)(2)(A). Here, the USPTO has grossly misinterpreted and overreached the scope of its authority under Section 2.

As stated in the Federal Circuit opinion of Merck & Co. v. Kessler, "the broadest of the PTO's rulemaking powers … authorizes the Commissioner to promulgate regulations directed only to 'the conduct of proceedings in the [USPTO]'; it does not grant the Commissioner the authority to issue substantive rules." Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (emphasis added). The holding in Merck & Co. has been cited to affirmingly in Eli Lilly & Co. v. Board of Regents of the University of Washington, 334 F.3d 1264, 1269 n. 1 (Fed. Cir. 2003).

The USPTO has maintained that the Revised Rules are merely "changes to the rules of practice that concern the process for applying for a patent," that they are "interpretive rules" exempt from the APA's requirements for prior notice and comment under 5 U.S.C. § 553(b) and the RFA. 72 Fed. Reg. at 46830 (emphasis added). An agency's "characterization of its [rule] as an exposition of its policy or interpretation of the standard [however] does not preclude [a court's] finding that it is something more." Jerri's Ceramic Arts, Inc. v. Consumer Products Safety Comm'n, 874 F.2d 205, 207 (4th Cir. 1989) (citing Nat. Knitwear Mfr.'s Ass'n v. Consumer Products Safety Comm'n, 666 F.2d 81, 83 (4th Cir.1981); see also Bragg v.

Robertson, 54 F.Supp.2d 653, 665-66 (S.D.W.Va.1999). Indeed, courts owe no deference to an agency's resolution as to whether an agency action represents a "rule" and/or whether an agency is required to conduct rulemaking procedures pursuant to the standards set forth at 5 U.S.C. § 553(b). See Nat'l Family Planning and Reproductive Health Ass'n v. Sullivan, 979 F.2d 227, 230-31 (D.C. Cir. 1992) (Chevron deference inapplicable in determining "whether [the agency] followed proper procedure in implementing" a regulatory change).

Only Congress has the power to pass substantive law setting down the terms and conditions for patent eligibility. See, e.g., In re Hogan, 559 F.2d 595, 604 n.13 (CCPA 1977)("[A] limit upon continuing applications is a matter of policy for congress, not for us."); In re Henricksen, 399 F.2d 253 (CCPA 1968) (finding the USPTO has no statutory basis to limit the number of continuation applications); Merck & Co. v. Kessler, 80 F.3d 1543, 1549 (Fed.Cir. 1996) ("As we have previously held, the broadest of the PTO's rulemaking powers – 35 U.S.C. §6(a) [now 35 U.S.C. § 2(b)(2)(A)] – authorizes the Commissioner to promulgate regulations directed only to 'conduct of proceedings in the [USPTO]'; it does NOT grant the Commissioner the authority to issue substantive rules.") (emphasis in original) (decision reaffirmed in Elli Lilly & Co. v. Bd. Of Regents of University of Washington, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003)).

In this case, a review of the Final Rules demonstrates that the USPTO is simply wrong in its characterization that they are merely procedural, a fact of which the USPTO was undoubtedly aware, as it made a pro forma, but legally inadequate, attempt to comply with the APA and RFA. The Final Rules do not meet the definition of interpretive rules. Instead, they are plainly substantive requirements foisted on the community of inventors that have the force and effect of law. As such, the Final Rules are legislative or substantive rules, which the USPTO

simply does not have authority to pass. Furthermore, as substantive rules, the Final Rules are subject to the APA and RFA.

"Interpretive regulations 'clarify ambiguous terms found in the statute or explain how a provision operates.'" Hanley v. Hand'N Heart, L.L.C., 2007 WL 201088, at *3 (E.D. Va. Jan. 22, 2007) (quoting Pelissero v. Thompson, 170 F.3d 442, 446 (4th Cir. 1999). In contrast, substantive rules (also known as "legislative rules") "grant rights, impose obligations, or produce other significant effects on private interests ... or ... effect a change in existing law or policy." Am. Hosp. Assoc. v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (citations omitted). Unlike substantive rules, "interpretive rules simply state what the administrative agency thinks a statute means, and only remind affected parties of existing duties." Chen Zhou Chai v. Carroll, 48 F.3d 1331, 1340-41 (4th Cir. 1995) (emphasis added) (citations omitted); see also Guardian Fed. Savs. & Loan Ass'n v. Federal Savs. & Loan Ins. Corp., 589 F.2d 658, 664 (D.C. Cir. 1978) ("[A]n interpretive rule is merely a clarification or explanation of an existing statute or rule.").

Here, the Final Rules do not "clarify" or "explain" the Patent Act, nor do they merely purport to "remind affected parties of existing duties." Rather, they constitute significant and onerous new restrictions on inventors' statutory rights and effect a substantive change to existing law. Moreover, as set forth in the Tafas Declaration (Appendix A) and Fenili Declaration (Appendix B), the Final Rules' substantive impact is evidenced by their substantial economic impact on multiple levels. Along the same lines, the outpouring of *Amici* filings from a broad cross-spectrum of society further exemplifies that these Rules are widely perceived to be of great substantive import.

c. The Final Rules Impermissibly Violate International Treaties

35 U.S.C. §2(b)(2) requires that the USPTO's regulations not be inconsistent with the law, which includes law enacted through treaty. (See Ex parte Cooper, 143 U.S. 472, 501 (1892) ("The constitution of the United States places such [treaty] provisions … in the same category as other laws of Congress"); O Centro Espirta Beneficiente Uniao De Vegetal v. Ashcroft, 342 F.3d 1170, 1884 (10th Cir. 2003) ("Treatises are part of the law of the land; they have no greater or lesser impact than other federal laws."). Final Rules 37 C.F.R. §§1.75(b) and 1.265 are ultra vires, because such laws violate Article 27 of the Patent Cooperation Treaty ("PCT"), in particular Article 27(1) which states:

> No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.

28 UST 7645, TIAS 8733 (Jan. 24, 1978).

35 U.S.C. § 363 states that '[a]n international application designating the United States shall have the effect, from its international filing date … of a national application for patent regularly filed in the Patent and Trademark Office …." Final Rules 37 C.F.R. §§ 1.75(b) and 1.265 apply to patent applications filed under the PCT when they enter the U.S. national phase.

PCT Rule 6.1(a) allows only for a formal objection against claims in a particular application on the basis of a lack of clarity or a lack of conciseness, and states in part that: "(a) The number of the claims shall be reasonable in consideration of the nature of the invention claimed." PCT Rule 6.1(a) does not allow, as Final Rule 37 C.F.R. § 1.75(b) mandates, the imposition of an arbitrary de facto maximum number of patent claims (i.e., 5/25) on any applicant. Further, Rule 51 *bis*.1 PCT specifies national requirements that may be allowed for

under Article 27 PCT. 28 UST 7645. Submission of an Examination Support Document ("ESD"), as required under Final Rule 37 C.F.R. § 1.265, is not among these requirements. Id.

d. The Final Rules Violate 35 U.S.C. §§ 41 and 112 By Altering Congressionally Specified Definitions and Fees

35 U.S.C. § 112 sets forth what is meant by the terms "dependent claim" and "multiple dependent claim." A claim in dependent form is defined as a claim "contain[ing] a reference to a claim previously set forth [which] … specif[ies] a further limitation of the subject matter claimed." 35 U.S.C. § 112, ¶ 4. A claim in dependent form is "construed to incorporate by reference all of the limitations of the claim to which it relates." Id. A multiple dependent claim, on the other hand, is defined as a claim containing "a reference, in the alternative only, to more than one claim previously set forth and [which] … specif[ies] a further limitation of the subject matter claimed." 35 U.S.C. § 112, ¶ 5. A multiple dependent claims is required to be construed "to incorporate by reference all of the limitations of the particular claim in relation to which it is being considered." Id. at ¶ 5.

Here, Final Rule 37 C.F.R. 1.75(b)(2) purports to engraft a further limitation onto the statutory definition of a dependent claim as set forth in 35 U.S.C. § 112, ¶ 4, by stating that "[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." Such rule is clearly designed to reach "product-by-process" claims that have long been counted as dependent claims. The USPTO has no right to alter fees set by Congress. See e.g., Boyden v. Commissioner of Patents, 441 F.2d 1041, 1044 (C.A.D.C. 1971). The USPTO acknowledges as much in its comments to the Final rules: "[c]laim fees are set by statute, **not** the Office." 72 Fed. Reg. at 46787 (emphasis added). Nonetheless, by changing the definition of "dependent claim" the USPTO has in fact changed the claim fees under 35 U.S.C. § 41.

