

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

TRIANAFYLLOS 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 OPPOSITION TO DEFENDANTS' SUMMARY JUDGMENT MOTION**

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Exhibit 4 Record and presentation of a meeting with USPTO, the Office of Management and Budget and Biotechnology Industry Organization (May 16, 2007).

Exhibit 5 Record and presentation of a meeting with USPTO, the Office of Management and Budget and the Innovation Alliance, represented by two of its members (June 14, 2007).

Exhibit 6 Record and presentation of a meeting with USPTO, the Office of Management and Budget and parties including Cantor Fitzgerald, GlaxoSmithKline and Polestar (June 15, 2007).

Exhibit 7 Record of a meeting with USPTO, the Office of Management and Budget and the Research and Manufacturers of America (PhRMA) (June 25, 2007).

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Exhibit 9 Letter and comments on USPTO rules filed by Cecil D. Quillen, Jr. with the Office of Management and Budget (May 11, 2007).

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Exhibit 12 Letter and comments on USPTO rules filed by Ron D. Katznelson with the Office of Management and Budget (June 29, 2007).

Exhibit 13 Richard Belzer, letter to Honorable Susan E. Dudley, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, with attachment “OMB Control Number: 0651-0031, ICR Reference Number: 200707-0651-005, Alternative Burden Estimates,” (Revised January 17, 2008).

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<http://www.whitehouse.gov/omb/oir/0651/comments/460-patent.pdf> .

- Exhibit 15** E-mail from John Collier to Jennifer McDowell and Robert Bahr, “Bottom up analysis of ESD”, (May 8, 2007), (A08249 A08250).
- Exhibit 16** USPTO internal memorandum “Relevant Data regarding USPTO filings”, (August 3, 2006), (A04546 – A04553).
- Exhibit 17** Patrick Doody, The Patent System Is Not Broken, *Intellectual Property & Technology Law Journal*, Vol. 18, No. 12, pp. 10-24, (December 2006).
- Exhibit 18** USPTO, “Continuing applications over time”, (June 5, 2007) (A05061 – A05062).

I. INTRODUCTION

A. Plaintiff Dr. Tafas and the Present Action.

Dr. Triantafyllos Tafas (“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 brought this action to permanently enjoin the USPTO 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, having an effective date of November 1, 2007, which were published at 72 Fed. Reg. 46716, 46835-43 (Aug. 21, 2007) and were to be codified at 37 C.F.R. Part 1 (the “Revised Rules” or “Final Rules”).

Tafas requests a declaration that the Final Rules are in toto, null, void and without legal effect, inter alia, as beyond the USPTO’s rule-making power and inconsistent 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. Tafas seeks an order 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 Final Rules.

Tafas, an inventor and proprietor of certain energy recovery patent applications, and a named inventor on numerous robotic microscopy patents and patent applications, filed his complaint and his motion for preliminary injunction within twenty-four (24) hours of the publication of the Final Rules. Thereafter, despite enormous opposition to the Final Rules throughout the patent and technology communities, Tafas stood alone in this action for almost two (2) months .

Tafas filed this action based on principle and the strong moral conviction that the Final Rules would seriously hamper the American Dream for future inventors and emerging companies. Tafas has proceeded in this case always with the highest of intentions, not for fame or fortune, even foregoing his own preliminary injunction motion, irrespective of the time and effort expended by his counsel in preparing it, and the public acclaim that he knew would ensue if he proceeded with the motion, to allow another plaintiff, which he felt could demonstrate significantly more harm deriving from the Final Rules than he could, to make the motion on substantially identical grounds (and then having to further wither the blows of the USPTO who chastised him in open court for joining GSK's motion in purported contravention of an agreed scheduling order when the motion for preliminary injunction was heard).¹

Tafas is a founder of Ikonysis, Inc. ("Ikonysis"), which manufactures a technologically-complex robotic microscope designed to automatically read microscope slides and proffer tentative diagnoses. Tafas started his company with very little capital. After many years of unsuccessful attempts to raise funds in Europe, Tafas turned to the United States, where he joined a colleague from the University of Connecticut, to raise the funds necessary to support the significant research and development needed to develop such a complex instrument. Tafas found this country exceptional in that it provided strong patent protection affordable not only by large corporate entities, but also by individuals. Based on the patent applications which he filed after coming to this country, Tafas and his colleagues were able to raise the needed seed funding to start their microscopy company. After many painstaking and lean years, Ikonysis now manufactures and sells a fully automated microscope.

¹ Similarly, Tafas vigorously fought for limited discovery in this action due to his strong belief in open government.

Tafas is not a “patent troll” who obtains patents solely to bring infringement lawsuits. In fact, Tafas has never filed suit under any of his patents or patent applications nor has he ever licensed any of his intellectual property to a third-party. Tafas is not some unsophisticated “basement inventor.” Tafas’ ultimate goal is to use his robotic microscope to detect early stage cancers, on a wide scale, using proprietary biological markers. His theory is this could be accomplished through monitoring of blood samples taken at routine physician visits. This is possible because Tafas’ automated microscope will allow for rapid, twenty-four (24) hour screening of blood samples. This is something that is not presently feasible on any large-scale absent the automated microscope due to the limited number of histologists available in the medical field.

Early results obtained in this project have been extremely promising. Of course, cancer treatment success rates are substantially greater when cancers are detected early before they have time to grow and metastasize. As would be known by anyone who suffers from, or knows anyone one who has suffered from, or died, due to cancer (which unfortunately encompasses almost everyone), Tafas’ research holds out the potential to revolutionize the field of early cancer detection and treatment. Tafas brings this suit in substantial part so that he and others are not thwarted by the Final Rules from pursuing such life saving medical advances.

Additionally, Tafas owns and is presently prosecuting as a sole proprietor several patent applications related to energy recovery from an automobile’s internal combustion engine manifold. Tafas filed these patent applications in connection with inventive concepts he had concerning different methods to reduce emissions, and resultant global warming. Again, actual research is being undertaken by Tafas with respect to these inventions and again he is seeking venture capital to support such research.

Tafas agrees with co-plaintiff GSK, whose case has been consolidated into the present action, and *amici* BIO, Pharma, Monsanto, Croplife America, Pennsylvania Greenhouses, Human Genome Sciences, and Elan Pharmaceuticals that the Final Rules will have a draconian adverse effect on life science industries including, without limitation, impairing the development of future diagnostics and treatments. Absent strong and affordable patent protection, Tafas is justifiably fearful that new medical technologies and biotechnology advances will be copied and sold by others who have not incurred the research investments borne by the innovators. Life science companies (such as Ikonysis) and medical research universities will be less willing or unable to undertake the huge investments and substantial risks necessary to bring life saving technologies and pharmaceuticals to the public if the Final Rules ever become effective.

Tafas also strongly concurs with the Minnesota *amici*, TELES AG Informationstechnologien, and the R&D Licensing Companies, that the Final Rules will have a dramatic negative impact on many other technology companies including, without limitation, those that concentrate on the development of software, mechanical, electrical, and chemical inventions. Tafas shares the serious concerns expressed by *amici* CFPH, LLC and Washington Legal Foundation that the Final Rules will dramatically restrict the ability of emerging companies to obtain the patent protection they need to raise capital funds and that the Final Rules -- if not permanently enjoined -- portend the death knell of the small individual inventor, who has been the lifeblood for many of the truly technological breakthroughs of the past in the United States.²

² For example, the telephone (Alexander Graham Bell), the airplane (the Wright Brothers) and the television (Filo Farnsworth).

B. Dr. Tafas's Disagreement With the USPTO'S "Undisputed Facts".

Tafas disagrees with many of the USPTO's purported "Undisputed Facts." In particular, Tafas disagrees with all of the USPTO assertions of "undisputed fact" to the extent the USPTO does not "cit[e] the parts of the record relied on to support the listed facts as alleged to be undisputed" pursuant to Local Civil Rule 56(b). Tafas also objects to the USPTO simply restating prior *ipse dixit* statements the USPTO made in its Federal Register publication of the Proposed Rules and Final Rules (which were submitted as part of the administrative record) without any support for a reasonable and good faith analysis of actual data found in the administrative record. See, HLI Lordship Indus. Inc. v. Committee for Purchase from the Blind, 791 F.2d 1136, 1141 (4th Cir. 1986)(finding that while the "APA does not require an exhaustive explanation of an administrator's reasoning" it does require "evidence" that the administrator undertook "examin[ation] [of] relevant data" which should form part of the administrative record).

Tafas also disagrees with certain legal conclusions/argument made by the USPTO, which do not properly belong in a statement of undisputed facts and, as such, need not be specifically controverted. These argumentative statements include the USPTO's contention that a "substantial portion of [its] backlog" is attributable to the filing of continuations or multiple claims (Def. Mem. at pp. 7-8); that without the new rules the USPTO "risks being swamped by continuation filings" (Def. Mem. at p. 8); and, that the "USPTO structured the Final Rules to Ensure that Applicants Could Receive the Patent Protection They Seek" (Def.. Mem., pp. 12-13). Similarly, the USPTO's description of how the Final Rules work and/or interpretation of the Final Rules throughout the undisputed facts section do not constitute statement of fact, but rather the USPTO's self-serving interpretation of law (i.e., mere legal argument by the USPTO). (See Def. Mem., "Overview of Final Rules Concerning Claims and

Continuation Practice” at pp. 9-13). For example, Tafas objects to the USPTO’s legal conclusion in its statement of undisputed facts that the Final Rules are “procedural” or “interpretive” rather than substantive in nature. (Def. Mem. at 8).

