United States Court of Appeals

for the

Federal Circuit

Appeal No. 08-1352

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

– and –

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline), SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

– v. –

JON DUDAS, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent & Trademark Office, and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA IN CONSOLIDATED CASE NOS. 1:07-CV-846 AND 1:07-CV-1008, SENIOR JUDGE JAMES C. CACHERIS

BRIEF FOR PLAINTIFF-APPELLEE TRIANTAFYLLOS TAFAS

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September 24, 2008

Form 6. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TAFAS v. DUDAS

No. 2008-1352

Certificate of Interest

Counsel for the Plaintiff-Appellee,
Triantafyllos Tafas certifies the following (use "None" if applicable; use extra sheets if necessary):

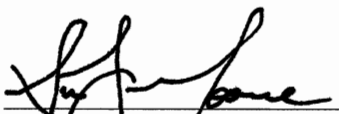
1. The full name of every party or amicus represented by me is:
Triantafyllos Tafas.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:
The parties listed above are the real parties in interest.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:
None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:
Steven J. Moore, James E. Nealon, Kelley Drye Warren & LLP, 400 Atlantic Street, Stamford, CT 06901

September 24, 2008
Date



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MISCELLANEOUS

Plaintiff-Appellee Dr. Triantafyllos Tafas ("Tafas") replies to the brief of Defendants-Appellants Jon Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent & Trademark Office, and the United States Patent and Trademark Office (collectively, "USPTO").

STATEMENT OF RELATED CASES

Pursuant to Rules 28 and 47.5 of the Rules of this Court, counsel to Plaintiff-Appellee Tafas states as follows:

(1) There is no other appeal in or from the same civil action in the lower court that was previously before this or any other appellate court.

(2) Counsel is not aware of any other case pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

JURISDICTIONAL STATEMENT

Tafas agrees with the USPTO's Jurisdictional Statement (USPTO Br. 2), except to the extent that it implies that Tafas only challenged the USPTO's Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,715, 46,716-843 (Aug. 21, 2007) (to be codified at 37 C.F.R. Pt. 1)(the "Final Rules") under the Administrative Procedure Act (the "APA"), 5 U.S.C. § 701 *et seq.* and the Patent Act, 35 U.S.C. § 1 *et seq.* Tafas also

challenged the validity of the Final Rules under the U.S. Constitution, the judicial review provisions of the Regulatory Flexibility Act (5 U.S.C. § 611), international treaties (the Patent Cooperation Treaty and the Paris Convention) (the "Treaty Claims"), and the Bayh-Dole Act (35 U.S.C. §§ 200-212), which the Federal Circuit has held is not part of the Patent Act, Wisconsin Alumni Research Found. v. Xenon Pharms., Inc., 252 Fed. Appx. 319, 320 (Fed. Cir. Oct. 24, 2007), which were not adjudicated by the district court below. (JA. 10-11.)[1]

STATEMENT OF THE ISSUES

Tafas agrees with the USPTO's "Statement of Issues" 1 - 3, except Tafas asserts that:

Issue 1 should be limited to the question of whether the District Court properly found that the USPTO lacks authority under 35 U.S.C. § 2(b)(2) to promulgate "substantive" rules.

Issue 2 should be limited to the question of whether the District Court properly found that the USPTO's Final Rules were "substantive" in nature, *inter alia*, because they abrogate statutory rights Congress granted to patent applicants under Sections 102, 103, 112, 120, 131 and 132 of the Patent Act. Tafas also notes that the District Court did not reach the issue of whether portions of the Final Rules

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[1] References to the Joint Appendix hereinafter referred to as "JA. __".

contravened Sections 41, 101, 111, 121, 122 and 151 of the Patent Act (as raised by Tafas in the underlying summary judgment proceedings). (JA. 10-11.)

The USPTO has framed Issue 3 so as to improperly seek an advisory opinion on a purported issue that the District Court merely addressed as *dicta* below (*i.e.*, whether the USPTO is required to engage in notice and comment rulemaking under Section 2(b)(2) of the Patent Act) and which was not otherwise determinative as to the District Court's grant of summary judgment.

STATEMENT OF THE CASE

Tafas agrees with the USPTO's "Statement of the Case", except Tafas disputes that the final rules were intended by the USPTO to "conduct a better and more thorough and reliable examination of patent applications ... by reduc[ing] the large and growing backlog of unexamined applications while maintaining or improving the quality of issued patents." Further, Tafas finds the USPTO's Statement of the Case incomplete, *inter alia*, in failing to reference the relevant procedural history set forth below.

The USPTO published the Final Rules in the Federal Register on August 21, 2007, with an effective date of November 1, 2007. (JA. 51.) On August 22, 2007, Tafas filed a complaint and motion for preliminary injunction seeking to preliminarily and permanently enjoin the Final Rules, as well as requesting a declaratory judgment that they were null and void. Tafas filed an amended

complaint on September 7, 2007.

Tafas alleged that the Final Rules were beyond the USPTO's rulemaking power, *inter alia*, because they were inconsistent with: (i) the United States Constitution, including Article I, Section 8, Cl. 8 and the Due Process and Takings Clauses of the Fifth Amendment (the "Constitutional Claims"); (ii) Sections 2, 41, 101, 102, 111, 112, 120, 121, 122, 131, 132 and 151 of the Patent Act (35 U.S.C. §§ 1 *et seq.*) and Sections 200-203 of the Bayh-Dole Act (35 U.S.C. §§ 200-212)(the "Statutory Claims"); (iii) Sections 553(b)-(c) and 706(2) of the APA, among other ways, because of the Final Rules' retroactive application, with the public being denied a meaningful ability to be informed of and comment on "the terms or substance of the proposed rule"; and, in that the USPTO's rulemaking was arbitrary, capricious and an abuse of discretion (the "APA Claims"); and (iv) the Regulatory Flexibility Act (the "RFA"), 5 U.S.C. §§ 601-612, because the USPTO erroneously certified under Section 605(b) of the RFA that the Final Rules would not have a significant impact on a substantial number of small businesses and, in reliance on this flawed certification, failed to prepare a Final Regulatory Flexibility Analysis (the "RFA Claims").

Appellees Smithkline Beecham Corporation d/b/a GlaxoSmithKline and Glaxo Group Limited (collectively "GSK") filed a complaint on October 9, 2007 that, as recognized by Judge Cacheris, was "largely similar" to Tafas' complaint

(except for the RFA Claim, which GSK did not have standing to bring, and several additional statutory and treaty arguments raised by Tafas), as well as a motion for preliminary injunction. (JA. 8.) The District Court preliminarily enjoined the Final Rules on October 31, 2007. Tafas v. Dudas, 511 F. Supp. 2d 652 (E.D. Va. 2007) (*"Tafas I"*).