Final Rule 37 C.F.R. § 1.75(b)(4) also engrafts another limitation on the statutory definition of "multiple dependent claim" (as set forth in 35 U.S.C. § 112, ¶ 5), by redefining such claims so as to be counted for purposes of its 5/25 rule as the number of claims to which direct reference is made. However, the USPTO does not have the right to alter statutory definitions to cause additional consequences to an applicant unforeseen by Congress.

e. The Final Rules Violate 35 U.S.C. §§ 101, 111, 112, 131 and 151 By Impermissibly Altering the Burden Of Proof Between Applicants and the USPTO, and Causing a Loss of Substantive Rights Due to Claim Limitations

35 U.S.C. § 101 permits an applicant to obtain a patent with respect to any "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" if all conditions of the Patent Act are met including novelty (35 U.S.C. § 102) and non-obviousness. (35 U.S.C. § 103).

Section 131 requires the Director "to cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law," mandates that the USPTO issues a patent therefor ("the Commissioner shall issue a patent thereof"). Likewise, Section 151 requires ("shall be given") the USPTO to issue "a written notice of allowance of [an] application" if "it appears that [an] applicant is entitled to a patent under the law." 35 U.S.C. § 151.

The Final Rules impermissibly shift the burden of proving when an application should issue to the applicant by requiring the applicant to file an ESD. An ESD requires the applicant to argue for the patentability of each independent claim with respect to the prior art uncovered. (Final Rule 37 C.F.R. § 1.265). The Final Rules also create a rebuttable presumption of patentably indistinct claims in two (2) or more applications that are: (1) filed on the same date; (2) name at least one inventor in common; (3) are owned by the same person; and (4) contain

substantially overlapping disclosures. Final Rule 37 C.F.R. § 1.78(f)(2). This rebuttable presumption, which results in a shift of burden of proof, arises without consideration of the claims in the respective applications

As remarked by the Federal Circuit in the case of In re Oetiker, "the examiner bears the initial burden, on review of the prior art or, on any other ground, of presenting a prima facie *case* of unpatentability. In re Oetiker, 977 F.2d 1443, 1444-45 (Fed. Cir. 1992) (emphasis added). If that burden is met, "the burden of coming forward with evidence or argument shifts to the applicant … If examination at the initial state does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." Id.; see also In re Piasecki, 745 F.2d 1468, 1472 (Fed. Cir. 1984). The USPTO simply does not have the right, pursuant to 35 U.S.C. § 2, to shift the burden of proof to an applicant. The specter of a shifted burden if an applicant files an ESD clearly forecloses the opportunity for an applicant to determine the optimum number of claims necessary to adequately protect his or her invention.

Further, Final Rule 37 C.F.R. § 1.265 requires cancellation of claims if the claims exceed five (5) independent or twenty-five (25) total claims in an application in which an ESD was not filed before a first office action. If Section 1.265 is applied to second continuation applications in which an ESD was not filed before a first office action, and in which, upon examination, six (6) or more dependent claims are found patentable upon incorporation of all the limitations of one or more independent claims, an applicant will be required to forego patentable subject matter related to a new invention, although the claim to such invention has been found to meet all of the requirements of the patent law.

This result violates Sections 101, 131, and 151 of the Patent Act because it allows the USPTO to withhold a patent on a new invention even though upon examination it is

determined that the applicant is otherwise entitled to a patent. It is only within the discretion of Congress to specify the substantive eligibility criteria and circumstances under which patents shall be granted. Mast, Foos & Co. v. Stover Mfg. Co., 177 U.S. 485, 494 (1900). This type of discretion, however, does not exist with respect to the USPTO. When the USPTO does not find any sufficient ground for rejection, and all conditions prescribed by the statute exist, the USPTO is duty-bound to issue a patent. In re Wagner, 28 F.Cas. 1327, 1329-30 (D.C. Cir. 1857); see also 35 U.S.C. § 102 ("A person shall be entitled to a patent unless . . .")

35 U.S.C. §§ 111(a)(2) and 112(2) allow for "one or more claims" in the specification of a patent and, indeed, mandate the same. The predecessor court to the Federal Circuit, the United States Court of Customs and Patent Appeal, made it eminently clear that "there is no statutory authority for rejecting claims as being 'unnecessary' … [and that] an applicant should be allowed to determine the necessary number and scope of his claims, provided he pays the required fees and otherwise complies with the statute." In re Wakefield, 422 F.2d 897, 900 (CCPA 1970). Here, the USPTO exceeded its authority under Section 2 and the Final Rules violate 35 U.S.C. §§ 111(a)(2) and 112(12).

f. The Final Rules Violate 35 U.S.C. § 121 By Removing the Right of An Applicant to File a Voluntary Divisional Application

Section 121 of the Patent Act defines what is meant by the term "divisional application." By implication, in authorizing the USPTO Director to dispense with formalities in divisional applications "directed solely to subject matter described and claimed in the original application as filed," Section (121) recognizes that the term "divisional application" includes situations wherein the divisional application is not "directed solely to the subject matter described and claimed in the original application as filed." Furthermore, Section 121 provides a special benefit for involuntary divisionals by providing that "[a] patent issuing on an application

with respect to which a requirement for restriction under this section has been made, or an application filed as a result of such requirement, shall not be used as a reference either in the [USPTO] or in the Courts against … the original application …," again emphasizing that a divisional application need not be due to a restriction requirement. That is, Congress understood in passing the statute that a divisional application could be directed to subject matter described but not claimed in the original application (a so-called "voluntary divisional"). No provision was made in the statute to allow the USPTO to change the definition of "divisional application" so that it no longer applied to voluntary divisionals.

The right to file "voluntary divisionals" under the patent statutes has long been recognized by Federal Circuit. See In re Schneller, 397 F.2d 350, 353 (CCPA 1968) ("there is … no direct indication before us of why appellant chose this voluntary division"); In re Ornum, 686 F.2d 937, 943 (CCPA 1982) (citing In re Schneller as pertinent because it involved a "voluntary divisional application"). No case has ever found voluntary divisionals are not permitted under the law.

Lastly, Final Rule 37 C.F.R. § 1.78(d)(1)(iii) does not permit a continuation-in-part application to be filed seeking priority to a divisional application. Such requirement is contrary to Sections 120/121.

g. The Final Rules Violate 35 U.S.C. § 122 which Requires the USPTO to Keep in Confidence Information Pertaining to Applications that Will Not Publish Until Issuance.

Section 122 requires the USPTO to keep applications for patents in confidence with "no information concerning the same given without the authority of the applicant or owner unless necessary to carry out the provisions of any Act of Congress or in such special circumstances may be determined by the Director." Other than for allowing the publication of an application within eighteen (18) months if the applicant has not sought a waiver upon initial

filing wherein the applicant agrees not to file internationally, or if special circumstances exists with respect to a particular patent application, the Patent Act does not authorize or allow the USPTO to publicly disclose any information pertaining to applications. The constitutionality of this provision has been upheld by the Fourth Circuit. Sears v. Goltschalk, 502 F.2d. 122 (4th Cir. 1974), motion denied 420 U.S. 921, cert. denied 422 U.S. 885, reh'g denied 423 U.S. 885, cert. denied, 425 U.S. 904.

There is nothing, however, in the Final Rules to prevent disclosure of information about an application that may need to be disclosed before the publication date of the application. This is in abrogation of Section 122's clear mandate that "no information concerning pending and abandoned applications shall be disclosed" except when the application has been published.[4] See Irons v. Diamond, 670 F.2d 265, 267-68 (D.C. Cir. 1981) (recognizing that such information is not available even through a Freedom of Information Act request).

Final Rule 37 C.F.R. § 1.78(f)(1)(i) requires that an applicant identify by series code and serial number each other commonly owned non-provisional applications filed within two (2) months of the claimed filing or priority date of the application. Such filing must be made even if the first filed application is to be published, but the second filed application is not to be published. As all filings made in an application to be published are made public, an applicant is faced with having information disclosed to the public which should be held confidential by the USPTO under Section 122 upon publication of the first application (i.e., information concerning the filing of the second application will be known through the first application). This disclosure is required even though the courts have found information concerning filing dates of patent

[4] Section 122(B)(i) permits an application not to be published if the applicant certifies upon filing the application that the invention disclosed in the application has not and will not be the

applications to be protected information for purposes of Section 122. Irons and Sears v. Dann, 606 F.2d 1215, 1218-19 (D.C. Cir. 1979).