As concerns the USPTO’s assertions of “undisputed facts” (made at pages 7–13 of its brief in support of its motion for summary judgment), only the facts specifically enumerated below (as qualified) are truly undisputed. Except as expressly admitted and subject to the caveats set forth below, Tafas controverts and/or objects to the balance of the USPTO’s purported undisputed facts:

- (a) The USPTO proposed and ultimately promulgated and published its so called Final Rules (both reflected in the Federal Register) in January 2006 and August 2007 and Tafas refers the Court to the Proposed Rules and Final Rules for their terms.
- (b) A05072 indicates that continuing applications, exclusive of divisional applications, increased from fiscal year 1980 to fiscal year 2006 (see Def. Mem at 7). However, as CIP applications necessarily disclose, and nearly always claim new matter, such applications are not appropriately included in USPTO’s statement with respect to continuation applications. Without counting of continuation-in-part applications and divisional applications, the data focused on in A05072 indicates continuation applications have risen from about 1.5% of applications in 1980 to about 4% in fiscal year 2006;
- (c) A07099 indicates that the number of claims per application grew from an average of 14.4 claims in fiscal year 1990 to about 21 claims in fiscal year 2005 (Def. Mem. at p. 7);
- (d) The USPTO represents in its Federal Register publication of its Final Rules that it had a backlog of 701,147 applications (Def. Mem. at 7);
- (e) Proposed Rule 78 would have restricted applicants to only one (1) continuation application, while Proposed Rule 75 would have required applicants to provide an Examination Support Document (ESD) for any applicant that requested examination of more than ten (10) representative claims (Def. Mem. at 8);
- (f) The USPTO received more than 500 comments from the public after publication of its proposed rules (Def. Mem. at 9), provided however, that Tafas disputes that the USPTO took the overwhelming and unprecedented outpouring of negative comments into account in formulating its Final Rules;

- (g) Final Rules 78 and 114 regulate continuation and RCE filing in accordance with their words (Def. Mem. at 9);
- (h) Final Rules 75 and 265 require the filing of an ESD if the applicant seeks protection in any one (1) application of more than five (5) independent claims and/or twenty-five (25) total claims (Def. Mem. at 10), provided however, Tafas disagrees: (i) that such number of claims are “unusually large,”; (ii) that the ESD was designed to “assist the examiner”; (iii) that requirements for an ESD are set forth in “supplemental guidance issued by the USPTO”; and, (iv) that an applicant may invariably present 15 independent claims and 75 total claims for each invention without an ESD;
- (i) Final Rules 75 and 78 contain other requirements (Def. Mem. at pp. 10 - 11). Tafas disagrees, however, that such other provisions merely overcome “confusion as to how the other provisions apply,” or that 78(f)(2) may properly legally set forth a rebuttable presumption of patentably indistinct claims;
- (j) Final Rule 142 allows for a suggested restriction requirement (Def. Mem. at 11), but Tafas disagrees that he has not challenged the validity of Rule 142;
- (k) The Final Rules did permit applicants to file continuation or continuation-in-part applications for approximately two (2) months after the Final Rules were published (Def. Mem. at 12); provided however, Tafas notes that the USPTO published materials that indicated to the public that such filings could not be made, as well as published materials indicate that if they were filed would be subject to serious negative repercussions (See e.g., slide 33 of “Claims and Continuations Final Rule” – Webinar August 23, 2007) 37 CFR 1.75(b)(4) and 1.78(f)(2);
- (l) 72 Fed. Reg. at 46736-37 asserts that an applicant under the Final Rules could file “one more continuation or continuation-in-part application” if the applicant had already filed two or more of such applications and the applicant did not file any application in any such patent family between August 21, 2007 and the effective date (Def. Mem. at 12). However, Tafas asserts no knowledge as to the intent of the USPTO with respect to applicants who file a continuation between August 21, 2007 and a new effective date of the Final Rules if they are not permanently enjoined and disputes the USPTO’s allegation as to its intent.
- (m) The Final Rules allow for the filing of a divisional application if the USPTO agrees to issue a restriction requirement in response to a Suggested Restriction requirement (SRR), from which an applicant can file two (2) continuation applications without presenting any petition or showing (Def. Mem. at 12). Tafas disagrees with this statement, however, to the extent that it is implied that the USPTO has any requirement to or intention to actually issue such restriction requirements in actual practice.

In particular, Tafas notes no factual support in the USPTO's administrative record for the entire purported *raison d'etre* of the Final Rules – the USPTO's assertion that such rules are necessary to ameliorate the USPTO's backlog:

These filings [continuation applications and applications with more than 25 claims] are hindering the Office's ability to examine newly-filed applications and maintain quality examination. ... (Def. Mem. at 7)

* * * *

The growing number of such continuation filings are hobbling the Office's efforts to examine new filings. ... (Def. Mem at 8)

* * * *

Applications containing large numbers of claims also present difficulties for the Office; they absorb an inordinate amount of patent examining resources because they are extremely difficult to properly process and examine. (Def. Mem. at 10)

Rather, Tafas notes that applications with more than 25 claims, and continuation applications filed pursuant to 35 U.S.C. § 120, carry substantial extra filing fees, at a level that the USPTO itself requested from Congress.³ Therefore, any resources absorbed may not logically be asserted to be “inordinate,” as they are already bought and paid for by patent applicants. For RCE continuations, the USPTO has both the authority and obligation to set fee

³ Compare <http://web.archive.org/web/20030618051735/www.uspto.gov/web/offices/com/strat21/feeproposalcomparison.htm> (listing PTO's requested fee levels) with 35 U.S.C. § 41(a) (2004 statute setting fees at exactly the level requested by the PTO for the classes of examination services at issue in this litigation) for claims over 3/20 threshold, at levels from \$25 to \$200 each) – all fee levels (“This legislative proposal [establishes] a new schedule of patent fees ... realigning fees so they better reflect the needs of customers and better correlate fees with the extra effort required to meet the demands of certain kinds of patent requests. This proposal would generate the levels of patent and trademark fee income needed to implement the goals and objectives of the strategic plan.”). A genuine copy of the relevant website pages are attached hereto as Exhibit 1.

levels at a cost-recovery level.⁴ The only evidence in the record on this point is that continuation and multi-claim applications tend to keep the PTO financially afloat, because of the larger fees paid relative to a relatively small amount of examining effort.⁵ This issue and incongruity was raised in a number of public comment letters. In response, the USPTO stated “revenue” was outside the agency’s “view” in the rulemaking (see 72 Fed. Reg. 46757, Comment 39). Thus, the USPTO admitted that it had not and would not develop any contrary evidence that would have undercut the rationale for the Final Rules by demonstrating that there were ample financial resources available to the USPTO for the express purpose of adequately dealing with an extra “burden” imposed on the office by continuation or multiple claim filings.

One of the reasons Tafas believes that the USPTO fought Tafas’ efforts to take limited discovery with such ferocity is that there are so many alternative explanations for any “hindrance of the Office’s ability to examine” that better fit the facts than those posited by the USPTO. The USPTO’s irrational allocation of examination resources (which was discussed in several of the comment letters, for example in Polestar Ex. 9.2, Docket No. 174-3, P000287-292 and has long been an issue raised by the Examiners’ Union) and the USPTO’s poorly-chosen and poorly-implemented efforts at automation are prime examples of reasons the USPTO has failed to deal effectively with its “backlog.” As concerns automation, both the patent community and the Examiners’ Union told the USPTO’s management that certain tasks are better done on paper than by computer (Exhibit 3 of Polestar *amici* brief). Nonetheless, the USPTO’s management didn’t listen, and took the USPTO’s paper search resources away from examiners in 2003 and 2004.

⁴ See 35 U.S.C. § 41(4)(2) (USPTO is required to set fee for all services not specified earlier in § 41 at a cost-recovery level, a residual class that includes RCE’s).

The USPTO has continually argued that continuation applications are inappropriately adding to its backlog as they comprise nothing more than “rework.” (See Testimony of Jon W. Dudas before the subcommittee on Intellectual Property Committee on the Judiciary April 21, 2005 (p. 9), Ex. 26 to Rueda Declaration dated December 20, 2007 (“Rueda Decl.”). Nonetheless, the USPTO cites no evidence to support this assertion in the record other than rehashing Mr. Dudas’ own earlier unsupported assertion, which type of *ipse dixit* statement does not become fact through mere repetition. At one of the public “Town Hall” meetings concerning the Proposed Rules⁶, Commissioner Doll confirmed that the USPTO did not analyze its data to ascertain the underlying cause of “rework” in respect of the USPTO’s backlog:

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.

Likewise, as demonstrated in the *amicus* brief of Polestar Capital and Norseman, the USPTO admitted in its FOIA Reply letters to others that it had done no assessment of whether its assertions as to “rework” had any true factual basis.⁷

⁵ Letter to Office of Management and Budget from David Boundy July 3, 2007, commenting on relative revenues and costs. (A genuine copy of this letter is attached as Exhibit 2).

⁶ Transcript of afternoon session of AIPLA meeting in New York, April 7, 2006. Original CD on request, pursuant to the USPTO’s request that transcripts be submitted, rather than originals. Paper No. 85 (Nov. 26, 2007).

⁷ Polestar *amici* brief dated December, 2007, ¶ 1, Ex. 7, Docket No. 173-8 (USPTO admits is has “no documents” relating to “any factual investigation or analysis of underlying causes for 'rework' applications used in developing the proposed 'Continuations,' 'Examination of Claims,' or 'IDS' rules”).

II. ARGUMENT

A. **The USPTO’S Exercise Of Rulemaking Authority Is Substantive And Does Not Qualify For *Chevron* Deference**

Irrespective of the USPTO’s comments to the contrary and the *amicus* brief of the Law Professors⁸ in Support of the USPTO’s motion for summary judgment,⁹ as stated in the *amicus* brief of William Mitchell College of Law, the elevated deference to agency determinations set forth in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)(“Chevron”) does not apply in the present case.