Following the District Court's preliminary injunction ruling, Tafas sought to take discovery from Appellants (including obtaining document production and depositions) in aid of his APA and RFA Claims. GSK sought document discovery from Appellants in support of its APA claim. On November 28, 2007, Magistrate Thomas Rawles Jones denied both Tafas' and GSK's discovery requests. Tafas objected to Magistrate Jones' ruling, which objection the District Court (*per* Judge Cacheris) overruled on January 9, 2008. Tafas v. Dudas, 530 F. Supp. 2d 786 (E.D. Va. 2008)(*"Tafas II"*). Tafas filed a motion for reconsideration on January 18, 2008, which was still *sub-judice* when the Court issued its summary judgment ruling in favor of Appellees on April 1, 2008. Tafas v. Dudas, 541 F. Supp. 2d 805 (E.D. Va. 2008); (JA. 27-28). In its summary judgment ruling, the Court denied Tafas' discovery related motion for reconsideration of the *Tafas II* decision as moot. (Id.)

The Court granted summary judgment to Tafas and GSK finding that the Final Rules were 'substantive' and thus beyond the USPTO's rulemaking authority

under Section 2(b)(2) of the Patent Act (35 U.S.C. § 2(b)(2)). The District Court never reached Tafas' Constitutional Claims, a number of his Statutory Claims (with the exception of those relating to the USPTO exceeding its rulemaking authority under Section 2(b)(2) of the Patent Act), Treaty Claims, APA Claims and RFA Claims -- concluding that there was no need given the District Court's threshold finding that the USPTO lacked any substantive rulemaking authority to promulgate the Final Rules in the first place. (JA. 10-11.)

In the event that this Court were to reverse the District Court's summary judgment ruling, Tafas' above referenced claims would need to be considered by the District Court on remand.

STATEMENT OF THE FACTS

Tafas agrees with the USPTO's "Statement of Facts," except as stated below:

1. Tafas disagrees with USPTO's assertion that 35 U.S.C. § 132(b) provides the USPTO with authority to issue regulations "regarding requests for continued examinations (RCEs)." (USPTO Br. 3.) Rather, Tafas asserts that 35 U.S.C. § 132(b) mandates that the USPTO "prescribe regulations" under its rulemaking authority "to provide for the continued examination of applications for patent at the request of the applicant."

2. Tafas disagrees with the USPTO's implication that the notice it gave in the Federal Register, and the public comments it solicited for its published proposed regulations, complied with the notice and comment requirement of Section 553 of the APA. (USPTO Br. 3.) Tafas contends that there were radical changes made to the proposed rules between the time they were published and the promulgation of the Final Rules. As such, the public was deprived of the opportunity to meaningfully review and comment on the Final Rules.

3. Tafas disagrees that his challenge to the Final Rules pertained only to four (4) sections of the Final Rules, rather than to the Final Rules *in toto*. (See, e.g., JA. 313-14); (USPTO Br. 3).

4. Tafas disagrees with the USPTO's assertion that Final Rule 78 and Final Rule 114 were "designed to assist the Office ... by discouraging unnecessarily repetitive use of continuation-in-part applications and RCEs," and its assertion that Final Rule 75 and Final Rule 265 were "intended to improve the Office's examination process." (USPTO Br. 3, 4, 9.)

5. Tafas disagrees that the USPTO provides any basis in the administrative record for its assertion that "excessive use of continuation and continuation-in-part applications ... has contributed ... [to] the 'large and growing backlog of unexamined patent applications." (USPTO Br. 4.) As discussed at the District Court level, others have come to entirely different conclusions. For

example, Ayal Sharon and Yifan Liu of George Mason University have clearly demonstrated, using a queuing model, that the Final Rules' limitations on continuation applications, as well as RCEs, would not reduce the USPTO's backlog. (JA. 3820.) Sharon and Liu found continuation and divisional filings have remained fairly stable over the past seven years and the major cause of backlog of applications was due to the large number of non-final office rejections being issued per round of prosecution.[2] (Id.) Tafas acknowledges that the administrative record shows an increase in RCE filings since the introduction of the RCE in 2000. However, one would have expected a significant increase between 2000 and 2003 as the continuing prosecution application ("CPA") was phased out in lieu of the RCE. RCE growth since 2003 may simply be related to more stringent review of patent applications.

6. Tafas disagrees that there is any data in the administrative record establishing that the USPTO "spends more time reviewing applications 'that are a

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[2] This result is supported by a recent presentation by Ester Kepplinger, former Deputy Commissioner for Patent Operations. Donald Zuhn, Docs at BIO: Panel Discusses Impact of USPTO Rule Changes and Patent Reform Legislation on Biotech Patenting (June 23, 2008), at http://www.patentdocs.net/patent_docs/2008/06/docs-at-bio-pan.html. The actions per disposal ("APD") has increased by more than half an action per application since 2004. Id. Ms. Kepplinger ascribes the backlog to the increase in APD, not increased non-RCE continuation or divisional application filings. Id.

repetition of prior applications that have already been examined' than other types of applications." (USPTO Br. 5.)

7. Tafas disagrees that "unlimited recourse to continuation applications and RCEs has led to misuse and abuse." (USPTO Br. 5.) Tafas notes that 37 C.F.R. § 10.18(b)(2)(i) provides that the USPTO may sanction applicants that present a paper "for any improper purpose, such as to … cause unnecessary delay or needless increase in the cost of prosecution before the Office." The USPTO's own records indicate that not even a single case or proceeding was ever brought by the USPTO under § 10.18(b)(2)(i) against any party since the time these records became publicly available (1996). (See JA. 3193 n.31.)

8. Tafas disagrees with the USPTO position that it is a misuse of continued examination practice to broaden one's claims to encompass a competitor's product. (USPTO Br. 6); see, e.g., States Indus. v. A.O. Smith Corp., 751 F.2d 1226, 1235-36 (Fed. Cir. 1985) (finding it not improper for an applicant to keep track of its competitor's products and modify claims in a continuation application); Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 909 n.2 (Fed. Cir. 2004) (also involving a continuation application: "The district court recognized that it is not improper for an applicant to broaden his claims during prosecution in order to encompass a competitor's products, as long as the disclosure supports the broadened claims"); Multiform Desiccants, Inc. v.

Medzam, Ltd., 133 F.3d 1473, 1482 (Fed. Cir. 1998) ("it is neither illegal nor bad faith for an applicant to amend the claims in view of a competitor's product"); PIN/NIP, Inc. v. Platte Chem. Co., 304 F.3d 1235, 1247 (Fed. Cir. 2002) ("[I]t is legitimate to amend claims or add claims to a patent application purposefully to encompass devices or processes of others ...."). Tafas further disagrees that the submission of a continued examination filing to correct an error or "deficiency" in the claims or disclosure constitutes misuse of continued examination practice as asserted by the USPTO. (USPTO Br. 6.) For example, there is nothing abusive about obtaining claims of narrower scope from an obstinate examiner, and then seeking broader claim scope later. It may simply relate to the economics of obtaining a patent now, rather than later.