Further, Final Rule 37 C.F.R. § 1.78(f)(2)(i) sets forth a rebuttable presumption that two (2) non-provisional applications having the same filing date and at least one (1) common inventor, which is under an obligation of assignment to the same entity, contain at least one (1) claim that is not patentably distinct between one another. Under the Final Rules, to overcome such a presumption, an applicant is required to "rebut this presumption by explaining" in each non-provisional application how the applications contain claims that are patentably distinct form one another. Final Rule 37 C.F.R. § 1.78(f)(2)(ii)(2). Again if one of the applications is designated for publication, or has been published, while the other application is not to be published pursuant to a waiver under Section 122(B)(i), information pertaining not only to the application, but what is actually being claimed in the non-published application, becomes publicly disclosed. Such disclosure is in abrogation of the USPTO's obligations under Section 122 of the Patent Act.

h. The Final Rules violate 35 U.S.C. § 132 by Limiting the Right to Reexamination of an Invention After Rejection

35 U.S.C. § 132(b) provides that the "Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." (emphasis added). No provision is made for the USPTO to deny an applicant to the right to file a continued examination and/or promulgate regulations having the practical effect of denying an applicant a continued examination of an application. Furthermore, 35 U.S.C. § 132(a) requires the Director to allow an applicant that "persists in his claim for a patent" after receipt of a

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subject of an application filed in another country or under a multilateral international agreement that requires publication of applications eighteen months after filing.

rejection to have his application reexamined ("the application shall be reexamined"). No provision is made for the Director to disallow re-examination simply because an applicant has run out of a mandated allotment of continuation or divisional applications. Final Rule 37 C.F.R. § 1.114 in restricting in a patent family by limiting an applicant to only one RCE, is invalid.

Furthermore, the USPTO maintains that it has retained "a first action final rejection practice under which the first Office Action in a continuing application, or in the prosecution of a request for continued examination, may be made final" pursuant to MPEP §706.07(b) and 706.07(h). 72 Fed. Reg. at 46722. This is at odds with the plain statutory language of 35 U.S.C. § 132(a), which specifically requires an reexamination of the application without exception. See 35 U.S.C. § 132(a). The USPTO has no statutory right under the Final Rules, or under the presently existing rules, to fail to reexamine an application if an applicant persists in seeking claims for a patent as long as all other statutory obligations (such as payment of fees) are satisfied. Under the Final Rules, the application of MPEP §§ 706.07(b) and 706.07(h) will have a particularly egregious effect when the applicant has expended all of his or her continuation or divisional applications that may expend as of right.

i. The Final Rules Violate the Bayh-Dole Act by Impermissibly Interfering with Government March-In Rights and the Statutory Goal of Promoting the Early Commercialization of Inventions Deriving From Public Funding

35 U.S.C. §§ 200-212 is known as the Bayh-Dole Act. 35 U.S.C. § 200 sets forth the congressional policies and objectives of the Bayh-Dole Act, which is to promote the use of the patent system to advance the utilization of inventions arising from federally supported research or development. 35 U.S.C. § 201 indicates that such promotion relates both to

inventions and discover which are or "may be" patentable.[5] See 35 U.S.C. § 201 (d) ("any invention or discovery that is or may be patentable").

Final Rule 37 C.F.R. § 1.78(d) (B) dictates that an applicant withdrawing species claims that could be rejoined, while proceeding with prosecution of a generic claim, needs to exhaust prosecution of its generic claim in its initial application and its continuation/ continuation-in-part applications (including exhaustion of any available appeals) before a divisional application directed to a non-elected species may be filed. Such provision may significantly delay the commercial utilization of non-elected species later found by contractors under the Bayh-Dole Act to be valuable. This is contrary to the statutory objectives of the Bayh-Dole Act as set forth at 35 U.S.C. § 200.

Thus, Final Rule 37 C.F.R. § 1.78(d)(B) interferes with the commercialization of inventions developed under the Act by causing delay in filing claims to an anticipated commercial product in an involuntary divisional when the Applicant is forced to traverse an inappropriately tendered restriction requirement. The delay may further impact the right of the federal agency funding the contract to effectively utilize the technology (because no one is making it) and to obtain a needed license under its march-in rights under the technology.[6]

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[5] The Act undertakes a balancing act to promote the development of inventions by contractors (that is a "subject invention" under 35 U.S.C. § 201 (e)) receiving federal funds. "[T]he Act provides nonprofit organizations and small business firms the right to elect title to a subject invention, [but] … also vests in the government the right to a paid-up license to practice the invention when the contractor elects to retain title [pursuant to § 202(c)(4), and the right to receive title to the invention in the United States, or any other country in which the contractor has not filed a patent application on the invention, prior to any pertinent statutory bar date." Campbell Plastics Engineering v. Brownlee, 389 F.3d 1243, 1247 (Fed. Cir. 2004). Under 35 U.S.C. § 203, a federal agency providing federal funds is granted "march-in rights" to require a contractor to grant a non-exclusive, partially exclusive or exclusive license in the subject invention to a "responsibility applicant or applicants" in any field of use.

[6] The limitation of the number of claims that may be filed under Final Rule 37 C.F.R. § 1.75 (unless an ESD is filed) may also negatively impact the commercialization of inventions

Point II

THE FINAL RULES VIOLATE THE U.S CONSTITUTION

a. The USPTO Has Unlawfully Usurped Congress's Exclusive Authority under the Patent Clause to Enact Substantive Rules of Patent Law in Violation of Article I, Section 8, Cl. 8, of the United States Constitution

Article I, Section 8, Clause 8 of the U.S. Constitution (the "Patent Clause") grants Congress the exclusive and Plenary power to enact laws relating to patents:

> Congress shall have power . . . to promote the progress of science and useful arts, by securing, for a limited time, to authors and inventors the exclusive right to their respective writings and discoveries.

U.S. Const. Art. I, Section 8 § 8.

In exercising its patent power, Congress may not overreach the restraints imposed by the stated constitutional purpose.[7] Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 5-6 (1966)("Graham"). In Graham, the United States Supreme Court noted that "Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of … useful Arts.'" Id. at 6 (Emphasis added).

Here, Tafas asserts that USPTO's promulgation of the Final Rules -- taken in its capacity as part of the Executive Branch, exceeds the limitations set forth in the Constitution, inter alia, because under the Patent Clause only Congress has the power to pass substantive laws setting down the terms and conditions for patent eligibility. (See also Point I, infra, at pp. 7-

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developed under the Bayh-Dole Act due to the inability of some contractors to obtain adequate protection for the inventions developed under the federal contract. Thus, Final Rule 37 C.F.R. §1.78(d) interferes with the commercialization of inventions developed under the Act because it causes delay in the filing of claims to an anticipated commercial product in an involuntary divisional when the Applicant is forced to traverse an inappropriately rendered restriction requirement.

10)(USPTO also lacks statutory authority, and it has not been delegated authority to promulgate substantive patent eligibility conditions and limitations). This is consistent with long-standing judicial precedent (e.g., Hogan, Henricksen, Merck & Co., etc.) recognizing that Congress has exclusive authority in this area and that the USPTO may not enact substantive regulations -- no less ones that would conflict with existing statutes enacted by Congress. Infra at pp. 7-10. Thus, the Final Rules, which are substantive in nature, constitute a usurpation by the Executive Branch of Congressional power in violation of the Patent Clause and the constitutional principle of separation of powers.

b. The Final Rules Are Contrary to the Patent Clause.

As set forth below, even assuming arguendo that Congress had delegated substantive rule-making authority to the USPTO (which Congress did not), the USPTO's rule-making resulting in the Final Rules is still contrary to the Patent Clause in that they fail to advance the promotion of science and the useful arts.

Congress may delegate its power to make rules and regulations to an administrative agency. See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) ("Bowen"). However, the rule-making authority delegated to administrative agencies by Congress is limited by the statute conferring the power, and, ultimately, by the limitation imposed on Congress's power by Article I. Id. When enacting administrative rules, governmental agencies must act within constitutional parameters.