The USPTO has asserted that the Final Rules are not substantive, but rather are “interpretive rules, or rules of agency practice and procedure.” 72 Fed. Reg. 46830 at col. 3, ¶ 1. From this the USPTO argues that the Final Rules are “exempt from the Administrative Procedure Act’s notice and comment period” under 5 U.S.C. 553(b)(A) “or any other law.” 72 Fed Reg. at 46830, Col. 3, ¶ 1. Along the same lines, the USPTO asserts that the so-called “logical outgrowth” doctrine is inapplicable as to whether the public received adequate notice as to provisions in the Final Rules that were not in the Proposed Rules. (See Def. Mem. at 59).

⁸ It is notable that only three (3) of these professors are registered to practice before the USPTO and only one (1) has more than one year of patent experience in private practice, but apparently little experience in patent prosecution. There is no indication from USPTO records that any of the these three (3) professors ever filed and prosecuted a patent application through to issuance. Consequently, Tafas respectfully submits that their views on patent prosecution and the effect of the Final Rules of the patent prosecution process should be given no or little consideration.

⁹ Based on telephone calls seeking Tafas’s consent for the filing of an *amicus* brief, the Law Professor *amici* effort appears to be spearheaded by Professor Arti K. Rai, who is also a member of the Board of Directors of the Public Patent Foundation, a foundation whose Board members also sit on the boards of at least the Computer & Communications Industry Association, Initiative for Medicines, Access & Knowledge, Software Freedom Law Center, Prescription Access Litigation, Research on Innovation, all of which are named as *amici* on the brief of the Public Patent Foundation in Support of the USPTO.

Of course, it is not surprising that the USPTO would seek to masquerade its Final Rules as non-substantive¹⁰ given that the Federal Circuit and its predecessors have ruled that the USPTO does not have substantive rule making authority. Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1549-1550 (Fed. Cir. 1996)(“Merck”); Eli Lilly & Co. v. Bd of Regents of Univ. of Washington, 334 F.3d 1264, 1269 n. 1 (Fed. Cir. 2003)(“Eli Lilly”)(reaffirming Merck); Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 927 (Fed. Cir. 1991)(“ALDF”); see also 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 us.”); In re Henricksen, 399 F.2d 253 (CCPA 1968)(finding no statutory basis to limit the number of continuation applications); see also Tafas Mem. In Supp. of Motion for Summary Judgment dated December 20, 2007 at pp. 8-10.

While the USPTO (Def. Mem. at 15) and the Law Professor *amici* (at page 3 of their brief) reach for dicta in United States v. Mead Corporation, 533 U.S. 218 (2001) for the proposition that interpretative rules are due Chevron deference, neither concentrates on the actual holding of the court:

We hold that administrative implementation of a particular statutory provision qualifies for Chevron deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of such authority.

Mead, 533 at 218.¹¹

¹⁰ The USPTO admitted that it did not have substantive rule making authority in one of its earlier memoranda. (See Def.’s Mem. In Opposition to Preliminary Injunction dated October 28, 2007 at pp. 20-21).

¹¹ Justice Scalia in his dissent describes the ruling as “the Court collaps[ing] [the Chevron] doctrine, announcing instead a presumption that agency discretion does not exist unless the statute, expressly or impliedly, says so.” *Id.* at 240.

Neither the general grant of procedural rulemaking authority to the USPTO in 35 U.S.C. §2(b)(2), nor any other statutory provision, expressly or impliedly authorizes the USPTO to make rules that “carry the force of law” -- that is provide for substantive or legislative rulemaking authority, with respect to long established continued examination practice or claim practice provided for under the Patent Act.

Thus, Chevron deference cannot apply to the Final Rules if they are adjudged as interpretative or procedural. As noted by Professors R. Carl Moy and Jay Erstling of the William Mitchell College of Law in their *amici* brief,¹² instead of granting Chevron deference to interpretative rules, the Supreme Court has found interpretative rules to generally not warrant Chevron-style deference, but rather only to be “entitled to respect” under its Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) decision to the extent that the interpretations have the “power to persuade.” Christensen v. Harris County, 529 U.S. 576, 587 (2000). The Law Professor *amici* implicitly recognize the lack of deferential treatment in acknowledging that Congress has not given the PTO notice-and-comment rulemaking authority in the area of interpretative/procedural rulings (See, footnote 4 of the Law Professors *amici* brief at p. 5).

More importantly, Section 2(b)(2) of the Patent Act does not empower the USPTO to restrict patent applicants’ statutory rights to file continuation statements and/or multiple claims. Instead, it merely authorizes the USPTO to implement rules -- *not inconsistent with law* -- to facilitate and expedite the processing of patent applications:

¹² Professor Erstling, who received his B.S. and J.D. degrees from Cornell University, was the Director of the Patent Cooperation Treaty (PCT) and Advisor to the Director General of the World Intellectual Property Organization. Professor Moy, who received his B.M.E. from University of Minnesota and his J.D. from George Washington University of Law, was a former Patent Examiner of the USPTO (1978-1982), a clerk for the Daniel M. Friedman of Washington, DC and the former Chair of the Committee on Patent Litigation for the American Bar Association (1993-1995).

§ 2 Powers and Duties

(b) Specific Powers. The Office –

* * *

(2) may establish regulations, *not inconsistent with law*, which

(A) shall govern proceedings in the Office;

(B) shall be made in accordance with Section 553 of Title 5;

(C) shall facilitate and expedite the processing of patent applications...

35 U.S.C. § 2(b)(2)(A)-(C)(Emphasis Added).

Section 2(b)(2) is not an open ended license to the USPTO to re-write the Patent Act to suit its own administrative convenience. Rather, Section 2(b)(2)(A)-(C) merely grants the USPTO *procedural* rule-making authority obviously intended to facilitate the processing of patent applications through the patent office. It cannot reasonably be deemed an open-ended license for the USPTO to engage in rule-making admittedly calculated to restrict the number of continuation applications and/or the filing of multiple claims as the USPTO admits that it is seeking to accomplish:

Unrestricted continued examination filings and multiple applications...., however, are now having such an impact on the Office's ability to examine new applications that it is now appropriate for the Office to clarify the applicant's duty to advance the application to final action by placing **some restrictions** on the filing of multiple continuing applications, requests for continued examination, and other multiple applications to the same invention. See 35 U.S.C. 2(b) (authorizes the Office to establish regulations, not inconsistent with law, which shall govern proceedings in the Office, and shall facilitate and expedite the processing of patent applications). This would permit the Office to apply the patent examining resources currently absorbed by these applications to the examination of new applications and thereby reduce the backlog of unexamined applications.

A.00011 (71 Fed. Reg. 49)(Emphasis Added).

In short, the USPTO is saying that it intends to reduce its backlog by restricting and/or denying patent applicants the ability to make filings (e.g., continuations and multiple claims) expressly contemplated by various provisions of the Patent Act. It is only a small exaggeration to say the USPTO's approach would be akin to the manager of an amusement park seeking to reduce lines for rides by not admitting anyone to the park. Only applying the most extreme bootleg logic could such an approach be characterized as reasonably calculated at "expediting" or "facilitating" a reduction in amusement park lines. The same is true here.

In any event, the USPTO may not do so because the Final Rules abridge and are inconsistent with various provisions of the Patent Act. It is well established that no deference is mandated with respect to rule-making that is contrary to or inconsistent with a statute. Regulations may not serve to amend or to modify a statute or to add something to the statute that is not already there and must always be consistent with the statutes they are promulgated under. See e.g., Formula v. Schweiker, 572 F.Supp. 862, 866 (D.D.C. 1983); Ruley v. Nevada Bd. Of Prison Commissioners, 628 F.Supp. 108, 111 (D. Nev. 1986).

Lacavera v. Dudas, 441 F.3d 1380 (Fed. Cir. 2006) (also cited by the Law Professors)("Lacavera") and Stevens v. Tamai, 366 F.3d 1324 (Fed. Cir. 2004)("Stevens"), relied upon by the USPTO for the proposition that the Federal Circuit has recognized plenary rule making authority having been provided to the USPTO by Congress, are inapplicable and otherwise readily distinguishable.

Lacavera did not address whether the USPTO had the power under Section 2(b)(2) to enact regulations inconsistent with rights afforded to applicants under the Patent Act. Rather, Lacavera dealt with whether the USPTO properly applied the standard for determining

the qualifications as to who was permitted to practice before the USPTO, which included interpretations found in the USPTO's General Requirements Bulletin. The USPTO's rule-making power in this specific area, however, is specifically provided in Section 2(b)(2)(D). Moreover, unlike here, there was no complaint in Lacavera that the USPTO abridged substantive rights afforded to applicants under specific provisions of the Patent Act. In fact, the Patent Act was entirely silent as to whether the USPTO could impose the visa restriction at issue in Lacavera.

Stevens is likewise distinguishable and dealt with a simple procedural question raised during the course of an adjudicatory proceeding as to whether an English translation of a foreign document could be required as part of an interference proceeding. Moreover, unlike here, the Stevens court found it significant that Section 372(b)(3) of the Patent Act gave express authority to the USPTO to require verification of foreign language documents and none of the parties argued otherwise. Id. at 1333. The statement of "plenary authority" at p. 1333 of the Stevens case simply related to the USPTO's rulemaking authority with respect to purely procedural matters in respect of patent interference process. Such is clearly shown by the Federal Circuit's approving citation to Merck with respect to Merck's characterization of USPTO rule making authority. Id.

The USPTO further argues that if the Final Rules are found to be substantive (which they must be, simply because as set forth below, they assign a new burden of proof to a patent applicant – See, Director, Office of Workers Compensation Programs v. Greenwich Collieries, 512 U.S. 267, 271 (1994) which states "the assignment of the burden of proof is a rule of substantive law"), then Chevron deference stands on a much stronger footing as "Congress

has expressly authorized the USPTO to promulgate rules using APA notice and comment procedures” pursuant to 5 U.S.C. §553(b) (Def. Mem. at 20).