9. Tafas disagrees that a patent application "can continue without end." (USPTO Br. at 6.) As a practical matter, as any application approaches twenty years from the priority date it becomes less and less commercially viable. Tafas further disagrees that the present rules of practice "impose a burden on innovation ... by undermining the function of claims to notify the public as to what technology is or is not available to use." (USPTO Br. 7.) Tafas notes that as long as the patent application is pending, the public will never understand what claims will ultimately be obtained, and as a claim can only be understood in terms of a

reading of the specification, the public will always be burdened with understanding the disclosure of an application and its breadth and limitations.

10. Tafas disagrees with the USPTO that Final Rule 78 does not set a limit on the number of continuing applications that an applicant may make (USPTO Br. 6) because, as stated by Judge Cacheris, "the USPTO intends to deny additional applications in almost all circumstances, see 72 Fed. Reg. at 46769 – 77…." (JA. 19.)

11. Tafas disagrees with the USPTO's mischaracterization at JA. 109-112 concerning the petitions which the Office "expects" to grant. Tafas notes a substantial broadening of the actual text by ignoring the many provisos set forth in the actual Federal Register text.

12. Tafas disagrees that data in the record demonstrates that "the number of claims has contributed to the Office's backlog." (USPTO Br. 9.) The USPTO's analysis does not distinguish between the total number of claims and the number of independent claims. (JA. 181.) Generally, independent claims are the central time sink in USPTO searching -- not dependent claims. It is statistically impossible to determine whether "the error rate for applications with more than 25 claims is significantly higher than the error rate for applications containing fewer than 25 claims" based solely on one year of data ranging from Fiscal Year 2005 to Fiscal Year 2006 as is suggested by the USPTO. (JA. 181.)

13. Tafas disagrees that Final Rule 75 "places no limit of any kind on the number of claims that may be presented." (USPTO Br. 9.) Rather, Tafas argued below, and the District Court properly found, that the "5/25 Rule … imposes a mechanical limit" on the number of claims unless the applicant agrees to alter the examination burden to make a *prima facie* case of patentability, as placed by the law on the USPTO, onto the applicant instead.

14. Tafas disagrees with the USPTO's assertion that the District Court did not determine whether the Final Rules were permissible under 35 U.S.C. § 2(b)(2)(A), (C) (D). Compare USPTO Br. 11 with JA. 14–15 and 23.

15. Furthermore, Tafas disagrees with the USPTO's Statement of Facts as incomplete, *inter alia*, in failing to reference the relevant facts set forth below.

Tafas is an inventor and sole proprietor of certain energy recovery patent applications, and a named inventor on numerous robotic microscopy patents and patent applications. (JA. 3734 ¶ 9.) Tafas filed this action based on the strong conviction that the Final Rules would seriously hamper innovation. (JA. 3738 ¶¶ 21-22.)

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. (JA. 3733 ¶ 6.) Tafas started Ikonysis with little capital. After many unsuccessful attempts to raise capital in

Europe, Tafas turned to the United States. (Id. ¶ 7.) Tafas found this country exceptional in that it provided strong patent protection affordable not only by large corporate entities, but also by small businesses and individuals. (JA. 3734 ¶ 10.) 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. (Id.) After many painstaking and lean years, Ikonysis now manufactures and sells a fully automated robotic microscope.

Tafas is not a "patent troll" who obtains patents solely to bring infringement lawsuits. (JA. 3152.) 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. (Id.) Tafas's ultimate goal is to use his robotic microscope to detect early stage cancers, on a wide scale, using proprietary biological markers. (JA. 3734 ¶ 11.) Tafas' theory is this could be accomplished through monitoring of blood samples taken at routine physician visits. (JA. 3152.) This is possible because Tafas' automated microscope will allow for rapid, twenty-four (24) hour screening of blood samples. (JA. 3152.) 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. (JA. 3734 ¶ 11.)

Cancer treatment success rates are substantially greater when cancers are detected early before they have time to grow and metastasize. (JA. 3152.) As

would be known by anyone who suffers from, or is related to anyone suffering from, cancer, Tafas' research holds out the potential to revolutionize the field of early cancer detection and treatment. (Id.) 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. (Id.)

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. (Id.) Tafas filed these patent applications in connection with inventive concepts he had concerning different methods to reduce emissions, and resultant global warming. (Id.) Again, actual research is being undertaken by Tafas with respect to these inventions and he is seeking venture capital to support such research. (Id.)

SUMMARY OF THE ARGUMENT

Federal Circuit case law, and the statute itself, make clear that the USPTO has no authority under 35 U.S.C. § 2(b)(2) to make substantive rules or, for that matter, any rules, procedural or substantive, inconsistent with existing law.

Here, the Final Rules change existing law and policy so as to affect individual rights and obligations. As such, the Final Rules are substantive in nature.

Neither *Chevron* nor *Skidmore* deference is granted to an agency's rulemaking when it acts outside its statutory grant of power and/or promulgates rules inconsistent with existing law. Thus, the District Court was correct in not giving the USPTO's Final Rules deference under *Chevron* or *Skidmore.*

Due to Congressional amendment of the text of former 35 U.S.C. § 6, all USPTO rules promulgated pursuant to 35 U.S.C. § 2 are required to be noticed in the Federal Register for public comment, and the public is to be informed that each comment is to be given the sort of consideration as required by 5 U.S.C. § 553. Thus, the USPTO is wrong in arguing that public notice and comment was not required for the Final Rules.

ARGUMENT

I. STANDARD OF REVIEW

Tafas agrees with the USPTO that this Court reviews a grant of summary judgment by a district court *de novo* applying the same standard as the District Court. See, e.g., Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1281 (Fed. Cir. 2005); Pellegrini v. Analog Devices, Inc., 375 F.3d 1113, 1115 (Fed. Cir. 2004) (a district court's grant of summary judgment is reviewed *de novo*, reapplying the summary judgment standard); Cortland Line Co. v. Orvis Co., Inc., 203 F.3d 1351, 1355-56 (Fed. Cir. 2000). Here, Tafas and GSK challenged the Final Rules pursuant to the APA, for which the ordinary summary judgment

standard under Rule 56 of the Federal Rules of Civil Procedure applies. See Star Fruits, 393 F.3d at 1281.

As discussed more particularly in Section IV, *infra*, Tafas disagrees with the USPTO's characterization of *Chevron* and *Skidmore* deference, as well as the USPTO's proposed application of those doctrines to the Final Rules. (USPTO Br. 17–23.) The proper standard of review is set forth under the APA, which provides parties "suffering a legal wrong because of agency action" the right of judicial review (5 U.S.C. § 702), with the reviewing court applying the legal standard enunciated in Section 706 of the APA:

> [T]he reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall –
>
> * * * *
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be –
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law:
>
> * * * *

> In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party....