It is well established that the Patent Clause is a substantive limit on the power granted to Congress and imposes the same constitutional duty on the USPTO in areas of authority delegated by Congress as it does on Congress itself. See e.g., Figueroa v. United

[7] It is interesting to note that of all the powers granted to Congress pursuant to Article I of the Constitution, only the power in the Patent Clause is specifically limited to a particular purpose.

States, Figueroa, 57 Fed.Cl. 488, 498-99 (2003); Graham, 383 U.S. at 5-6 ("It is the duty of the Commissioner of Patents … in the administration of the patent system to give effect to the constitutional standard by appropriate application … of the statutory scheme of Congress."); A.F. Stoddard & Co., LTD v. Dann, 564 F.2d 556, 563-64 (D.C. Cir. 1977) (overturning USPTO's decision to reject an amended continuation application because to do so "would frustrate the constitutional objective" underlying the Patent Clause). In fact, the Patent Clause is the very basis on which the USPTO was established. Sperry v. Florida, 373 U.S. 379, 402 (1962); Graham v. Deere, 383 U.S. 1, 5-6 (1966).

Here, in proposing and subsequently enacting the Final Rules, the USPTO failed to adequately consider (and the administrative record is devoid of any meaningful consideration or debate) the impact of the Final Rules on the progress of science and the useful arts. For example, the USPTO received hundreds of critical and highly detailed comments concerning the proposed rules, and the administrative record contains no meaningful indication that the USPTO ever meaningfully reviewed each comment, no less performed a reasoned weighing of the pros and cons of its Final Rules in light of the constitutional command of the Patent Clause. Tafas contends that not only do the Final Rules not promote this constitutional imperative, but in fact retard it, rendering them unconstitutional.

The USPTO makes clear the basis of the Final Rule pertaining to voluntary divisional continuation applications:

> "The former unrestricted continued examination practice was impairing the office's ability to examine new applications. As a result, the office is modifying continued examination practice in this final rule to address the backlog of unexamined new applications."

72 Fed. Reg at 46753.

The USPTO's stated reason for altering continuation practice, however, simply does not fulfill the Constitutional mandate of the Patent Clause that the USPTO must consider the effects of its regulations on the promotion of the progress of science and the useful arts. The USPTO's failure in the past to hire appropriately to deal with an increase in patent application filings, or to otherwise effectively deal with its backlog, simply has no relationship to the promotion of the progress of science and the useful arts. In all events, it is not a license for the USPTO to choke off the flow of patent filings in the hopes of reducing its own workload.

The USPTO's constitutional duty concerning its regulations is much more than simply mimicking back the purpose of the patent system, or citing to some perceived abuses which the USPTO feels need to be addressed. In order to promote the progress of science and the useful arts, the USPTO must actually investigate and weigh, in a detailed manner, whether its proposed regulations interfere with the progress of science and the useful arts in contradiction to Constitutional mandates. The administrative record is devoid of anything evidencing this occurred in connection with this rule making. The USPTO has simply elevated its own self-serving bureaucratic concerns of alleviating its own self-created backlog over all other considerations rendering its rule making unconstitutional.

c. The Final Rules Contravene the Due Process Clause and Takings Clause of Fifth Amendment of the U.S. Constitution

It is well established under long-standing statutory and common law that the possessor of an issued patent has property rights in that patent. 35 U.S.C. § 261 ("[P]atents shall have the attributes of personal property."); see also Consol. Fruit-Jar Co. v. Wright, 94 U.S. 92, 96 (1876) ("A patent for an invention is as much property as a patent for land."); Florida Prepaid Postsecondary Educ. Expense Bd v. Coll. Sav. Bank, 527 U.S. 627, 642 (2002) ("Patents, however, have long been considered a species of property."); Cammeyer v. Newton, 94 U.S.

225, 226 (1876) ("the right of the [patent] holder is as much entitled to protection as any other property"). As property, patents are subject to the Fifth Amendment of the United States Constitution which states that no person shall be "deprived of life, liberty, or property, without due process of law." U.S. Const. Amend. V.

"Although Congress is not required to create intellectual property rights at all, once it has done so, there may be some constitutional constraint upon retroactive modification to those rights … The Supreme Court has long recognized that the federal government, as well as the states, ought not change expectations retroactively, particularly to impair previously conferred benefits supported by investment-backed expectations." Price, PROPERTY RIGHTS Ch. 4, at 8 (ABC-CLIO, 2003).

In determining whether a constitutional "taking" has occurred, courts consider three factors: (1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action. Penn Central Transp. Co. v. City of New York, 438 U.S. 104, 124 (1978). In Ruckelshaus v. Monsanto Co., the Supreme Court found that there are property rights in many forms of intangible property, including trade secrets, liens and contracts, and that such property rights are protected by the Fifth Amendment. 467 U.S. 986, 1003 (1984). The court held that a retroactively applied law which allowed a government agency to consider or disclose an entity's trade secrets constitutes a taking under the Fifth Amendment. Id. In exchange for the public disclosure of ideas and the benefits that such disclosure brings to society, the government grants a patentee the right of exclusion in his patent. See Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974).

In disclosing their ideas, which until disclosed by applicants were held as trade secret (and in which they maintained a property right), patent applicants rely on the exclusivity that results from the quid pro quo between patent applicants and the federal government. Patent applicants meet their part of the quid pro quo bargain by fully disclosing their ideas in their patent applications. Prior to the Final Rules, and as required under the Patent Act, patent applicants (such as Tafas) fully disclosed their original ideas in their patent applications with the reasonable expectation of being able to file as many voluntary-divisional and continuations, requests for continuing examination and continuations-in-part as might prove necessary to secure protection on their inventions.

Here, by retroactively denying applicants their right to proceed with prosecution of patents having more than 5/25 claims without an onerous and vague[8] ESD requirements, and to file unlimited continuation applications, the USPTO has effected a taking satisfying all three (3) factors. The Final Rules clearly interfere with a reasonable and distinct investment-backed expectation that applicants would be able to file multiple continuation applications and patent their ideas in the future. By the USPTO's retroactive application of the Final Rules to most pending patent applications (including those of Dr. Tafas), the USPTO has unfairly taken away their ability to claim to their fullest all patentable ideas incorporated in their already filed applications. In short, the USPTO has deprived prior applicants of their property without due process of law in violation of their Fifth Amendment rights.

[8] Dr. Tafas further asserts due process violation in the vagueness of the ESD requirements (discussed more fully below in respect of his arbitrary and capricious argument under the APA), and in respect to Final Rule 75(b)'s requirement that an applicant not files that are "unduly multiplied." That is, the ESD requirements may be said to be void-for-vagueness.

By virtue of all the foregoing, Tafas has suffered and will continue to suffer substantial harm, both retroactively and prospectively, if the Revised Rules are not invalidated and permanently enjoined. (See Tafas Decl., ¶¶ 17-68).

Point III

THE FINAL RULES WERE PROPOSED AND PROMULGATED CONTRARY TO THE APA

a. The Final Rules Are Invalid Under the APA Because They Are Retroactive.

It is a well established principle under the APA that changes in agency rules are generally only to have future effects, which is engrained right within the APA's definition of a "rule":

> [T]he whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization procedure, or practice requirements of an agency ….

5 U.S.C. § 551(4) (Emphasis added). The underlined language above explicitly suggests that rules must have legal consequences only for the future and does not sanction retroactive rule-making. Such an interpretation would make "rules" essentially indistinguishable from "orders" and thus destroy the entire dichotomy upon which the most significant portions of the APA are based. See 5 U.S.C. § 551(6).

Moreover, the United States Supreme Court has disapproved of administrative agencies promulgating retroactive rules without express statutory authority:

> Retroactivity is not favored in the law. Thus congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result…By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules **unless that power is conveyed by Congress in express terms**. Even where some substantial justification for retroactive rulemaking is presented,

> courts should be reluctant to find such authority absent an express statutory grant.

Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) (emphasis added) (citiations omitted) ("Bowen"). As Justice Scalia noted in his concurring opinion in Bowen, "a rule that has unreasonable secondary retroactivity -- for example, [by] 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'… and thus invalid." Id. at 220. The USPTO clearly lacks the power to engage in retroactive rulemaking under Bowen. See, e.g., Leland v. Fed. Ins. Admin., 934 F.2d 524, 527 (4th Cir. 1991).