As stated in Tafas’ motion for summary judgment, the problem with the USPTO’s argument is that the Federal Circuit has made it clear that the USPTO does not have any substantive rulemaking authority. The Supreme Court has made clear that an agency cannot claim Chevron deference when promulgating a regulation outside of the authority actually granted to them. See, Adams Fruit Co. Inc. v. Barrett, 494 U.S. 638, 649 (1990) (“A precondition to deference under Chevron is a congressional delegation of administrative authority”); see, also, Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988); NLRB v. Food and Commercial Workers, 484 U.S. 112, 123 (1987) (Chevron review of agency interpretations of statutes applies only to regulations “promulgated pursuant to congressional authority”).

Finally, Centigram Communications Corp. v. Lehman, 862 F.Supp. 113 (E.D.V.A. 1994)(“Centigram”), Morganroth v. Quigg, 885 F.2d 843 (Fed Cir. 1989)(“Morganroth”), Dickinson v. Zurko, 527 U.S. 150 (1999)(“Dickinson”), and In re Rubinfeld, 270 F.2d 391 (CCPA 1959)(“Rubinfeld”), all relied upon by the USPTO, are likewise distinguishable and not helpful to the USPTO.¹³

¹³ The holding in the case of In the Application of Don L. Rubinfeld, 270 F.2d 391 (C.C.P.A. 1959) does not imply, as suggested by the USPTO at page 29 of its brief, that the USPTO “certainly can require applicants who file more than five independent claims or more than twenty-five total claims to submit additional information to assist in examination without contravening Section 112.” The Rubinfeld court only dealt with the very narrow question of whether the USPTO’s rule to allow only one (1) claim in a design patent case was valid under then existing statutes pertaining to design patents. The limitation to one (1) claim in design patent applications was upheld solely because the court deemed the design patent statute to limit presentation to only a single inventive concept (Id. at 396) and, therefore, “no useful purpose [that] could be served by the inclusion of more than one claim in a design application or patent.” Id. at 395.

In Centigram, the Court never reached the second part of the Chevron test because the court found that the statute in that case expressly clothed the commissioner with the authority to deal with the exact question at issue through regulation. That is not the case here.

Morganroth did not address whether an exercise of rule-making power was valid and instead simply found, in an adjudicatory setting, that the USPTO's *interpretation* of Section 41 of the Patent Act in the context of dealing with very narrow and technical questions within the USPTO's expertise was reasonable and entitled to some deference. Morganroth is very distinguishable from the instant case, which poses the very different question as to whether the USPTO may utilize rule making to effectively modify and restrict statutory rights provided to applicants under the Patent Act under the guise of "facilitating" and "expediting" patent applications. Dickinson likewise is an adjudicatory case and distinguishable because deference was given to the agency's fact-finding and not rule-making.

B. The USPTO'S Final Rules Are Not Consistent With The Patent Act or Other Law

1. 35 U.S.C. §120

The USPTO asserts that "[n]othing in the text, history, or case law interpreting Section 120 ... deprive[s] the USPTO of authority to make regulations." (Def. Mem. at 20). Again, as first set forth in his preliminary injunction motion, Tafas respectfully submits that there is nothing in Section 2(b)(2) of the Patent Act or otherwise that authorizes the USPTO to engage in substantive rule making limiting the rights and benefits afforded Congress afforded to patent applicants under Section 120. (See Tafas Mem. In Supp. of Motion for Summary Judgment dated December 20, 2007 at pp. 5-8).

As set forth in the *amicus* brief of the Bar Association of the District of Columbia, Federal Circuit Judge Giles S. Rich, in his 1952 commentary as a member of the drafting

committee that promulgated Section 120 of the Patent Act, clearly indicated that Section 120 was intended to provide for unlimited continuations to be filed: “Section 120 ... on careful reading ... [indicates] that the number of generations of the lineage is unlimited.” *Transcript of Address of Giles S. Rich on the Patent Act of 1952*, publication of the New York Patent Law Association (1952). 35 U.S.C. § 154 was amended in 1995 to effectively constrain the unlimited nature of such filings to the number of filings that could be made to a term of 20 years from the filing date of the earliest application from which priority was sought.

The USPTO urges that the cases cited by Plaintiffs are inapplicable because some of them issued before 1952. (Def. Mem. at 22). That is simply not the case as courts have consistently acknowledged that “a limit upon continuation applications is a matter of policy for the Congress.” In re Hogan, 559 F.2d 595, 604 n. 13 (CCPA 1977); Ricoh Co. Ltd. v. Nashua Corp., 185 F.3d 884, 199 WL 88969, *3 (Fed. Cir. 1999)(“[S]ection 120, governing continuation applications, does not contain any time limit on an applicant seeking broadened claims”); In re Henriksen, 399 F.2d 253, 254 (C.C.P.A. 1968) (there is “no statutory basis for fixing an arbitrary limit to the number of prior applications”). Respectfully, the USPTO’s argument that such a reading of Section 120 would conflict with Section 112, 121, and 251 is simply unsupported given that all these statutes existed when Judge Giles issued his commentary (and the Federal Circuit, and its predecessor court, ruled otherwise). Furthermore, the USPTO’s assertions in this regard are contravened by the USPTO’s own long practice since 1952 in not reading such statutes so narrowly as to suggest that all inventions possibly disclosed in an invention must be claimed at the time of the initial filing. The words of the statutes cited by the USPTO simply do not support the interpretation posited by the USPTO.

The USPTO and *amicus* Micron Technology, Inc. (“Micron”) assert that the majority of the three-member panel in In re Bogese II, 303 F.3d 1362 (Fed. Cir. 2002) (“Bogese II”) (Judge Newman, vehemently dissenting that the statutes even provided for the USPTO to have the limited power to regulate extreme cases of prosecution laches), “opined that the USPTO’s power went beyond mere enforcement of prosecution laches.” While both cite to isolated statements made in the Bogese decision to the effect that “[t]he USPTO has inherent authority to govern procedure before the USPTO,” neither demonstrates that the Bogese decision grants the USPTO the power to *ab initio* limit continuation practice.

To the contrary, 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 such an application in a case of *unreasonable* and *extreme* delays 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.

Irrespective of the USPTO’s public policy rhetoric, the courts have consistently held “[T]here is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.” Kingsdown Medical Consultants Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988).

Many continuations are filed simply to expedite issuance of claims, or to overcome rejections which may not have basis. For example, in the case of Moore v. U.S., 194 USPQ 423, 435 (Ct. Cl. 1977), the court found that the filing of six continuations to the same invention not to be unconscionable as the applicant had made good faith efforts to move prosecution forward with amendments, affidavits, new arguments, etc., and in recognition that the route to allowance can be “arduous.”

In all events, the Bogese II court made it clear that the prosecution laches doctrine was limited and reserved for extreme circumstances¹⁴ and implied that the USPTO would not have a similar power to adopt a broad across the board rule applicable to all patent applicants. Bogese II, 303 F.3d at 1368 n. 6.

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 any 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, although it has no statutory authority to do so.¹⁵ As discussed on p. 12 of *amicus* CFPH, LLC, the addition of a factual presumption is substantive rulemaking. See Paralyzed Vets. of Am. v. Secretary of Veterans Affairs, 308 F.3d 1262, 1266 (Fed. Cir. 2002).

¹⁴ Similarly, Symbol Techs, Inc. v. Lemelson Med. Educ. & Research Foundation, 277 F.3d 1365 (Fed. Cir. 2002)(“Symbol II”), relied upon by the USPTO, merely upheld the application of the judicial doctrine of prosecution *laches* in an action between private parties where there were claims of resulting prejudice.

¹⁵ The APA does not permit an administrative agency to change the burden of proof unless explicitly permitted by statute. See, Heckler v. Campbell, 461 U.S. 458, 468 (1983); accord, Director, Office of Workers Compensation Programs v. Greenwich Collieries, 512 U.S. 267, 271 (“the assignment of the burden of proof is a rule of substantive law”).

2. 35 U.S.C. §132

The USPTO asserts that Final Rule 114 is consistent with 35 U.S.C. § 132. More particularly, the USPTO contends that its power to limit an applicant to file one RCE derives from Section 132(b), which “expressly directed the UPSTO to ‘prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.’” The problem with the USPTO’s argument, as set forth in the excellent brief by *amicus* Federation Internationale, is that the statutory language “provide for” in Section 132(b) implies only the power to enact *procedural* rules to provide for and facilitate such filings -- not to prohibit or restrict the filings themselves or the number of filings that may be made.

Furthermore, the American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1) (1000) makes it clear that Section 132(b) was to apply to all applications filed after June 8, 1995 -- not just one application per family. The USPTO itself has acknowledged this in its own prior interpretation of the statute, stating that “an applicant ... is not limited in the number of times” the applicant can file an RCE. (See Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 Fed. Reg. 50,092, 50,095 (Aug. 16, 2000).

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 mandates both a notification and a reexamination of the application without exception:

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or

objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. § 132(a)(Emphasis Added). The Final Rules essentially re-write Section 132(a) by imposing impose conditions precedent on the USPTO's statutory obligation to engage in reexamination upon request. Id. In short, Tafas agrees with *amicus* Mitchell College of Law's argument (pp. 13–20) that first action final reject practice in continuing applications is in itself contrary to existing law.

3. 35 U.S.C. §§ 101, 111, 112, 131 and 151

The USPTO urges the Court to “uphold Final Rules 75 and 265 as a reasonable exercise of the USPTO's Section 2(b)(2) authority.” (Def. Mem. at 27). The USPTO claims that 35 U.S.C. §§ 111, 112, 131, and 151 do not prohibit the USPTO from imposing an absolute limit on the number of claims nor do they preclude the USPTO from requiring an Examination Support Document (ESD) if an artificial threshold number of claims set by the USPTO are exceeded. Again, the USPTO purports to derive its rule making power from the generic language in 35 U.S.C. § 2(b)(2)(A)-(C) authorizing the USPTO to “facilitate and expedite the processing of patent applications.” (Def. Mem. at 29).