5 U.S.C. § 706(2)(A)-(D)(emphasis added). In other words, a reviewing court has the duty to make an independent assessment as to whether an agency's regulations are in excess of statutory jurisdiction or otherwise contrary to law.

II. THE USPTO LACKS STATUTORY AUTHORITY TO PROMULGATE SUBSTANTIVE RULES

A. Section 2(b)(2) does not empower the USPTO to limit continuation filings or claims in a patent application

Section 2(b)(2) of the Patent Act does not empower the USPTO to restrict patent applicants' statutory rights to file continuation applications 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:

> **§ 2 Powers and Duties.**
>
> (b) Specific Powers. The Office –
>
> * * *
>
> (2) may establish regulations, not inconsistent with law, which
>
> (A) shall govern the conduct of 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 under the guise of its limited procedural rulemaking authority. Rather, Section 2(b)(2)(A)-(C) merely grants the USPTO strictly procedural rulemaking authority intended to expedite and/or facilitate the processing of patent applications. It does not authorize the USPTO to engage in informal rulemaking which the USPTO admits was calculated to restrict the number of continuation applications and/or the filing of multiple claims, in contravention of numerous provisions of the Patent Act:

> 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.

JA. 30 (emphasis added).

As this Court has just recently unequivocally re-confirmed in Cooper Technologies, Co. v. Dudas, Appeal No. 2008-1130, 2008 WL 3842893, *6 (Fed. Cir. Aug. 19, 2008), Section 2 of the Patent Act does not empower the USPTO to issue "substantive" rules:

> We have also previously held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue "substantive" rules. See Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996). "A rule is 'substantive' when it 'effects a change in existing law or policy' which 'affect[s] individual rights and obligations.' Animal Legal Defense Fund, 932 F.2d at 927...." (citations omitted). "In contrast, a rule which merely clarifies or explains existing law or regulations is 'interpretative.'" Id. In this case, the Patent Office's interpretation of "original application" does not effect any change in existing law or policy; rather, it is a prospective clarification of ambiguous statutory language regarding a matter of procedure. It is therefore "interpretive" -- rather than "substantive". We conclude that the Patent Office had the authority under 35 U.S.C. § 2 to interpret section 4608, because that interpretation both governs the conduct of proceedings in the Patent Office, not matters of substantive patent law, and is a prospective clarification of ambiguous statutory language.

Id. at 6 (emphasis added).

Cooper is a logical extension of, and reaffirms, Merck & Co. v. Kessler, 80 F.3d 1543 (Fed Cir. 1996), which held that the USPTO lacked any substantive rulemaking powers:

> [T]he broadest of the PTO's rulemaking powers ... authorizes the Commissioner to promulgate regulations directed only to "the conduct of proceedings in the

> [USPTO]"; it does not grant the Commissioner the authority to issue substantive rules.

Merck, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (emphasis added).

The bedrock principle that only Congress has the power to pass "substantive" law setting down the terms and conditions for patent eligibility flows not only from application of APA principles, but also from the Congressional branch's exclusive prerogative and plenary authority to enact laws relating to patents pursuant to Article I, Section 8, Clause 8 of the U.S. Constitution (the "Patent Clause"), which provides:

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

U.S. CONST. art. I, § 8 cl. 8.

Here, the USPTO's enactment of the Final Rules -- taken in its capacity as part of the Executive Branch -- exceeds the limitations set forth in the Constitution, *inter alia*, because under the Patent Clause only Congress has the power to pass substantive laws setting down the terms and conditions for patent eligibility.

Congress only granted the USPTO limited authority under Section 2(b) of the Patent Act to make rules concerning the processing of patent applications. Congress never delegated authority to the USPTO to re-write other provisions of the Patent Act. There is also nothing to indicate Congress intended to make the

USPTO the final interpreter/arbiter, in lieu of the Federal Circuit, as to whether any of the USPTO's Final Rules enacted pursuant to Section 2(b) conflict with other parts of the Patent Act. Thus, the Final Rules, which are substantive in nature, constitute a usurpation by the Executive Branch of Congressional power in violation of the Patent Clause and the constitutional principle of separation of powers.

Lacavera v. Dudas, 441 F.3d 1380 (Fed. Cir. 2006) and Stevens v. Tamai, 366 F.3d 1325 (Fed. Cir. 2004), relied upon by the USPTO for the proposition that the Federal Circuit has supposedly recognized the USPTO as having some plenary substantive rulemaking authority, 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. Lacavera, 441 F.3d at 1383. The USPTO's rulemaking power in this specific area, however, is specifically provided for 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 other specific

provisions of the Patent Act. In fact, the Patent Act was entirely silent as to whether the USPTO could impose the restriction at issue in Lacavera. Id.

Stevens is likewise distinguishable. Stevens 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. Unlike the case with the Final Rules, 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 (nor did any of the parties argue otherwise). Id. at 1333. The Stevens court's statement on page 1333 that the USPTO had "plenary authority" simply related to the USPTO's rulemaking authority concerning purely procedural matters in respect of patent interference process. Such is clearly shown by the Federal Circuit's approving citation to Merck as limiting the scope of the USPTO's rulemaking authority. Id.

III. THE FINAL RULES ARE SUBSTANTIVE AND CONFLICT WITH SECTIONS 102, 103, 112, 120, 131 AND 132 OF THE PATENT ACT

A. The USPTO is wrong in asserting that it may promulgate rules that "change the law," or "change the patent system," in ways that "alter rights or obligations" under statute without Congressional authority

The USPTO argues that "[p]rocedural rules, like substantive rules, change the law; if they did not, there would be little point in promulgating them … the mere fact that a rule alters a pre-existing 'right' does not make the rule

substantive." (USPTO Br. 35 (emphasis added).) John Whealen, former Deputy General Counsel and Solicitor of the USPTO, who was intricately involved in the promulgation of the Final Rules (see, e.g., JA. 3718-31), confirmed the existence of the Final Rules' substantive effects in a speech concerning the proposed rules at Duke Law School in February 2006:

> What we have realized is that we are an agency, and we write rules, and we can actually change policy a lot quicker by making some rules that might change the patent system ... Patent legislation up on the hill ... is stalled, [but] we don't have that problem, we write rules, and they issue, and maybe they get overturned.

(JA. 3590 (emphasis added).)

As stated by the Federal Circuit in Animal Legal Defense Fund v. Quigg, "[a] rule is 'substantive' when it 'effects a change in existing law or policy' which 'affect[s] individual rights and obligations.'" 932 F.2d 920, 927 (Fed. Cir. 1991) (citations omitted) (emphasis added). Again, the Federal Circuit has consistently held that 35 U.S.C. § 2(b)(2) does not authorize the Patent Office to issue "substantive" rules. See, e.g., Merck, 80 F.3d at 1549-50; Eli Lilly & Co. v. Bd. of Regents, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003); Cooper, 2008 WL 3842893, at *6.