Here, Final Rules 37 C.F.R. §§ 1.75 (e.g., by adding an ESD requirement) and 1.265, 78 and 114 (e.g., by adding a petition and showing requirement) indisputably retroactively and adversely affect patent applications that were filed before the effective date of the Final Rules (and which have not received a first Office action on the merits before November 1, 2007), inter alia, by purporting to require applicants to file Examination Support Documents (ESD's) if their applications contain more than five (5) independent or twenty-five (25) total claims. 37 C.F.R. § 1.75(b)(1). Consequently, the Final Rules must be invalidated and permanently enjoined due to their improper retroactive effect in contravention of the APA.

b. The Final Rules Are Invalid under the APA Because the Public Was Not Given Adequate Notice and Opportunity to Comment and the Final Rules Are Not a Logical Outgrowth of the Proposed Rules.

As a federal administrative agency, the USPTO is bound to comply with the rule-making procedures set forth in Section 553 of the APA. Among other things, an agency such as the USPTO must publish a notice of proposed rulemaking that apprises the public of "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). "After notice required by this section, the agency shall give interested

persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." Id. § (c). "Whether the agency has provided notice and an opportunity to comment, and has fairly considered all significant data and comments, is the heart of the judicial inquiry." Kennecott v. U.S. Envtl Prot. Agency, 780 F.2d 445, 449 (4th Cir. 1986), citing Chocolate Mfrs. Ass'n v. Block, 755 F.2d 1098 (4th Cir. 1985).

Here, the USPTO maintains that the rules at issue are merely "changes to the rules of practice that concern the process for applying for a patent," or "interpretive rules" exempt from the APA's requirements for prior notice and comment under 5 U.S.C. § 553(b) and the RFA. [9] 72 Fed. Reg. at 46830. While maintaining that its new rules are "procedural" in nature, the USPTO nonetheless set up an *ersatz* "comment and notice" period as a public relations ploy to create the impression that public input would be carefully considered by the USPTO. It may also have been intended as a hedge in case the USPTO's assertion that the new Final Rules were entirely within its procedural rulemaking authority was ever successfully challenged in Court. As is discussed in subsection (c) below, the USPTO acted arbitrarily and capriciously in failing to appropriately consider and analyze the unprecedented plethora of written comments (almost all of which were extremely negative) submitted by the public in response to the USPTO's invitation.

In any event, the USPTO has plainly failed to meet its obligations under the APA by adding new substantive regulations to its Final Rules that were not noticed for comments during the above referenced *ersatz* notice and comment period for the Proposed Rules. As such,

[9] An "agency's compliance with procedural rules" and "procedural integrity" are reviewed de novo, with no deference whatsoever to the agency. Chocolate Mfrs.' Ass'n of the United States v. Block, 755 F.2d 1098, 1103 (4th Cir. 1985).

the public had no opportunity to provide commentary concerning the rules in violation of 5 U.S.C. §553(b)(3)(c). Numerous provisions in the Final Rules were not noticed to the public until they were actually published in late August 2007 including, without limitation, the following aspects of the Final Rules:

> (a) the 5 independent claims/25 total claim limitation ("5/25 threshold limitation") before which an examination support document is needed (37 C.F.R. § 1.75(b);
>
> (b) treating each application having at least one (1) patentably indistinct claim between them as having the summation of the all of the claims present in each application for purposes of determining whether each application exceeds the 5/25 threshold limitation for an examination support document;
>
> (c) the prohibition of filing a continuation-in-part application off of a divisional application (37 C.F.R. § 1.78(d)(1)(iii));
>
> (d) expanding the pre-examination search requirement from each limitation in designated dependent claims to all dependent claims pending in the application if the 5/25 threshold limitation is exceeded (37 C.F.R. § 1.265(a)(l)(b);
>
> (e) allowing for patent term adjustment if an application contains more than 5/25 claims and no examination support document, and the applicant did not file an examination support document until after four months from the filing date of the application (37 C.F.R. § 1.704);
>
> (f) adding a requirement under 37 C.F.R. § 1.265(a)(4) that an applicant must explain in an examination support document why a person of ordinary skill in the art would not have combined the references to arrive at the claimed subject matter (as opposed to the proposed rule that merely stated the applicant would need to argue patentability); and
>
> (g) adding a requirement under 37 C.F.R. §1.104 that the Examiner take into consideration "other requirements," such as the Manual of Patent Examining Procedure, in making determinations as to the patentability of an invention.
>
> All of the above referenced new matter introduced in the Final Rules causes

significant and substantive impacts on the patent community. Tafas and the public were denied

their statutorily guaranteed right to comment because the Proposed Rules did not alert them that these restrictions and changes were under consideration. As the Fourth Circuit stated in Chocolate Mfrs., there is "no doubt that the final rule in the instant case was the 'outgrowth' of the original rule proposed by the agency, but the [primary questions are] whether the change in it was in character with the original scheme and whether it was a 'logical outgrowth' of the rule proposed." Chocolate Mfrs., 755 F.2d at 1105. Tafas asserts that the additional requirements at issue were not met here. [10]

Here, the USPTO's switch from a proposal to limit applicants to 10 representative claims (37 C.F.R. 1.75(b)(3)) to the 5/25 claims limitation subsequently incorporated in the Final Rules (with all the attendant new regulatory limitations and conditions noted above) was a significant change that the public could not reasonably have anticipated. Approximately twenty (20) months transpired between the time the Proposed Rules were issued and the announcement of the Final Rules. Thus, the USPTO had ample time to provide a public notice and comment period for these new changes, either by re-proposing the original rule (as modified) or, alternatively, simply announcing them as second proposed rule for additional comment. The USPTO's failure to do either violates the APA and necessitates a remand.

Additionally, the USPTO's notice and comment period for the Proposed Rules was also inadequate because the USPTO failed to provide the public with the technical studies and data that it employed in reaching it decision to propose the new rules during the notice and comment period as is required. As stated in Hanover Potato Products, Inc. v. Shalala, 989 F.2d

[10] The Fourth Circuit has admonished that when deciding the issue of whether a final rule is indeed a "logical outgrowth" of the rule as originally proposed, "that, although helpful, verbal formulations are not omnipotent talismans . . . in the final analysis each case 'must turn on how well the notice that the agency gave serves the policies underlying the notice requirement.'" Id.

123, 130 n. 9 (3rd Cir. 1992), 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:

> In Texaco, Inc. v. Federal Power Commission, 412 F.2d 740, 744 (3d Cir.1969), we stated that one of the purposes of notice-and-comment rulemaking "was to give the public the opportunity to participate in the rulemaking process." Other courts have agreed. For example, in Connecticut Light & Power Co. v. Nuclear Regulatory Commission, 673 F.2d 525, 530 (D.C. Cir. 1982), the court noted in dictum that the purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process.... In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.
>
> * * * *

Id. at 130.

Here, the "administrative record" provided by the USPTO amply demonstrates that the USPTO had considerable data and computer models before the publication of its January 3, 2006 proposed rules which it did not disclose during the notice and comment period including: (a) A07096 which portrays "key model assumptions" underlying their computer generated data, including the admission that much of its pendency reduction was anticipated to come from reduced patent application filings; (b) A06725 (which reflects that the USPTO understood that the 5/25 rule would impact "a sizeable portion of the population (20%)" and (c) A04524-A04525 which indicates that USPTO was misinformed as to the growth in continuation filings in using

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(quoting Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 547 (D.C. Cir. 1983).

data that did not account for pre-1997 "file wrapper continuations." This information and data should have been made available to the public during the notice and comment period, and was not.

c. The Final Rules Constitute an Abuse of Discretion and are Arbitrary and Capricious.

The APA provides that a reviewing court should find any agency action unlawful if the action is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law.[11] 5 U.S.C. § 706(2)(A).

The USPTO's stated rationale for the Final Rules is that they will enable it to overcome its backlog. This rationale, however, is clearly arbitrary and capricious and the basis for the rules. Moreover, it is apparent that the USPTO simply ignored far less damaging alternatives than the Final Rules that were audible to reduce the backlog. See, e.g., Motor Vehicle Mfrs., 463 U.S. 29 (finding that agency decisions should be set aside when they are not adequately explained, fail to consider important alternatives, and not supported by the data which an agency supplies in its administrative record).