The USPTO's arguments are plainly unsupported. As admitted by the USPTO at A07333, the “patent statute and rules of practice **do not limit** the number of claims (independent or dependent) that may be presented in an application.” This is because, as stated in the case of In re Wakefield, 422 F.2d 897, 900 (C.C.P.A. 1970), the courts have consistently held that “[A]n applicant should be allowed to determine the necessary number and scope of his claims ...”

The consistency of this holding has even been acknowledged by the USPTO's own Board of Patent Appeals and Interferences:

As to the issue of 'undue multiplicity,' **it is well established** that an applicant has the choice of deciding as to the number of claims so long as they are consistent with the disclosure and the requisite filing fees are paid.

Ex Parte John E. Maloney et al., 1999 WL 33205694 (Bd. Pat. App. & Interf. 1999) (non-precedential) at *2 .

As explained in Tafas' summary judgment brief, and the *amici* briefs filed by William Mitchell College of Law (pp. 9–12), Elan Pharmaceuticals (pp. 13–17), Intellectual Property Owners (pp. 3–5, 12–14), CFPH, LLC (pp. 18– 20) and others, the Final Rules are contrary to 35 U.S.C. §§ 101, 111, 112, 131, and 151, inter alia, because they impermissibly shift the burden of persuasion of patentability to the applicant. Tafas also asserts that the Final Rules are contrary to such statutes in that certain provisions impermissibly impose presumptions contrary to the statutes. None of Tafas arguments are addressed in the USPTO's own summary judgment brief.

As the Federal Circuit remarked 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, 1445 (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).

4. **35 U.S.C. §§ 2, 41, 112, 121, 122, 200-212 & Patent Cooperation Treaty**

As stated more particularly herein and in Tafas' summary judgment memorandum at pp. 11-20), 35 U.S.C. § 2(b)(2) does not authorize the USPTO to engage in substantive rulemaking to set the conditions of patentability or to modify the Patent Act. Nor is it consistent with Section 2(b)(2) for the USPTO to pass regulations that violate International Treaties. Supporting arguments with respect to the Final Rules violating the Patent Cooperation Treaty may also be found in the *amici* briefs by Federation International (pp. 3-4) and Robert Leikes (pp. 2- 8). Tafas respectfully refers the Court to same.

The USPTO asserts at pages 29-33 of its brief certain arguments said to be raised by Tafas concerning different ways that the Final Rules violate 35 U.S.C. § 41, 112, 121, 122, 200-212. Unfortunately, the USPTO either misapprehends Tafas' arguments and proceeds to make non-responsive rebuttal arguments, or simply mischaracterizes Tafas' positions and proceeds to pen a diversionary artillery barrage.

For example, the USPTO fails to address on pages 31-33 of its brief Tafas' assertion that the USPTO does not have the power to alter statutory definitions, particularly if the change in definition affects fees set by Congress (as specified in 35 U.S.C. §41) as the USPTO has done in changing the definition of "dependent claim" as set forth in 35 U.S.C. § 112.

Further, the USPTO mischaracterizes Tafas's argument that Final Rule 1.78(d)(1)(ii) and (iii) improperly prohibits an applicant from filing a continuation-in-part application seeking priority under 35 U.S.C. §120 through a divisional filed pursuant to 35 U.S.C. §122 without a petition and showing. More particularly, the USPTO seemingly attempts to skirt the argument through obfuscation by going into a diversionary and entirely extraneous diatribe concerning the difference between a divisional application and a continuation-in-part application (implying that Tafas was suggesting that such applications are equivalent). (See Def.

Mem. at 31). The USPTO's argument ends with an entirely unsupported and conclusory statement to the effect that "[t]he law has never allowed an applicant to file a continuation-in-part application off of a divisional application and obtain the protections of 35 U.S.C. §121 [sic - §120]." Def. Mem. at p. 31.

Similarly, the USPTO's brief skirts the issue as to whether the statutory language of 35 U.S.C. §121 permits a divisional application to be filed which is not subject to a restriction requirement, also known in the art as a "voluntary divisional," by lecturing that the phrase "voluntary divisional" is a misnomer, and that such application type should be called a "continuation application" instead. This is irrespective of the USPTO's own acknowledgement and use of the term, and the parallel term of "involuntarily divisional," throughout their own documents. (See, e.g., 72 F.R. 46720, Col. 3; 46731, Col. 3; 46745, Col. 1; 46746, Col. 2; 46746, Col. 3; 46747, Col. 1; 46755, Col. 3; 46771, Col.3; 46785, Col. 2; A00159, A08539, A08614, A00221, A00077, A08776, A08889, A09148, A09271, A09351 all collected at Exhibit 3).

Lastly, the USPTO entirely ignores Dr. Tafas's assertion that the USPTO impermissibly ignored the Congressional policies and objectives of 35 U.S.C. § 200 (the Bayh-Dole Act) by failing to analyze whether any of its rule changes would interfere with the promotion of the use of the patent system to advance the utilization of inventions arising from federally supported research or development. Instead, the USPTO simply makes unsupported assertions of no impact on of federally supported research or development, without pointing to any documents in the administrative record that demonstrate the USPTO considered this issue (e.g., the "Final Rules simply do not speak to these issues.") (See Def. Mem. at 33)

The only issue correctly characterized by the USPTO at pp. 31 -33 of its brief concerning Tafas' position concerning the above referenced statutory provisions is the USPTO's assertion that Tafas alleges the requirement to identify "patentably indistinct claims" in Final Rule 78(f) and that this may force applicants to disclose subject matter that they want to maintain in confidence contrary to 35 U.S.C. §122. (See Def. Mem. at 33). Nonetheless, the USPTO asserts "Final Rule 78(f) does not erode any confidentiality protections owed to applicants" by suggesting that nearly all applications filed in the United States publish within 18 months of the filing date. (See Def. Mem. at 33). The USPTO ignores, however, the fact that many applications filed with the USPTO do NOT publish within 18 months of their filing date due to a request for non-publication, which leads to the problem described in Tafas' motion for summary judgment.

Further grasping for straws, the USPTO also attempts to argue that Tafas has somehow waived raising this clear violation of statute "because it was not raised to the USPTO during the notice and comment period." (Def. Mem. at 33). The USPTO makes this bold statement despite the fact that it has consistently and repeatedly maintained that its rules were simply procedural and, therefore, not subject to notice and comment rule-making. (See 72 Fed. Reg. 46830 – "these rule changes involve interpretative rules, or rules of agency practice and procedure ... exempt from the Administrative Procedure Acts notice and comment requirement"; See also, 71 Fed. Reg. 50 referencing that the Proposed Rules were to "revise the rules of practice"), and therefore that the USPTO was not under the stricture of the APA requiring the USPTO to give any comments it received due consideration before promulgating its rules. 5 U.S.C. § 553(c).

Furthermore, the case upon which the USPTO relies for its waiver proposition, Ohio v. U.S. E.P.A., 997 F.2d 1520 (1993), is simply inapposite. The matter before the Ohio court did not deal with a challenge asserting that a regulation was contrary to statute (something it cannot be under the APA , 35 U.S.C. § 2, and the United States Constitution), but whether a plaintiff had cause to argue against the EPA's reasonable interpretation of a statute (which each party admitted included ambiguous terms) without ever having notified the EPA in proceedings before it of the alternative interpretation later advanced by the plaintiff.

Moreover, nothing in Ohio supports the proposition that aggrieved parties are somehow estopped from subsequently challenging an *ultra vires* agency action in contravention of statutes and the U.S. Constitution unless they affirmatively bring the matter to the agency's attention during the notice and comment period. Moreover, assuming *arguendo* that these rules are strictly procedural as the USPTO contends (which *Tafas* disputes), then in such case the notice and comment period would arguably be superfluous anyway because same is normally not required for procedural or interpretive rules. U.S.C. § 553(b)(3)(A).

C. The Final Rules Are a Result Of Arbitrary And Capricious Rulemaking

The USPTO asserts that it amply satisfies the standard set forth in Motor Vehicle Manufactures Ass'n of the United States, Inc. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29 (1963) in respect of examining relevant data and articulating a satisfactory explanation for its action including a rational connection between the facts found and the choice made. *Tafas* disagrees.

Tafas respectfully points the Court to the brief of *amici* Polestar Capital and Norseman Group, adopting the arguments therein. As noted in such brief, and as further expounded upon in *Tafas*' summary judgment brief, the USPTO declined to make essential information available to the public during its rulemaking procedure; failed to disclose

information about its computer models by which the USPTO purported to analyze its data; failed to consider important aspects of its backlog; failed to properly consider the effect of its rules on its own revenues and the cost burden on the public, and relied on factors which Congress did not intend. The Polestar/Norseman brief sets forth at pages 6–7 numerous documents found in the administrative record which go to data and assumptions used during the rulemaking process which were not made available to the public, as they should have been, during the rulemaking process.

Item No.	Date	Type	Submitting Party	USPTO Participants	Produced by USPTO in the Administrative Record	Record attached herein as	Referred to previously in this case	
							Docket No.	Exhibit No.
<u>1</u>	May 16, 2007	meeting	Biotechnology Industry Organization	J. Dudas, M. Peterlin, J. Doll, J. Love, R. Bahr, J. Toupin	A08503-04	Exhibit 4		
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/meetings/606.html							
<u>2</u>	June 14, 2007	meeting	Intermolecular Inc.; Fallbrook Technologies Inc.	J. McDowell, R. Bahr, W. Jenks, J. Love	NO	Exhibit 5		
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/meetings/617.html							
<u>3</u>	June 15, 2007	meeting	Cantor Fitzgerald, Glaxo Smith Kline	J. McDowell, J. Love	NO	Exhibit 6	173	9
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/meetings/619.html							
<u>4</u>	June 25, 2007	meeting	PhRMA	J. Love, R. Bahr	NO	Exhibit 7		
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/meetings/626.html							
<u>5</u>	June 25, 2007	meeting	Nano Business Alliance	John Love, Robert Bahr	NO	Exhibit 8		
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/meetings/624.html							
<u>6</u>	May 11, 2007	comment	Cecil D. Quillen, Jr.	N/A	NO	Exhibit 9		
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/comments/462.html							
<u>7</u>	May 21, 2007	comment	Marcia S. Wagner	N/A	NO	Exhibit 10		
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/comments/459.html							
<u>8</u>	June 21, 2007	comment	Eduardo E. Drake	N/A	NO	Exhibit 11		
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/comments/463.html							
<u>9</u>	June 29, 2007	comment	Ron D. Katznelson	N/A	NO	Exhibit 12	231	1
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/comments/460.html							
<u>10</u>	July 3, 2007	comment	David E. Boundy	N/A	A08433-42; A08506-15	Exhibit 2	173	19
	OMB Link: http://www.whitehouse.gov/omb/oir/0651/comments/461.html							

Table 1 List of meetings and comments as recorded by OMB in connection with USPTO's New Rules.