A change in the law that alters a preexisting right or obligation under statute constitutes "substantive" rulemaking beyond the USPTO's authority. Cooper, 2008 WL 3842893, at *6. As discussed below, even assuming arguendo that

Congress actually delegated authority to the USPTO to engage in substantive rulemaking (which it did not), the Final Rules must still be stricken because the preamble in Section 2(b)(2) requires that any such rules not be "inconsistent with existing law."

B. The USPTO's authority to promulgate procedural rules does not authorize it to "incidentally" affect substantive rights

The USPTO argues that the Final Rules are procedural in nature and that any affect that they may have on the substantive rights of patent applicants are merely incidental. It argues that "the district court's approach to classifying rules as 'substantive' rather that 'procedural' would transform many of the Federal Rules of Civil Procedure into invalid substantive rules." (USPTO Br. 36-38.)

The USPTO carries its analogy further by suggesting that since the Supreme Court has the ability to limit the number of times a litigant may amend a pleading, that the USPTO should have the right to limit the number of claims that a patent applicant may file as well as the right to limit the permitted number of requests for continued examination. (USPTO Br. 37-38.) Its reasoning is flawed.

Contrary to the USPTO's suggestion, the Supreme Court has taken the limitation on its power under the Rules Enabling Act, 28 U.S.C. § 207 to promulgate procedural rules of civil procedure seriously. The Supreme Court has continually required a limited construction of certain of its rules of civil procedure to prevent the abridgement of substantive rights. See Semtek Int'l Inc. v.

Lockheed Martin Corp., 531 U.S. 497, 506-07 (2001) (adopting a limited construction of F.R.C.P. 41(b) because to afford claim preclusion to every decision rendered by a federal court just because the court states that the decision is "on the merits" would violate 28 U.S.C. § 207(2); Ortiz v. Fibreboard Corp., 527 U.S. 815, 842 (1999) (adopting a limited construction of F.R.C.P. 23(b)(1)(B) in order to minimize potential conflict with the Rules Enabling Act).

C. The Final Rules change existing law or policy affecting individual rights and obligations

The USPTO maintains that the District Court "found itself comparing the Final Rules with the provisions of the Act in order to determine whether the rules were procedural or substantive … [and] [i]n so doing … disregarded its obligations under *Chevron*." (USPTO Br. 41.) Of course, such complaint is ill-founded because the District Court would be unable to even reach the question of whether a preexisting right or obligation under the statute was being affected by a rule asserted by the USPTO to be procedural under 35 U.S.C. § 2(b)(2)(A) if it was required to simply defer to the USPTO's self-serving, *ipse dixit* interpretation that the Final Rules are not substantive. See Cooper, 2008 WL 3842893, at *5 (the Federal Circuit determined that it was appropriate to first determine whether the USPTO had the right to promulgate the rule under 35 U.S.C. § 2(b)(2) and only after that should the court proceed to consider whether to apply *Chevron* deference to the procedural rule).

The Final Rules, and in particular the limitation on continuation filings and RCE filings, retroactively applied to applications filed at a time when the applicant may have disclosed, but not yet claimed, all subject matter. (See JA. 52-53.) This clearly affected rights and expectations of applicants who filed prior to the promulgation of the Final Rules and who depended on long standing Federal case law to support their filing strategies. Applicants often seek less than the full scope of their disclosure, not because they are hiding anything, but because they seek, for example, not to overwhelm an Examiner with multiple inventive embodiments being claimed in one application (i.e. too many claims), or to expedite allowance of certain claims prior to proceeding with yet possibly more expensive prosecution of claims that they perceive may be more difficult to obtain.

1. Rule 78 Affects Individual Rights Granted by 35 U.S.C. § 120

The District Court found that Final Rule 78 "changes existing law and deprives applicants of their valuable rights under 35 U.S.C. § 120 to an unlimited number of continuation and continuation-in-part applications as a matter of right … [and] may also impact applicant's rights under Section 102 and 103 and result in denial of otherwise meritorious patents." (JA. 20.)

The USPTO urges that Rule 78 "does not place any limit on how many filings the applicant may make" with an applicant being "free to pursue" a continuation filing if the required showing is not made under the rule "albeit

without the priority benefit of earlier applications." (USPTO Br. 42-43.) Thus, the USPTO explicitly acknowledges that Rule 78 will not allow an applicant under certain circumstances to file a second application "hav[ing] the same effect" as a prior application "as though filed on the date of [a] prior application" even though the second application discloses, in the manner provided by the first paragraph of Section 112, the same invention, and the second application was "filed before the patenting or abandonment of or termination of proceedings on the first application" (with the applicant seeking reference to the first filed application). Id.

Certainly, an applicant's right to obtain priority in a subsequent application is a right provided by 35 U.S.C. § 120. Thus, Rule 78 is substantive in nature because it removes such right if certain new conditions are not met by an applicant filing the subsequent application.

The USPTO erroneously argues that "Section 120 does not specifically and unambiguously address whether applicants have an affirmative right to file an unlimited number of continuation applications, or whether its enumerated conditions are exclusive or non-exclusive," and that a reading to permit an unlimited number of continuation applications is at "odds with the legislative history of the provision." (USPTO Br. 47, 50.)

The Federal Circuit, and the Court of Customs and Patent Appeals, have repeatedly held that Section 120 has a "plain and unambiguous meaning" in that

"any application fulfilling the requirements therein 'shall have the same effect' as if filed on the date of the application upon which it claims priority." Transco Prods. Inc. v. Performance Contracting, 38 F.3d 551, 556 (Fed. Cir. 1994) (noting that "The courts have repeatedly recognized this principle") (emphasis added); see also Cooper, 2008 WL 3842893, at *21 (construing the meaning of "same effect" in Section 120 as meaning '"having the benefit of the filing date of the earlier filed application,'" and noting that "the statute itself makes this clear.") (quoting Transco, 38 F.3d at 556). Furthermore, the Federal Circuit in Transco, reviewing the legislative history of the provision, did not find such a reading of the statute to be in "odds with the legislative history." Transco, 38 F.3d at 556-57. Reading the legislative history of Section 120 to allow for an unlimited number of continuations is in accord with the interpretation of former Federal Circuit Judge Giles S. Rich, as set forth in his 1952 commentary as a member of the drafting committee that promulgated Section 120 of the Patent Act: "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, The New York Patent Law Association (1952).