The "administrative record" here does not include many documents that should be found in administrative record, and in particular, does not include many publicly-available

[11] An agency's decision is arbitrary and capricious under the APA if the agency has relied on factors which Congress has not intended it to consider; entirely failed to consider an important aspect of the problem; offered an explanation for its decision that runs counter to evidence before the agency; or, is so implausible that it could not be ascribed to a reasonable difference in view. Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). In making its determination as to whether rule making by an administrative agency is arbitrary, capricious, or an abuse of discretion, a court should consider whether the agency's decision was based on an evaluation of the relevant factors and whether there has been a clear error of judgment. Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 285 (1974). When an agency has serious misperceptions as to the limits of its statutory authority, actions undertaken due to the misperception should be vacated and remanded to the agency so that it may conform its actions within the true bounds of the law. See Prill v. NLRB, 755 F.2d 941, 942 (D.C. Cir. 1985).

documents that contradict USPTO statements to the public concerning the effect of the final rules. [12] (See Rueda Decl., Exhibits 4 to 27). It is clear from publicly available material (which was not included in the administrative record), that the USPTO did not analyze its own internal data to ascertain the underlying cause of "rework," the presumed cause of backlog. For example, at a "Town Hall" meeting sponsored by the AIPLA, New York, April 7, 2006, a question was asked by a member of the audience, and answered by Commissioner Doll as follows:[13]

> Question: Commissioner Doll, did you do any studies to identify where these rework applications are coming from? Do you have any sense for whether they're caused by the examiner screwing up or the applicant screwing up? …
>
> Commissioner Doll: No, I didn't differentiate between whether it was an applicant error or an examiner error.

Rueda Decl., Ex. 43.

Thus, the USPTO cannot "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Motor Vehicle Mfrs., 463 U.S. at 43. That renders the Final Rules "arbitrary and capricious." Id. at 42.

Arbitrary and capricious activity is also seen in the USPTO's contradictory statements concerning the Final Rules made both to public, this Court, and to other administrative agencies, the approval of which was needed to ultimately promulgate the rules, and in attendant forums. This USPTO's contradictory statements include:

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[12] Tafas has made the same arguments concerning seemingly missing parts of the administrative records (and attached most of the same exhibits) in his November 14, 2007 Memorandum in Opposition to Defendants' Motion for Issuance of a Scheduling Order (Docket No. 66-69) and Tafas' Memorandum of Law In Support of Objection to Magistrate Thomas Rawles Jones, Jr.'s Opinion and Order denying Tafas' Motion to Compel and Quashing Deposition Notices dated December 7, 2007 (Docket No. 99).

[13] Transcript of recording of afternoon session of AIPLA meeting in New York, April 7, 2006, obtained from AIPLA. The PTO has previously indicated it wishes parties to submit transcripts rather than media recordings.

(a) USPTO comments suggesting little impact on applicants in filing more than five independent claims or twenty-five total claims, while at the same time suggesting to the OMB that no more than 5,000 (out of the 143,070 who exceed such limitation each year) applicants would avail themselves of the ESD procedure, and indicating in other forums that it expected most applicants would not file an ESD (Rueda Decl., Exhibits 8 to 21);

(b) USPTO assertions to the OMB that "no comments or concerns" had been raised by the public in regard to the time to provide information under the ESD requirements (Rueda Decl., Exhibit 25 - September 26, 2007 ICR Supporting Statement, page 11) despite the negative comments received by the USPTO in response to its proposed rules published January 2006 were overwhelming;

(c) USPTO assertions to the public and to this Court that the final rules do not place any limit on the number of continuing applications an applicant can file, while asserting to the OMB that it expected only 1000 petitions to file a third or more continuation application (out of 11,326 filed in FY 2006 – A08227) (Rueda Decl., Exhibit 25 - September 26, 2007 ICR Supporting Statement); and

(d) USPTO assertions to the public that the affect of the continuation/claims rules would be offset by a rapidly decreasing inventory in the appeal process, while knowing that it was about to promulgate proposed appeal rules to significantly reduce appeals based on an understanding that its continuation/claims rules would increase workload in appeals by approximately one-third. (USPTO 2007 Budget to Congress, p. 32 note 27).

Arbitrary and capricious behavior by the USPTO is also reflected in:

(a) USPTO assertions to the OMB and the public in the USPTO's EO 12866 Regulatory Review that there was no economic significance to the proposed rules, while internal data at the USPTO as set forth at A04553 indicated a substantial economic effect (i.e., over the $100 million threshold of Executive Order 12866).

(b) USPTO data manipulation in 2007 wherein the USPTO "decreased" at the OMB the information collection burden on the public from 10,000 affected entities to 5,000 affected entities by making "two forms" to deal with the Examination Support Document requirements of its new rules. (Exhibit 23 - Rueda Declaration); and

(c) in asserting to Congress that nearly one-quarter of its applications were ones "they had previously rejected," without informing Congress that many, if not most, of these applications were seeking protecting on inventions that were disclosed but not claimed in the prior application, and in relaying to

> Congress numbers that were not supported by its internal data. (Exhibit 27 - Rueda Declaration).

Moreover, the ESD requirement set forth at Final Rule 37 C.F.R. § 1.75(b)(1) is particularly arbitrary and capricious, and hopelessly vague. See, United States v. Lanier, 520 U.S. 259, 266 (1997) (a regulation is vague when it "either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application …"). For example, the USPTO's new ESD requirements do not indicate whether electronic searches need to be supplement by manual searches, which databases must be searched or which libraries. Furthermore, it is clear that the USPTO relied on flawed statistics in enacting its pre-examination search report requirement for applicants identifying more than a specified number of claims for examination. In the Proposed Rules, the USPTO points to a 2003 AIPLA economic survey as providing support for the proposition that in 2006 a patent search of the scope required for a pre-examination search would be about $2,500. 71 Fed. Reg. 61, 66 (Jan. 3, 2009). This statement was seemingly made, however, without any investigation into standard patent novelty search practice in 2002 which forms the basis of the 2003 AIPLA economic survey.

Point IV

THE FINAL RULES WERE PROMULGATED IN VIOLATION OF THE REGULATORY FLEXIBILITY ACT

a. The Applicable Standard of Review for a Regulatory Flexibility Act Claim.

Congress passed the RFA, 5 U.S.C. §§ 601-612, so that agencies would consider the impact of their regulations on small businesses. 5 U.S.C. § 601(b). The law protects small businesses by prescribing a detailed process by which federal agencies must assess the impacts of regulatory proposals on small entities, and then develop and consider proposals to ameliorate

such negative impacts. Nat'l Ass'n of Psychiatric Health Sys. v. Shalala, 120 F. Supp. 2d 33, 43-44 (D.D.C. 2000) ("NAPHS").

The primary purpose of the RFA's requirement for prior analysis is so that agencies "consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment." See U.S. Small Business Admin. Office of Advocacy, A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act ("SBA Guide") at 1 (available at http://www.sba.gov/advo/laws/rfaguide.pdf); see also NAPHS, 120 F. Supp. 2d at 43-44. That is, while the RFA is considered primarily procedural, U.S. Cellular Corp. v. F.C.C., 254 F.3d 78, 88 (D.C. Cir. 2001), the statute imposes "action forcing provisions" that require agencies to focus attention on the impacts of various proposed alternatives on small businesses."[14] See North Buckhead Civic Ass'n v. Skinner, 903 F.2d 1533, 1540 (11th Cir. 1990).

The RFA is remedial in nature and "'is intended to be as inclusive as possible, and doubts about its applicability should be resolved in favor of complying with the provisions of the Act.'" Nat'l Ass'n for Home Care v. Shalala, 135 F. Supp. 2d 161, 164 n.4 (D.D.C. 2001) ("NAHC") (quoting 126 CONG. REC. H24589 (Sep. 8, 1980)); see also Id. at 168 ("Congress intended that agencies err on the side of caution in determining whether to perform regulatory flexibility analyses").

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[14] This requirement of the RFA is similarly to NEPA's requirement of "evaluating a proposed project's environmental impact." As the District of Columbia Circuit court has recently noted in the context of an RFA standing inquiry: "The Supreme Court has admonished that procedural rights are special, and that a person with standing who is injured by a failure to comply with the NEPA procedure may complain of that failure at the time the failure takes place, for the claim can never get riper." Nat'l Ass'n of Home Builders v. United States Army Corps of Eng'rs, 417 F.3d 1272, 1286 (D.C. Cir. 2005) (internal quotations and citations omitted).