In a similar line, Table 1 shows ten (10) items documenting meetings and comments compiled by the Office of Management and Budget (“OMB”) in connection with the government’s review of its New Rules. Of those, records for only two items (1 and 10) have been produced by the USPTO in the Administrative record, as the fourth column from the right shows. Eight (8) other items should have been produced in the administrative record but were not. There can be no doubt that the information conveyed to the USPTO and OMB in these comments and meetings was relevant to the Final Rules. Except for the fact that some of the omitted material contained information unfavorable to the USPTO, there appears to be no reason or basis for distinguishing between the items that were included and the 8 items that were omitted from the produced administrative record. Among other items not listed, as the two rightmost columns of Table 1 show, the USPTO had been specifically alerted to missing Items 3 and 9 by the *amici’s* summary judgment briefs, which discussed the significance of these items and their omission from the record.¹⁶

The Polestar *amicus* brief also discusses specific FOIA requests pertaining to the assumptions, methodology, and analysis used by the USPTO in promulgating its proposed rules (p. 9) made by the companies, in response to which the USPTO sent only conclusory numbers. Further, Polestar/Norseman’s FOIA requests seeking documents related to analyses and estimates of costs that would be imposed by the Proposed Rules on applicants and businesses

¹⁶ Item 3 in the table is discussed in: Brief of *Amicus Curiae* Polestar Capital and Norseman Group in support of plaintiffs, Dkt. No. 173, at 14, (Identifying Exhibit 6, one of the omitted communications, as a presentation made to OMB and senior USPTO officials, flagged a number of breaches of procedural rulemaking law and offering alternatives to the New Rules); Item 9 in the table is discussed in: Brief of *Amicus Curiae* by Ron D. Katznelson in support of plaintiffs, Dkt. No. 231, at 9, (“OMB contemporaneously published these comments and the USPTO had an obligation to consider them but omitted them from the Administrative Record”. Referring to Appendix C of its Exhibit 1 in footnotes 22-23).

(p. 12) resulted in no documents being provided. The Polestar/Norseman brief further includes a declaration of a Harvard-educated professional economist who worked for nearly a decade at the Office and Management and Budget to the effect that the USPTO “withheld form OMB information crucial for estimating, within even an order of magnitude, the likely costs” of the rules. All of the above support a finding that the USPTO’s rulemaking was arbitrary and capricious.

The PTO’s brief pointedly ignores the concerns that would be required to make its rules “fair” in all situations, the paperwork costs to be borne by applicants, and the value of patent protection that the PTO proposes to revoke. Exhibit 13 hereto is a letter from Dr. Richard Belzer to OMB’s Office of Information and Regulatory Affairs, that estimates the total burdens on the private sector that would be imposed by the Final Rules that the USPTO has proposed. Dr. Belzer notes numerous public burdens that were not included in the USPTO estimates and estimates these items at about \$ 10 billion in annual burden. (Belzer estimates, Exhibit 13, pages 83-90.) The USPTO cannot assert that the rules are “reasonable” when it omitted burdens of this magnitude. Failure to “consider an important aspect of the problem” is arbitrary and capricious. State Farm, 463 U.S. at 43.

Of the rules at issue in this litigation, Dr. Belzer estimates the total burdens are:

5/25 and ESD rule	\$10 to \$22 Billion
Continuations Rule	\$2.5 Billion
Rule 78(f) “Patentably Distinct Claims”	\$4.4 Billion
Total for these rules	\$17 to \$27 Billion

As a comparison of scale, the total paperwork burden for the entire Department of Commerce is \$1.6 billion, and the total budget for the entire Patent and Trademark Office is just under \$2 billion. In other words, the PTO proposes to multiply the total cost of the patent system, and the total private sector paperwork burden of the Department of Commerce, each by a

factor of ten. Dr. Belzer's estimates are based on investigation and consensus estimates of a number of patent attorneys who have actual hands-on experience preparing analogous documents. In contrast, the USPTO's "10,000 page" record discloses no "substantial evidence" underlying the USPTO's estimates; the USPTO apparently failed to make any inquiry of any person with any basis to know what is required to prepare a document for a public patent file with the appropriate level of care (RegFlex Certification, Polestar Ex. 11, Docket No. 174-9 at page A08287; (RFA Study "discussions with USPTO staff," not with experienced attorneys -- A08249-50 (Exhibit 15).

The USPTO's public representations often do not match its internal numbers. For example, in internal documents, the USPTO acknowledged that the "10 representative claims" rule would have affected 82% of applications (Exhibit 16, A04552). Yet, in contrast, in its statements to the public and the rest of the executive branch, the USPTO represented that only 1.2% of applications would require "additional effort" by the applicant. 71 Fed. Reg. 62, col. 3. Its reticence to take into account the costs that its rules is shown in its response to Comment 34 to the Final Rules, a comment that includes several estimates for costs, including prophylactic costs that applicants must bear to avoid running into the rules. The USPTO's response merely repeats the provisions of the rule, and notes that it affects "only 2.7 percent of applications," but evades estimating the costs that would fall on those 2.7%, as well as avoids estimating the costs of the prophylactic measures that were the subject of the comment that would fall on the vast majority of applicants. 72 Fed. Reg. at 46754-55.

The PTO's failure to answer well-founded issues raised in the Comments, failure to investigate to develop reliable and substantial evidence; and. failure to follow its own Information Quality regulations, shows that the rules are arbitrary and capricious. Morton v.

Ruiz, 415 U.S. 199, 235 (1974) (invalidating a rule where agency had violated its own rulemaking procedures: “it is incumbent upon agencies to follow their own procedures.”); Mistick PBT v. Chao, 440 F.3d 503, 512 (D.C. Cir. 2006) (“Unless an agency answers objections that on their face appear legitimate, its decision can hardly be said to be reasoned.”); Ass'n of Data Processing Serv. Orgs. v. Bd. of Governors, 745 F.2d 677, 683-86 (D.C.Cir.1984) (arbitrary and capricious standard incorporates substantial evidence test); Belzer Dec., Docket No. 178-2 at ¶¶ 55-58.

D. The Final Rules Are Not A Logical Outgrowth Of The Proposed Rules

Disagreeing with USPTO’s assertion that the Final Rules “are clearly ‘procedural’ and not ‘substantive’ under the relevant APA jurisprudence” (Def. Mem. at 59), Tafas argues that there was no logical progression from the Proposed Rules to the Final Rules.

The USPTO asserts that even if the rules are substantive, and notice and comment provisions apply, that the notice was sufficient. However, Tafas points to many substantive changes in the Final Rules from the Proposed Rules at page 30 of his summary judgment brief. As set forth in Chocolate Mfrs. Ass’n of the United States v. Block, 755 F.2d 1098, 1105 (4th Cir. 1985), the question is not that posed by the USPTO, that is, whether “the final rule in the instant case was the ‘outgrowth’ of the original rule proposed by the agency,” but rather “whether the change[s]” noted in the new rules “was in character with the original scheme and whether it was a ‘logical’ outgrowth’ of the rule proposed.” Tafas notes the resounding cry of the *amici* in this case to the effect that they were sandbagged by the USPTO’s the Final Rules as resounding evidence that the Final Rules are not a “logical” and foreseeable outgrowth of the Proposed Rules. In particular, Tafas notes the Polestar/Norseman amicus brief which, as he does, vehemently urges that the amendment to Rule 104 was not a non-logical outgrowth. (See Polestar Brief at p. 20). Tafas also notes the change in the proposed rule from removing first

action final rejection to maintaining the same, as a substantial change from the proposed rules (effectively removing in most cases another swipe at the ball during the prosecution of an application). Otherwise, Tafas notes that the USPTO brief clearly either misconstrues, or mischaracterizes, Tafas's delineation of differences between the proposed rules, making it impracticable to respond to their arguments in this reply.

E. The Final Rules Are Retroactive And Result In An Unconstitutional Taking Under the Fifth Amendment and Due Process Clause of the Constitution

The USPTO argues that the Final Rules are “simply not retroactive” (Def. Mem. at 39) because they do not entail “vested rights” (*Id.* at 40–45). On the other hand, Tafas asserts, as set forth in his original preliminary injunction motion, and as set forth in the *amici* brief of AIPLA (pp. 1–19), IPO (pp. 10–12), Croplife America (pp. 10–12), Washington Legal Foundation (pp. 6–19) and Elan (pp. 15–17), the Final Rules clearly have a retroactive affect and comprise retroactive rulemaking. (*See* Tafas Mem. In Support of Summary Judgment Motion at pp. 24-32).

As set forth in Landgraf v. USI film Prods., 511 U.S. 244, 269 (1994), retroactivity is seen when the regulation or statute (1) “would impair rights a party possessed when he acted” or (2) “impose new duties with respect to transactions already completed.” These rights need not be completely vested as suggested by the USPTO. The USPTO recites to cases that precede the passage 35 U.S.C. §154(d) in 1999 which made it very clear that patent applications themselves vest rights in applicants. 35 U.S.C. §154(d) created a right to recover reasonable royalties for infringement that occurred in the period between publication of a patent application and issuance as a patent subject to certain conditions. Furthermore, as argued in Dr. Tafas's brief on summary judgment and in his preliminary injunction memorandum filed within

one day of the issuance of the Final Rules, rights in patent applications also derive from the *quid pro quo* involved in a patent applicant foregoing trade secret protection for patent protection.