USPTO rules must be not only consistent with statute but also Federal Circuit case law interpreting the Patent Act. In re Van Ornum, 686 F.2d 937, 945-46 (C.C.P.A. 1982). "[T]here is no statutory basis [under Section 120] for fixing

an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications, provided applicant meets all the other conditions of the statute." In re Henriksen, 399 F.2d 253, 254 (C.C.P.A. 1968). The USPTO tries to parse Henriksen arguing that "nothing in Henriksen suggests that Section 120 confers an affirmative right to file an unlimited series of continuation applications." (USPTO Br. 47.) The USPTO's assertion is wrong as this Court has consistently found that Section 120 allows for an applicant to file continuation applications as needed. See, e.g., Racing Strollers Inc. v. Tri Indus., 878 F.2d 1418, 1421 (Fed. Cir. 1989) ("In our view, § 120 gives to any applicant for a patent complying with its terms the right to have the benefit of the filing date of an earlier application. The language is mandatory.") (emphasis in original); Ricoh Co. v. Nashua Corp., 185 F.3d 884, 1999 WL 88969, *3 (Fed. Cir. 1999) ("[S]ection 120, governing continuation applications, does not contain any time limit on an applicant seeking broadened claims"). The Court has long recognized that any "limit upon continuation applications is a matter of policy for the Congress," not for the USPTO or the courts. In re Hogan, 559 F.2d 595, 604 n.13 (C.C.P.A. 1977).

Failed congressional bills, such as the Patent Reform Act of 2005 (H.R. 2795, 109th Cong. (1st Sess. 2005)), which sought to bestow the USPTO with

authority to limit continuing applications, also support the view that the USPTO does not have authority to limit continuing applications in any manner. Section 123 of the Patent Reform Act of 2005, which again was not passed by Congress, specifically dealt with Section 120: "The Director may by regulation limit the circumstances under which an application for patent … may be entitled to the benefit under Section 120 of the filing date of a prior-filed application." H.R. 2795, 109th Cong. § 8 (2005). Recognizing the importance of protecting the ability of applicants to obtain comprehensive patent protection, even the failed Patent Reform Act of 2005 attempted to protect inventors against such a rule by stating "[n]o such regulation may deny applicants an adequate opportunity to obtain claims for any invention disclosed in an application for patent," something the 5/25 rule clearly does. Id.

The USPTO urges that any interpretation of Section 120 that limits the USPTO's ability to restrict continuation application filing "cannot be reconciled with this Court's decision in In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002)" ("*Bogese II*"). The USPTO characterizes *Bogese II* as allowing it to "set reasonable deadlines and requirements for the prosecution of an application" and that Rule 78 of the Final Rules merely sets such reasonable deadlines. (USPTO Br. 44-45.)

A careful reading of *Bogese II*, however, 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. Indeed, 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 Federal Circuit specifically distinguished the applicant in *Bogese II* from an applicant who "maintain[s] pendency of an application . . .while competitor's products appear on the market. . .", implicitly accepting the later practice as being sanctioned under the law. Id. at 1369. In all events, the *Bogese II* panel made it clear that the prosecution laches doctrine was limited and reserved for extreme circumstances[3] and implied that the USPTO would not have similar power to adopt a broad rule applicable to all patent applicants. *Bogese II*, 303 F.3d at 1368 n.6.

2. Rule 114 Affects Individual Rights Granted by 35 U.S.C. § 132

The District Court found Rule 114 to change rights under the law in two ways: (1) by "plac[ing] a limit on RCEs as of right on the basis of application

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[3] Similarly, Symbol Techs. v. Lemelson Med., 277 F.3d 1361 (Fed. Cir. 2002), 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.

family, rather than on the basis of each individual application" and (2) removing the "invocation of the continued examination process [from] the discretion of the applicant" to the USPTO. (JA. 20-21.) The USPTO disputes this analysis arguing that: (1) Section 132 "does not specify the conditions and requirements for continued examinations" and (2) that Section 132(b) relates to continued examination of "an application," and the term "applications" as used therein "does not require continued examination of every application in an application family." (USPTO Br. 51-53.)

By its plain language, Section 132 grants the USPTO no additional authority. Instead, Section 132 mandates that the USPTO, under part (b) of the statute, "shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." 35 U.S.C. § 132(b) (emphasis added). In Section 132(a), the Director is mandated to continue prosecution of an application, via further examination, if the "applicant persists in his claim for a patent." 35 U.S.C. § 132(a). Nothing in Section 132(a) or 132(b) supports the USPTO's assertion that it has the right to set the "conditions and requirements for continued examinations." (USPTO Br. 51.) Clearly, in using the word "shall" and "at the request of the applicant," and in requiring the Director to continue examination if the "applicant persists in his claims for a patent," Congress

manifested its intent that RCEs be unlimited, and that continued examination be at applicant's discretion, not the discretion of the USPTO.

The American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1) (1999) 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 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). Clearly, if Congress had intended only one (1) application to be reviewed in any family it would not have used the word "applications" in the plural in Section 132(b).

3. Rules 75 and 265 Affect Individual Rights Granted by 35 U.S.C. § 112

The District Court found Rules 75 and 265: (1) placed "mechanical limits on the number of claims an applicant may file" irrespective of Section 112's provision to the applicant of the right to determine the necessary number and scope of claims, and (2) went "far beyond merely requiring additional information" for examination, but changed "existing law and alter[ed] the rights of applicants under the current statutory scheme by shifting the examination burden away from the USPTO and onto applicants." (JA. 22-25.)

The USPTO disagrees, arguing that: (1) Rule 75 allows an applicant to "file as many claims as necessary," and Section 112 only sets "a floor on the number of claims that an applicant must submit"; and (2) Rules 75 and 256 do not "change the burden of examination or [shift] the burden of proof" but rather merely "requir[e] an applicant to assist the examiner by providing information." (USPTO Br. 54-57).

The USPTO has acknowledged in the administrative record that the "patent statutes … do not limit the number of claims (independent or dependent) that may be presented in an application." (JA. 3825.) In fact, the USPTO has long held that an applicant could file as many claims as desired:

> 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, at *2 (Bd. Pat. App. & Interf. 1999) (non-precedential). In fact, the USPTO notes on its own website that:

> [O]ffice policy is that absent basis for a restriction requirement, applicants are entitled to an examination of the claims presented provided applicants pay the required fees and otherwise comply with the statute…

http://www.uspto.gov/web/offices/pac/dapp/opla/documents/multiplicity.pdf (emphasis added).

The USPTO's former position is in accord with longstanding Federal Circuit precedent. For example, in In re Wakefield, 422 F.2d 897, 900 (C.C.P.A. 1970), the court held that "[A]n applicant should be allowed to determine the necessary number and scope of his claims …." As long as an applicant, in filing claims, is trying to define his invention "and does not by undue multiplicity obscure the same, he is acting within the rights granted and the duties required by the patent laws." In re Clark, 97 F.2d 628, 631 (C.C.P.A. 1938).