An agency is, in general, exempt from the requirement that it prepare an initial and final regulatory flexibility analyses ("IRFA" and "FRFA") with respect to a rule, as the RFA defines that term, 5 U.S.C. § 601(2), only if the agency can certify the rule does not meet Section 605(b)'s threshold "significant economic impact on a substantial number of small entities" ("SEISNSE") standard. 5 U.S.C. § 605(b). The RFA also states that an agency shall prepare an IRFA whenever the agency "is required by section 553 of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule," 5 U.S.C. § 603(a), and a FRFA whenever it promulgates a final rule in accordance with the same publication requirements. 5 U.S.C. § 604(a) (2000).

Under the relevant provisions of the RFA, (5 U.S.C. § 605(b)), the USPTO was required to do a formal RFA analysis concerning whether the Proposed Rules would have a significant economic impact on a substantial number of small entities, unless the USPTO's director certified, pursuant to 5 U.S.C. § 605(b), that there would be no such impact ("SEISNE certification"). Section 605(b) of the RFA provides in pertinent part as follows:

> (b) Sections 603 and 605…shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities . . .

5 U.S.C. § 605(b).

The RFA's judicial review provisions, 5 U.S.C. § 611(a)(1)-(2), allow a small business to seek judicial review of a flawed certification of no SEISNE. Id. § 611. A certification based on a finding of no SEISNSE cannot be based on a myriad of suppositions purposefully designed to blind the agency to the rules' impacts on small entities. See, e.g., NAPHS, 120 F. Supp. at 43-44; SOFA, 995 F. Supp. at 1436; North Carolina Fisheries Ass'n v. Daley, 27 F. Supp. 2d 650, 654-55 (E.D. Va. 1998) ("NCFA II"). Review of an agency's

compliance with the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601-612, is subject to the standards set forth in "Chapter 7" of the APA, specifically 5 U.S.C. § 706. See 5 U.S.C. § 611(a)(1) & (2).

The Court owes no deference to the certifier's legal conclusions that the Final rules meets the certification standards under 5 U.S.C. § 605(b) relating to significant impacts nor that the RFA does not apply to the rule at issue.[15] A court does not generally defer to an agency's determination of an issue that is not within the agency's particular expertise. See Airlines Traffic Offices, Inc. v. Department of Defense, 87 F.3d 1356, 1361 (D.C. Cir. 1996) (stating that Chevron deference is inappropriate where agency has not been entrusted to administer the statute in question).

b. The USPTO Unlawfully and Erroneously Certified that the Rules Would Have No Significant Economic Impact on a Substantial Number of Small Entities and Failed to Issue a Required Final Regulatory Flexibility Act Analysis.

In the present case, Defendants were required -- absent a valid exception not present here -- to perform an RFA analyses because: (1) the Final Rule was a "rule," as the term is defined in 5 U.S.C. § 601(2), in that it meets the definition of legislative or substantive rule; (2) Section 553(b) of the APA "required" the USPTO to publish a general notice of proposed rulemaking for the Rules (see 5 U.S.C. §§ 603(a) & 604(a)); and (3) the Rules effect "a substantive change in a prior rule." U.S. Telecom Ass'n v. F.C.C., 400 F.3d 29, 30 (D.C. Cir. 2005). As set forth more particularly below and in the supporting declaration of Robert N. Fenili

[15] According to the legislative history of the Small Business Regulatory Enforcement Fairness Act ("SBREFA") of 1996, Pub. L. No. 104-121, 110 Stat. 857, which enacted the RFA's judicial review provisions: "[I]f the court finds that a final agency action was arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law, the court may set aside the rule or order the agency to take other corrective action." 142 CONG. REC. S3245 (daily ed. Mar. 29, 1996) (statement of Sen. Bond).

("Fenili Decl."), Defendants were required to perform an RFA but did not.[16] Instead, Defendants avoided this obligation by erroneously certifying the absence of SEISNE pursuant to 5 U.S.C. § 605(b) using an obviously flawed analysis more particularly described below.

First, Robert Fenili Ph.D ("Fenili"), an economist and expert, analyzed the USPTO's RFA Certification Analysis to determine if it provided sufficient support for the USPTO's conclusion that its proposed new continuation and claims rules "will not result in significant economic impacts on a substantial number of small entities," as stated in the Certification Analysis at p. 2 at A.08274 and in the Regulatory Flexibility Act ("RFA") compliance section of the USPTO's new rules.

As set forth more particularly in his Declaration, Fenili concluded that the major conclusions in the RFA's Certification Analysis were flawed, made without adequate support or documentation, did not rest upon firm foundations nor was Fenili able to find in the administrative record the basis for many assumptions used in the calculations that lie behind many of findings in the RFA Certification Analysis. (See Fenili Decl., ¶ 7-8). Fenili concluded that the new Final Rules will have a significant and disproportionate effect on small entities (contrary to the USPTO's RFA certification). (See Fenili Decl., ¶¶ 25-26).

More specifically, Fenili opined that: 1) the conclusions of the USPTO RFA Certification Analysis depend on data and assumptions that have no support in the administrative

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[16] The record is appropriately supplemented by Mr. Fenili's declaration because it meets several of the exceptions to the general rule regarding limitations to the administrative record outlined in Esch v. Yeutter, 876 F.2d 976 (D.C.Cir.1989), for instance "(1) when agency action is not adequately explained in the record before the court; (2) when the agency failed to consider factors which are relevant to its final decision; . . . (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly . . ." Amfac Resorts, LLC v. U.S. Dept. of Interior, 143 F. Supp. 2d 7, 12 (D.D.C. 2001) (paraphrasing Esch, 876 F.2d at 991-

record; (2) the USPTO RFA Certification Analysis does not take into account many costs entailed in filing an Examination Support Document; (3) the USPTO RFA Certification Analysis includes data that has been incorrectly counted and improperly assembled; (4) even if one adopts all figures adopted by the USPTO in its analysis, standard economic models that calculate the effect of the Rules indicate that a substantial number of small entities will be significantly economically impacted by the new rules even with respect to the USPTO's standards for such a finding; and (5) appropriate analysis indicates that small entities will be significantly, disproportionately affected by the new rules in comparison with large entities. (See Fenili Decl. at ¶¶ 3-26).

Moreover, under the applicable APA "arbitrary and capricious" standard, the USPTO's no SEISNE certification was improper for, among others, the following reasons: (1) the USPTO made assumptions that had a tendency to downplay or hide the economic impacts; (2) the USPTO underestimated the number of affected small entities, inappropriately defined the universe of small entities, and failed to recognize the disproportionate impacts on this sector; and (3) the USPTO used faulty data and data generated for an entirely different purpose, making it misleading based on the record sources from which they were derived.

The USPTO incorporated assumptions and conducted analyses with an explicit eye towards downplaying and masking small entity impacts. As one obvious example, the impacts analysis assumes that small entity inventors earn more than fifty percent above median family income "in light of the creative/technical abilities of an individual seeking a patent." A.

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92). However, all the flaws in the USPTO's analysis are apparent within the record itself, albeit the full suite of problems take some elucidation.

08290. This assumption lack a record basis[17] and also countervails USPTO's duty to err on the side of inclusiveness, as use of higher income levels raise the threshold at which impacts are deemed significant, increasingly the likelihood of not finding a significant impact where one, in fact, exists. (Fenili Decl. ¶ 7(b).

Similarly, no costs are assumed for the portion of the Final Rules that addresses "patently indistinct claims," triggered whenever "pending applications or patents … (1) have an effective filing date within two months of the filing date of the pending application; and (2) name at least one inventor in common with the pending application." A.08290. When applicable, entities must file "a terminal disclosure" or provide argument as why the claims are distinct. Id. No justification exists as to why these filings are considered costless (they are not); the only reason given is that this requirement is needed "to close a loophole." Id.; see also Fenili Decl. ¶ 7(g).