Tafas has (first tendering the argument in his motion for preliminary injunction filed one day after the publication of the Final Rules), and continues to urge an unconstitutional taking under both the Fifth amendment and the Due Process Clause of the Constitution.

The cases cited by the USPTO are in apropos for the positions asserted. In particular, the USPTO relies heavily on the case of Penn. Central Trans. Co. v. City of New York, 438 U.S. 104, 124 (1978) to argue that the Final Rules do not effect an unconstitutional taking. As set forth, however, in the Croplife America *amicus* brief at pp. 12–13, the USPTO misstates and misapplies Penn Central for regulatory takings. Further, the significant economic impact test of Penn Central alone would be met given the uncontradicted evidence of millions of dollars worth of research and development work which will be lost if the Final Rules go into effect. Finally, as urged by *amicus* Croplife America, the USPTO's failure to identify the taking implications of the Final Rules as required by Executive Order 12,630 is arbitrary and capricious in itself.

F. The USPTO Has Violated Article I, Section 8 Of The U.S. Constitution In The Promulgation Of The Final Rules

Article I, Section 8 of the U.S. Constitution grants Congress **NOT** the executive branch the power to enact substantive rules of patent law. The USPTO entirely avoids dealing with separation of powers issue raised by Dr. Tafas in his summary judgment motion (and first raised in his motion for preliminary injunction) on which it knows it stands on extremely weak ground. Instead, the USPTO concentrates only on the ancillary question raised by Tafas of whether the USPTO took into account the mandate of the patent clause in its rulemaking.

The USPTO maintains it need not take into account the Patent Clause in promulgating its rules, and even if it did, that it need only a rationale basis for believing its rules promote the progress of science and the useful arts (Def. Mem. at 50). Irrespective of the USPTO's misquoting of case law, the Supreme Court in the case of Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 6 (1966) emphatically stated that the patent system "by constitutional command **must** 'promote the progress of [the] useful arts.'" The Patent Clause is a substantive limit on the power granted to Congress and it imposes the same constitutional duty on the USPTO in areas of authority delegated to it. See, e.g. Figueroa v. United States, 57 Fed. C. 488, 498-99 (2003); A.F. Stoddard & Co. LTD v. Dann, 564 F.2d 556, 564 (D.C. Cir. 1977) (looking at whether USPTO actions "frustrate[d] the constitutional objective" under the patent clause).

Tafas stands on his position that the ridding itself of a self-induced backlog is not rationally related to whether the rules promote the progress of science and the useful art.¹⁷ Further, he asserts once more that the administrative record is simply devoid of any meaningful consideration or debate of the impact of the Final Rules on the progress of science and the useful arts. The USPTO cannot fix this reality with *post hoc* explanations not found in the administrative record.

G. The Final Rules are Invalid in Not Providing Sufficient Notice to Applicants of How to Comply With An ESD

Dr. Tafas' arguments made in his summary judgment motion with respect to the vagueness problem with the Final Rules directed to the ESD requirement are supported by *amicus* Monsanto Company (pp. 11–12) and Pharma (pp. 15–18), in that both agree that the ESD is impractical and unreasonable, and that its requirements are so vague as not to make it a

¹⁷ If it were, the USPTO could just take a ten year vacation after this case, come back, and change its rules again to rid itself of its decade long backlog without affecting the promotion of sciences and the useful arts.

meaningful option. Whether or not a constitutional void-for-vagueness challenge is appropriate with respect to such regulations,¹⁸ Tafas asserts that the degree of vagueness of the ESD requirements to provide ample evidence of the arbitrary and capricious nature of the Final Rules. As set forth in his declaration attached to his summary judgment motion, even search companies familiar with the Office's accelerated examination procedure were unwilling to certify to him that their search was ESD compliant as they could not make heads-or-tails of what was required. (See Tafas Declaration).

H. The Final Rules Were Promulgated In Violation Of The Regulatory Flexibility Act

At pp. 64–70 of its summary judgment brief, the USPTO asserts that it complied with the Regulatory Flexibility Act in certifying that the Final Rules will not have a significant economic impact on a substantial number of small entities. The USPTO relies entirely on its RFA and, inappropriately, on unsupported statements made its Federal Register notice indicating that it fully considered the economic impact of the Final Rules. The problem is that the RFA analysis, as shown in Tafas's summary judgment brief, is wholly inadequate, being both statistically flawed, and based upon unreasonable, arbitrary and capricious assumptions.

In further support of his argument that the USPTO failed in its obligations under the RFA, Tafas points not only to the declaration of his economic expert, Dr. Robert Fenili, but also to the *amicus* brief of Dr. Ron D. Katznelson, who provides an excellent review of the numerous mistakes and missteps that the USPTO took in preparing its certification of “no significant economic impact” on small entities. Dr. Katznelson concurs with Tafas's expert, that the “RFA Study grossly understated the number of small entities affected by the Claim Limit

¹⁸ Tafas agrees with GSK that it is appropriate.

Rule ... by asserting that only 1% would be impacted by this rule rather than 24% to 30% as plainly evident from the record.” (Katznelson Brief at 4).

Dr. Katznelson agrees that the information used in the USPTO’s certification was misleading, incomplete, erroneous and, that the USPTO’s economic impact analysis was entirely flawed. Dr. Katznelson presents copious data in a paper written by him at Appendix E to his brief indicating the RFA study grossly understated the number of small entities affected by the claim limit rule; failed to identify fundamental factors that govern the costs of preparing the ESD (as to this point, see also, the *amicus* brief of the Bar Association of the District of Columbia at 15, and the *amicus* brief of AIPLA¹⁹ at pp. 11–12); inappropriately annualized ESD costs over 20 years (he argues that such analysis assumes that the average small entity files one patent application every 20 years, rather than the true average of 1.2 applications per year – (See page 5 of his brief); impermissibly ignored the economic burdens of rebutting the presumption of patentably indistinct claims (he notes that the USPTO assumed the cost for such burden to be 0, while in fact his estimates show an average cost per small entity application to be in excess of \$4,200 – see page 5 of his brief); and, failed to analyze or consider other important aspects of the problem. Further, Dr. Katznelson carefully demonstrates that the USPTO’s assertion of equivalence between the 5/25 claim limit and the 15/75 claim limit lacked any support. Tafas urges the Court to review in particular Appendix E of his brief.

Tafas further points to Exhibit C to the Katznelson *amicus* brief wherein there is found a copy of a letter Dr. Katznelson sent to the Office of Management of Budget (“OMB”) in June 2007, in which he urged that the USPTO failed to provide information to the public to

¹⁹ The AIPLA is the purveyor of the information upon which the RFA relies for its ESD cost estimates. Even the AIPLA indicates that the number relied upon by the USPTO for its

determine the economic effect of its proposed rules, and in which he provided copious data to indicate that the effect of the proposed rules were economically huge.

Likewise, Tafas points to the brief of amici Polestar/Norseman at pp. 16-17, and incorporates by reference the appended declaration of Dr. Richard Belzer, a Harvard-educated economist with twenty years of experience in regulatory analysis, at Exhibit 21 to such brief. Based on his substantial experience working at the OMB, and his review of the pertinent documents including the ICF International certification analysis, Dr. Belzer states in such declaration (No. 54, page 21):

Based on two decades of experience performing and reviewing regulatory analysis, including ten years as an OMB economist with the specific duties of performing Executive Order 12,866²⁰ and its predecessor ... I have a *very high level of confidence* that the following inferences with respect to impacts on small entities are true: (a) PTO knew or should have known that any certification that the Final Continuations and Claims Limits Rule would not have a significant effect on a substantial number of small entities would be analytically invalid and unreliable; (b) PTO determined to certify the absence of substantial impacts on a significant number of small entities prior to commissioning ICF International to prepare the study ... upon which the certification depends; and (c) PTO knew or should have known that **its characterization of impacts on small entities** contained in its ICR submissions [] **were nonsensical.**” (bolding added for emphasis)

Taking at face value PTO’s estimate of *paperwork burden* that the public will face with respect to the Final Rules *alone*, Dr. Belzer asserts that it was almost certain that the Final Rule would require a Regulatory Impact Analysis (No. 47, page 18):

Taking at face value PTO’s estimate that *paperwork burden alone* exceeds \$80 million per year in costs ... the Final Continuations and

calculation is inappropriate, as the “cost for a validity/invalidity opinion” of \$15,241 is “more closely aligned with reality” with respect to the ESD expense. AIPLA Mem., p. 12.

²⁰ Dr. Belzer explains such Executive Order fully at pages 5–7 of his declaration. Such order requires and agency to “access both the costs and benefits of the intended regulation ...” §1(b)(6) using the “best reasonably obtainable scientific, technical, economic and other information concerning the need for, and consequences of, the intended regulation,” §1(b)(7).

Claims Limit Rule almost certainly met the objective, quantitative test for being “economically significant” regulatory actions under Executive Order 12,866 §3(f)(1) ... PTO acknowledged the \$80+ burden estimate three months after OMB had concluded its [ICR] review ...”