Judge Cacheris noted that even if the USPTO were to seek to limit claims based on a "undue multiplicity" rationale, the case law makes clear that such determination must be made based on review of the claims of a particular application and cannot be made by a blanket rule. (JA. 22-23, citing In re Flint, 411 F.2d 1353, 1357 (C.C.P.A. 1969) and quoting In re Chandler, 319 F.2d 211, 225 (C.C.P.A. 1963) (for the proposition that claims need to be evaluated "on the basis of the relevant facts and circumstances of each individual case.")).

Final Rule 1.265 requires cancellation of claims if the claims exceed five (5) independent or twenty-five (25) total claims in an application in which an ESD was not filed before a first office action. (JA. 79.) Thus, when Section 1.265 is applied to a second continuation application in which an ESD was not filed before a first office action, and in which, upon examination, six (6) or more dependent claims are found patentable upon incorporation of all the limitations of one or more

independent claims, an applicant will be required to forego patentable subject matter related to the invention, although the claim to such inventive embodiment has been found to meet all of the requirements of the patent law.

The USPTO's reliance on In re Rubinfield, 270 F.2d 391 (C.C.P.A. 1959) is misplaced. (USPTO Br. 54-55). Rubinfield simply does not imply that the USPTO can require applicants who file more than a certain number of claims to submit additional information to assist in examination without contravening Section 112. Rather, Rubinfield only dealt with the very narrow question of whether the USPTO's rule allowing 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. Of course, in that factual context there was "no useful purpose [that] could be served by the inclusion of more than one claim in a design application or patent." Id. at 395-96. Rubinfield is further distinguishable because it also depended on a "conflict" test between a rule and a statute, which test was effectively overruled by Adams Fruit Co. v. Barrett, 494 U.S. 638 (1990).

The reality is that the 5/25-ESD requirement is not only burdensome, but actually an insurmountable barrier for most applicants. (JA. 3743-44 at ¶¶ 35, 36; JA. 3780-98; JA. 3814). As indicated in the District Court *amicus* brief of

Polestar/Norseman, Dr. Belzer, an economist with twenty years of experience in regulatory analysis, calculated that if the 5/25 ESD Rule were to be applied to all applicable applications filed in a representative fiscal year that it would consume the full time efforts of between 8,000 and 23,000 patent attorneys. (JA. 3355-57.) There are only about 15,000 patent attorneys currently in practice in the United States. (JA. 3356.) Thus, as a practical matter, the 5/25-ESD is likely to bring nearly all other patenting activities to a halt rendering compliance with the 5/25-ESD rule effectively impossible. Furthermore, John Whealen, the USPTO's former solicitor during much of the rulemaking period, confirmed that the ESD requirement is not a *bona fide* alternative that the USPTO anticipates applicants will actually exercise (evidencing that the USPTO's true intent behind the ESD requirement is to force applicants to abandon property rights by making them too risky and too impractical to exercise):

> If you want all your claims examined up front, you can have it done, but it's going to cost you, you're going to have to do some work, which in the current law of inequitable conduct, **nobody's going to want to do**.

See Duke University Law School, Fifth Annual Hot Topics in Intellectual Property Law Symposium, at http://realserver.law.duke.edu/ramgen/spring06/students/02172006a.rm, at time mark 1:02:58 (JA. 3590, 3633-55) (emphasis added).

4. Rules 75 and 265 Affect Individual Rights Granted by 35 U.S.C. §§ 102, 103, and 131

35 U.S.C. § 102 states that "[a] person shall be entitled to a patent unless …" and then delineates various scenarios as exceptions, which by implication includes obviousness under 35 U.S.C. § 103. In In re Warner, 379 F.2d 1011, 1016 (C.C.P.A. 1967), the court found the preamble of Section 102 made clear that the initial burden of examination must be on the USPTO:

> We think the precise language of 35 U.S.C. §102 that "(a) person shall be entitled to a patent unless," concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under Sections 102 and 103 …

Id. at 1016.

Likewise, Section 131 mandates that the Director issue a patent if upon examination "it appears that the applicant is entitled to a patent under the law." 35 U.S.C. § 131. No right is given to permit the Director to fail to give a notice of allowance or to issue a patent if the applicant has satisfied all of the eligibility requirements of the patent statutes. Id.

The Federal Circuit, and its predecessor court, the Court of Customs and Patent Appeals, have consistently recognized that the patent statutes place the initial burden on the USPTO's examiners to demonstrate unpatentability. See, e.g., In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("[T]he examiner bears the

initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, [only then does] the burden of coming forward with evidence or argument shift[] to the applicant."); In re Piascki, 745 F.2d 1468, 1472 (Fed. Cir. 1984).

The ESD requirement is not, as urged by the USPTO, merely "designed to assist the examiner," but rather requires the applicant to argue for patentability of each independent claim with respect to the uncovered prior art:

> A general statement that all of the claim limitations are not described in a single reference does not satisfy the requirement of §1.265(a)(4). Section 1.265(a)(4) requires that the examination support document set out with particularity, by reference to one or more specific claim limitations, why the claimed subject matter is not described in the references, taken as a whole. The applicant must explain why a person of ordinary skill in the art would not have combined the features disclosed in one reference with the features disclosed in another reference to arrive at claimed subject matter. The applicant must also explain why the claim limitations referenced render the claimed subject matter novel and non-obvious over the cited prior art.

(JA. 78.)

The USPTO argues to this Court that its ESD rules are only seeking information permitted by the Court under Star Fruits, 393 F.3d 1277. However, the USPTO's arguments fall short for at least two reasons: (1) the Court in Star Fruits did not adjudicate whether the regulation in question was valid or not, but instead only determined that the USPTO interpretation of the regulation was

reasonable and not capricious; and (2) the Federal Circuit decided only that the USPTO could require the applicant to "submit such information when it is known or readily available" but did not determine that the USPTO could place new burdens on applicants to seek information that was not readily available or known and shift the burden of proof to the applicant to prove patentability. Id. at 1283 (emphasis added).

The ESD rules are not the only portion of the Final Rules wherein the USPTO impermissibly attempts to shift its burden of proof to the applicant. Final Rule 1.78(f)(2) erects a presumption that claims in two (2) applications are not patentably distinct if the applications meet certain criteria. (JA. 71.) This provision effectively eliminates the USPTO's statutory burden to make out a *prima facie* case of unpatentability because the presumption under the Final Rules is that claims in such applications are not patentable for double patenting. In short, the USPTO intended §1.78(f)(2) to shift the responsibility of demonstrating double patenting away from the USPTO and to the applicant:

> Therefore, with the benefit of §1.78(f)(2), double patenting issues could be resolved more expeditiously … thus saving the examiner time by eliminating the need to search for related applications, analyze the potentially conflicting claims, and make the rejection.

(JA. 116.)