Perhaps most egregious is USPTO's decision to amortize the cost impacts over a period of 20 years, shockingly based on its misunderstanding of the life of a patent[18] (it is less, as a patent's life is measured from the first filing). A. 08292; Fenili Decl. ¶ 7(j). This assumption assumes small entity inventors have ready access to cheap credit, highly unrealistic in today's

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[17] Where such record support is lacking, court's have questioned agencies' self-serving use of income and other estimates. See SOFA, 995 F. Supp. at 1435 ("The record fails to contain an adequate explanation of the agency's calculation [of income], if any, leaving no possibility to gauge its rationality, which is manifestly suspect.").

[18] The USPTO's Certification Analysis makes this error over and over again. See, e.g., A.8292 (1) "In the case of patents … it is reasonable to allocate the cost of obtaining a patent over the 20 year life of the resulting patent.") Certification Analysis, p. 2, Section 5.1.1 (emphasis added); (2) "Over the 20 year lifespan of the patent" page 4, Section 1.1 of Certification Analysis; and (3) "The incremental costs are annualized over a period of 20 years…to coincide with the life of the patent." Certification Analysis, p. 22, section 5.12.

market, and violates precepts of economic modeling and commonsense notions of how small businesses account for costs, i.e., at the time they are incurred.[19] See Fenili Decl. ¶ 17.

Taking the 5/25 rule as an example, the USPTO's analysis vastly understates the rule's impact in significant ways. For one, the analysis looks only at initial applications, despite the fact that the requirement for an ESD applies equally to continuation or CIP applications that exceed either of the two thresholds. A.08284; 72 Fed. Reg. at 46836; 37 C.F.R § 1.75(b)(3). For another, USPTO considered only applications exceeding 15 independent or 75 total claims as impacted by the rule on the theory that an initial application that contained fewer claims could be parsed among the initial and the two allowable continuations. Id. There was no recognition of the additional preparation costs associated with filing three applications where under existing rules one would suffice, nor was the loss of the right inventors currently have to add later discovered inventions through continuation applications recognized. (Fenili Decl. ¶ 11).

Even using the flawed data relied on by USPTO, and a methodology that both USPTO and SBA consider an appropriate measure of the significance of economic impacts -- specifically, incremental costs as a percentage of revenue (A. 08292, SBA Guide at 17-18) -- it is readily apparent the Final Rules' impacts meet USPTO's threshold for significance under the RFA. As Dr. Fenili shows, even using USPTO's low-balled cost estimates leads to a finding of significant impacts to small entities when the incremental costs are considered on a revenue basis, rather than amortizing over a long horizon. (See Fenili Decl. ¶¶ 17-20).

Significance can be deduced another way. Taking the numbers USPTO relies on as approximating the additional incremental costs of the 5/25 rule, shown in Table 5-1 of the

[19] In SOFA, the court chided another agency's similar " transparent and unbecoming effort to demonstrate limited economic" impacts on small entities. 995 F. Supp. at 1435. The court

Certification Report (A. 08297), the data show that the increased filing and maintenance fees stemming from the 5/25 limitation are more than 25 percent higher than the baseline costs under the current rule, which is undoubtedly significant.[20] However, these costs are skewed unrealistically low, based on incomplete and incomparable data. (See Fenili Decl. ¶¶ 8(f), 10, 14-15, 21.

A legally adequate Section 605(b) certification requires an agency to accurately assess the universe of small entities that its proposal affects. See SOFA, 995 F. Supp. at 1435-36 (rejecting an agency's attempt to dilute the universe of impacted entities). Here, the USPTO has masked the total impacts on small entities through such artifices as calculating percentages based on universes of large and incomparable aggregations.[21]

In its certification analysis, USPTO diluted the universe of small entity filers by failing to determine the total number of unique filers and segregating them by size class. (Fenili Decl. ¶ 8(i). Bias also exists in the comparisons to the total universe of applications, as single large entity may file scores of applications a year, as is clear even from the parties in this case. Looking at applications rather than entities inflates the denominator, thus shrinking the

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looked at the actual gross impact of the rule in finding an obvious significant impact. Id.; see also NCFA II, 27 F. Supp. 2d at 660 (not considering offsets to current year's economic impact).

[20] Those costs are estimated to "range from $19,940 to $49,155." A. 08295. The low end incremental cost associated with the claims rule is $5,170, 25 percent of $19,940, while the high end of cost of $13,121 is 26 percent of $49,155.

[21] For example, the agency estimated that only "about 4.8 percent" of small entity applications would be impacted by the continuations rule. 71 Fed. Reg. at 57. That percentage is based on a universe that includes original applications. When appropriately compared to the number of continuation or CIP applications filed during the same period, nearly 30 percent of all small entity filing continuation applications would have been affected.

percentage of apparently affected small businesses.[22] It is fair to assume that the actual impacts are orders of magnitude larger than shown in the analysis.

It is astonishing that USPTO's so-called "sensitivity analysis" considers all applications filed in 2006 to have been filed by small entities on the theory that over 99 percent of all businesses in the United States are small businesses. A.08283. Even so, USPTO's analysis in fact demonstrates unacknowledged but significant disproportionate impact on small businesses. (See Fenili Decl., ¶¶ 23-25). Disproportionate impact is apparent from a a quick glance at USPTO's Certification Report. See A. 08286 (Exhibit 3-2) (showing 2.9% of small entity applications impacted by the continued application filing requirement, while only 2.5% of all applications are so affected). This difference may appear modest, but a proper comparison shows small entity filers are 138 percent more likely to be impacted by 5/25 rule, 149 percent more likely to suffer adverse consequences from the limit on continuations, and nearly 200 percent more likely than larger entities to be affected by both. Id. Such disparate impacts can and should lead to a finding of significance within the meaning of the RFA.

In making its certification, USPTO relied on assumptions and data that find no support in the record, or which are characterized and used for purposes which the data cannot sustain. There are a myriad of particular examples of flawed, misleading, or unsupported data outlined in Dr. Fenili's declaration.[23]

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[22] In all, there appear to have been 111,178 total filings by small entities, and 408,396 total filings in 2006. A. 08286. Assuming, as does ICF, that the self-identified small entities are overwhelmingly likely to file only one application in any given year, while large companies file many (A. 08284), the ratio of small entity to large entity filers (and thus the percent impacted) will be far greater than the 27 percent of small entity applications filed in that year.

[23] See Fenili Decl. ¶¶ 7(d),(e) (blended labor rate), 7(g) (indistinct claims), 7(h) (assumption of fixed Section 1.98 costs), ¶ 9-10 (legal and preparation costs), ¶ 15 (failure to account for document review costs), ¶ 21 (lack of revenue data).)

For all the foregoing reasons, the USPTO's certification of no SEISNSE was erroneous arbitrary and capricious, and its attendant failure of the agency to complete a legally adequate FRFA violates the RFA. Thus, Tafas is entitled to summary judgment on this claim.

CONCLUSION

WHEREFORE, for all the foregoing reasons, as well as those set forth in Tafas' Motion for Summary Judgment, Declaration of Tafas, Declaration of Robert Fenili, Ph.D and the Declaration of Michael Rueda, Plaintiff Tafas respectfully moves the Court to grant Tafas summary judgment in his favor, and to enter the proposed form of Order being submitted along herewith as follows, along with such other, further and different relief as the Court deems just, equitable and proper:

Respectfully submitted,

/s/ Joanna Baden-Mayer

Joanna Baden-Mayer (VSB # 67920)
Joseph D. Wilson (VSB # 43693)
Steven J. Moore, Esq. *(pro hac vice)*
James E. Nealon, Esq. *(pro hac vice)*
KELLEY DRYE & WARREN LLP
Washington Harbor, Suite 400
3050 K Street, NW
Washington, DC 20007
Telephone: (202) 342-8400
Facsimile: (202) 342-8451
E-mail: jwilson@kelleydrye.com
jbaden-mayer@kelleydrye.com
jnealon@kelleydrye.com

Counsel for Plaintiff Triantafyllos Tafas

Of Counsel:

William R. Golden Jr., Esq.
KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, New York 10178-0002
Telephone: (212) 808-7992

Facsimile: (212) 808-7897
E-mail: wgolden@kelleydrye.com

-- and ---

Shaun Gehan, Esq.
David Frulla, Esq.
KELLEY DRYE & WARREN LLP
Washington Harbor, Suite 400
3050 K Street, NW
Washington, DC 20007
Telephone: (202) 342-8400
Facsimile: (202) 342-8451
Email: sgehan@kelleydrye.com
dfrulla@kelleydrye.com

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