Dr. Belzer further explains that the certifications of “no substantial economic impact” on small entities proffered by the USPTO did not take into account:

(a) an assessment of reasonably anticipated social benefits accruing from the proposed regulation ... (b) an assessment of reasonably anticipated societal costs imposed by the proposed regulations ... or (c) assessment, including the underlying analysis, of costs and benefits of potential effective and reasonably feasible alternatives to the proposed regulations... (No. 49, page 19)

Dr. Belzer also points out that USPTO’s Regulatory Flexibility Act Analysis was intrinsically flawed in basing its entire analysis on a unsupported “beliefs” of USPTO staff (No. 61, page 24) that a *de facto* limitation of an application to no more than 5 independent and/or 25 total claims and two possible continuation applications was equivalent to a single application of 15 independent claims and/or 75 total claims:

The most crucial elements of PTO’s Reg Flex Analysis rest solely on the “beliefs” of PTO staff. For example, on p. 12 it is stated: “[A]s described in the Federal Register notice accompanying the final rule, USPTO staff believe that once the final rule is adopted, applicant with more than five but less than 15 independent claims, or more than 25 but less than 75 total claims, will choose to prosecute their application in a manner that does not trigger the claims requirements. They will be able to do this under the final rule by submitting an initial application containing up to five independent claims and up to 25 total claims, and then adding a similar number of claims in each of two continuation applications ... as permitted without a petition.” This ‘belief’ is a ‘representation[] of knowledge such as facts or data’ and thus is covered by the Information Quality Act, and OMB’s and PTO’s Guidelines. As a practical matter, PTO’s ‘belief’ assumes away the very analytic question that Reg Flex Analysis is by law supposed to address. By relying on this ‘belief,’ the Reg Flex Analysis *logically requires* that the claims components of the Final Continuation and Claims Limits Rule will not have ‘significant impacts on a substantial number of small entities.

Dr. Belzer found it: “significant that ICF International declined to take responsibility for, or attempt to analytically support, PTO’s ‘belief.’” He notes several conditions that must hold for such a belief (that is, a limitation of a applications to five independent and 25 total claims²¹ plus two continuations is economically equivalent a single application having 15 independent claims and 75 total claims) including:

[T]he shorter patent terms for the first and second continuations must entail no reduction in economic present value, ... later patent grant date for the first and second continuations must entail no reduction in economic present value, ... Patent Law and PTP procedures must be applied consistently both within and across PTO Examiners such that neither the identity of the Examiner nor the timing of a claim affects its patentability ... transaction costs must be the same; and [] at the date of original application, applicants must be clairvoyant about (i) which attributes of their inventions are patentable, (ii) the full domain of relevant prior art, and (iii) future market conditions during the life of the prospective patent.

(No. 61, page 24).

I. The USPTO’s Assertions of Continuation Practice Abuse Is Not Supported By The Evidence

The USPTO asserts that its Final Rules limiting continuation applications and claims are aimed at “putting an end to *dilatory conduct*” of applicants filing multiple continuations.²² It further asserts that it promulgated the New Rules to “curb repetitive or otherwise vexatious filings”, and “*excess* filings.” In its brief, the USPTO urges the Court to see its Final Rules as nothing different from the rules adopted by judicial councils of the federal circuit proscribing the filings of “vexatious, repetitive, harassing, or frivolous complaints” or filings that “abuse the complaint procedure”.²³ In justifying the Final Rules, *all amici* supporting

²¹ Dr. Belzer’s declaration at No. 62, page 25, incorrectly refers to “25 dependent claims” and “75 dependent claims” but it is clear from context that this is an inadvertent repeated error.

²² See Defs’ Opp. to Pls.’ Mot. TRO and Prelim. Inj., Dkt. No. 46 in 1:07cv1008, at 23.

²³ See Defs’ Brief, at 19.

USPTO's position in this case join the allegations that the continuation practice is being abused.²⁴ The USPTO all but ascribes rampant abuse of the continuation process by applicants as being the cause for the historic growth in continuation applications:

“Relying only on a case-by-case approach *to address the most egregious cases of abuse would not be sufficient when continued examination filings* (other than divisional applications) *have grown* from less than twelve percent of total filings in 1980 to over twenty-nine percent of total filings in fiscal year 2006”.²⁵
(Emphasis added)

Irrespective of such statements, the USPTO, and its supporting *amici* do not point to a single document in the administrative record that supports such statements nor, for that matter, do they point to any real evidence outside of the record for such statements. In fact, nowhere in the administrative record, or in any submission by the abovementioned *amici*, can one find any evidence or an identification of applicants' abuse of the continuation process. The mere observation that there exists a historical trend for a relative increase in the number of continuation applications is *not* evidence of abuse. The mere observation that patents issued from continuations have longer pendencies does *not* prove that the delay is due to applicants' abuse.

Failing to provide any evidence of abuse, the USPTO, and the *Amici* supporting it, cite to an article by Lemley & Moore²⁶ (“Lemley article”) as an authority showing such abuse.

²⁴ See Brief of *Amici* Public Patent Foundation et al., Dkt. No. 228 in 1:07cv846, at 9-13 (“The Final Rules Will Enable The USPTO To Curtail Abusive Behavior By Exploitative Patent Applicants”); Brief of *Amici* Micron Technology, Dkt. No. 229 in 1:07cv846, at 5 (“Substantial Abuse of the System Justifies the Final Rules”); Brief of *Amici* Professors, Dkt. No. 232 in 1:07cv846, at 13, 15 (“The PTO Has Shown Satisfactory Reasons for Limiting the Abuse of Continuation Practice.” “[The PTO is] trying to impose some limits on abuse of the continuation process.”)

²⁵ New Rules, 46813, Col. 2.

²⁶ M.A. Lemley and K.A. Moore, Ending Abuse Of Patent Continuations, Boston University Law Review, 84, p. 63-123, (2004).

The fact is, however, that the Lemley article has shown nothing of the kind. The authors in this paper merely *allege* that the continuation process is abused without providing any evidence. Dr. Katznelson in his *amicus* brief clearly demonstrates that allegations made in the Lemley article are baseless and that the authors conclusions that very long prosecution delays were primarily due to the continuation practice were erroneous. Dr. Katznelson's analysis clearly shows that the population of applications with very long pendencies was in fact dominated by applications subject to national security secrecy orders, delaying patent issuances.²⁷ Dr. Katznelson's analysis is in line with numerous other authors that have found fault with the Lemley article. See, e.g., Patrick Doody, "The Patent is Not Broken," 18 INTELLECTUAL PROPERTY & TECHNOLOGY LAW JOURNAL 10 (December 2006) (Exhibit 17) which also presents data that refutes the allegations of continuation abuse in the Lemley article.²⁸

To the extent that abuse of the continuation process is a concern, this court should take judicial notice of the fact that the USPTO already has existing rules directed precisely at limiting abuses of the types it purports to address by the New Rules. In a language very similar to that cited by the USPTO from the rules adopted by the judicial councils of the federal circuits, USPTO's *existing* rules under 37 C.F.R. § 10.18 provide the following:

²⁷ For a detailed critique of the Lemley & Moore article, *see* Section 4.4.3 of: R.D. Katznelson, Patent Continuations, Product Lifecycle Contraction and the Patent Scope Erosion – A New Insight Into Patenting Trends, *Southern California Law Associations Intellectual Property Spring Seminar*, Laguna Niguel, CA, (June 8 - 10, 2007), available at <http://ssrn.com/abstract=1001508>. (Exhibit 14)

²⁸ Interestingly, the Lemley article relies in part on a paper by Quillen *et al.*, 11 Fed. Cir. B.J. 1 (2001) which recites as fact a 85- 97% patenting rate of applications. As pointed out by the Katznelson and Doody papers, Mr. Quillen, who is member of the board of USPTO amicus brief filer Public Patent Foundation, is entirely incorrect in this regard. Regardless of the actual facts, the tight knit and relatively small group of people behind the Public Patent Foundation, the Computer & Communications Industry Association, Initiative for Medicines, Access & Knowledge, Software Freedom Law Center, Prescription Access Litigation, Research on

“By presenting to the Office (whether by signing, filing, submitting, or later advocating) any paper, the party presenting such paper ... is certifying that-- ... [t]he paper is not being presented for any *improper purpose*, such as to *harass* someone or to *cause unnecessary delay or needless increase in the cost of prosecution before the Office ...*”²⁹ (Emphasis added).

Violations of this provision or the submission of a false declaration are subject to sanctions. In the case of patent continuation application filings, these sanctions include, but are not limited to, terminating the proceedings altogether,³⁰ resulting in forfeiture of any patent rights. One would expect that if the allegations of abuse among the growing number of continuations filed in the last decade had any factual support, actions under § 10.18 would have been taken against applicants of continuations who abuse the system. However, USPTO’s records indicate that since the time these records are available (1996), *not even a single case or proceeding* was ever brought by the USPTO under §10.18 against any party.³¹ According to USPTO data, 784,000 continuations/RCEs and CIPs were filed during FY 1996 – FY 2006.³² The fact that of these continuation applications, not even a single filing was held as abusive, speaks volumes as to the veracity of continuation abuse allegations. Thus, USPTO’s assertions that addressing on a case by case basis “egregious cases of abuse *would not be sufficient* when continued examination filings have grown ... to over twenty-nine percent of total filings in fiscal year 2006” are simply

Innovation have not been deterred in promulgating to the public at large their idea of a broken patent system.

²⁹ 37 C.F.R. § 10.18(b)(2), § 10.18(b)(2)(i).

³⁰ 37 C.F.R. § 10.18(c).

³¹ USPTO, Disciplinary Final Decisions of the Office of Enrollment and Discipline (OED), <http://www.uspto.gov/web/offices/com/sol/foia/oed/disc/disc.htm>, As of December 20, 2007, *none* of the records available (decisions against named or anonymous parties since 1996) indicate action under §10.18.

³² See A05062, (Exhibit 18) adding the number of continuations, CPAs, Rule 129, RCE and CIP applications.

nonsensical given that not even a single case of abuse was identified or addressed by the USPTO.

There is no reasonable basis for overbroad rules to address "abuse" when there is no evidence of its existence. Therefore, USPTO's and its *amici*'s assertion that the New Rules are "reasonable"³³ when the USPTO has made no effort to identify whether a problem exists, or to ascertain and establish its magnitude, must be rejected.

III. 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.

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³³ Brief of *Amici* Professors, Dkt. No. 232 in 1:07cv846, at 11-13.

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