The USPTO's unilateral shifting onto patent applicants of the USPTO's own statutory duty to determine double patenting[4] denies several statutorily-granted rights, including, without limitation, an applicant's right under 35 U.S.C. § 133 to have at least thirty (30) days to respond to any rejection or other action, as well as the right of *de novo* reconsideration and review to the USPTO's Board of Patent Appeals and Interferences, and to the courts, granted pursuant to 35 U.S.C. §§ 134, 141 and 145. As such, a double patenting rejection triggered by the new presumption under § 1.78(f)(2) improperly denies an applicant the right under the law to *de novo* review on appeal. 35 U.S.C. §§ 134, 141, 145. In short, by casting double-patenting rejections as procedural defects, the USPTO, with one blow, shed its own statutory duty to 're-examine' rejected applications and divested the Board of Appeals and the Federal Circuit of their statutorily-conferred jurisdiction to review double-patent rejections *de novo*. The USPTO may not unilaterally change its own duties to process patent applications and transfer them to patent applicants. Cf. In re Longi, 759 F.2d 887, 895-96 (Fed. Cir. 1985) (requiring that the USPTO

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[4] The USPTO on August 7, 2008 issued in the Federal Register 73 Fed. Reg. 45,999 *et seq.* a "clarification" indicating that the rebuttable resumption of double patenting of 37 C.F.R. § 1.78(f)(2) would not be retroactively applied to applications filed before the effective date even though the Final Rules as published, and numerous statements by the USPTO after promulgation indicated they would. The retroactive application of this provision only adds to the substantive effect of the Final Rules.

make out a "*prima facie* case of obviousness" when issuing a double-patenting rejection).

IV. *CHEVRON* AND *SKIDMORE* DEFERENCE DO NOT APPLY

Appellants erroneously suggest that the appropriate standard of judicial review is no review at all, arguing that the Final Rules, including the USPTO's contention that they are "procedural" and do not deprive patent applicants of substantive rights under the Patent Act, must be given special deference under the principles of judicial review prescribed by Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)("*Chevron*") or, alternatively, at least some deference under Skidmore v. Swift & Co., 323 U.S. 134 (1944)(*"Skidmore"*). (USPTO Br. 14.)

First, *Chevron* deference does not apply in the informal rulemaking context. National Org. of Veterans' Advocates, Inc. v. Secretary of Veterans Affairs, 260 F.3d 1365, 1378 (Fed. Cir. 2001), *quoting* Christensen v. Harris County, 529 U.S. 576 (2000) ("The Supreme Court has held that *Chevron* deference does not normally apply to informal rulemakings"). Although the USPTO did carry out a sort of ersatz notice and comment period with its proposed rules, as part of an attempt to lend a patina of legitimacy to its controversial Final Rules, the USPTO stated in its own interpretive material that it was not required to provide notice and comment because its Final Rules were strictly procedural. (USPTO Br. 38-40; JA.

166.) This draws the Final Rules into the realm of informal rulemaking exempt from *Chevron* deference. (JA. 3161-62.)

Second, it is well established that agency rulemaking outside of an agency's statutory jurisdiction is not subject to any *Chevron* or *Skidmore* deference. In United States v. Mead Corporation, 533 U.S. 218 (2001), the United States Supreme Court confirmed that a finding of statutory delegation of rulemaking authority is a precondition to the applicability of *Chevron* deference:

> 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 that authority.

Id. at 226-27 (emphasis added).

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 by Congress. See, e.g., Adams Fruit, 494 U.S. at 649 ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority"); 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").

The *Chevron* rule of giving deference to an agency rule where Congress has given an agency the power to promulgate substantive rules under a statute it is charged with administering does not apply to the USPTO's Final Rules. To begin with, Congress needs to have given the agency authority in the first place to promulgate substantive rules for *Chevron* deference to apply:

> Because Congress has not vested the [PTO] Commissioner with any general substantive rulemaking power, the 'Final Determination' at issue in this case cannot possibly have the 'force and effect of law' .... Thus, the rule of controlling deference set forth in *Chevron* does not apply.

Merck, 80 F.3d at 1550 (citations omitted).

The USPTO is not entitled to any *Chevron* deference where, as here, it engages in impermissible substantive rulemaking. See Pesquera Mares Australes Ltda. v. United States, 266 F.3d 1372, 1382 n.6 (Fed. Cir. 2001) (citing Merck for the proposition that the USPTO lacks substantive rulemaking authority, and, as such, the USPTO may not claim *Chevron* deference for a substantive rule).

Cooper confirmed again that the USPTO does not have substantive rulemaking authority:

> [I]t is a prospective clarification of ambiguous statutory language regarding a matter of procedure. It is therefore "interpretive" - rather than "substantive" - under the definitions put forward in Animal Legal Defense Fund. We conclude that the Patent Office had the authority under 35 U.S.C. § 2 to interpret section 4608, because that interpretation both governs the conduct of

> proceedings in the Patent Office, not matters of substantive patent law, and is a prospective clarification of ambiguous statutory language.

Cooper, 2008 WL 3842893, at *6 (emphasis added). The Cooper panel correctly only proceeded to apply the *Chevron* standard after it made a threshold determination that the USPTO's interpretation of Section 4608 was not substantive and within the USPTO's procedural authority. Id. at *6-13.

In determining the Final Rules were outside the scope of the USPTO's statutory authority, the District Court properly found that *Chevron* deference was not applicable based on its threshold finding that the Final Rules were substantive and outside the USPTO's limited statutory authority to promulgate procedural rules, provided they were not inconsistent with other law, to facilitate and expedite the processing of patent applications pursuant to Section 2(b)(2) of the Patent Act. (JA. 15-16.)

The USPTO's argument for *Chevron* deference is seemingly irrelevant to the determination of this appeal because it essentially presents a tautology. In order for *Chevron* to apply, the USPTO must first demonstrate that the Final Rules are not substantive. Of course, the reason for this is that if the Final Rules are substantive, the USPTO has absolutely no power to promulgate them consistent with Merck and Cooper. Such a determination would effectively end this appeal without any further need for this Court to utilize a *Chevron* or *Skidmore* analysis.

Alternatively, assuming *arguendo* that this Court were to determine that the Final Rules were not substantive, then the District Court's decision would presumably need to be reversed and remanded for a determination of the myriad of issues the district court never reached on the first go around, without the need for any *Chevron* or *Skidmore* analysis in this Court. Either way, *Chevron* and *Skidmore* deference are seemingly immaterial to a determination of the only true issue presently on appeal (*i.e.*, whether the Final Rules are actually substantive in nature). This is a determination that must necessarily be made by this Court as a matter of law.

Additionally, the USPTO is not entitled to any *Chevron* or *Skidmore* deference for its contention that the Final Rules are merely "interpretive rules, or rules of agency practice and procedure." (JA. 166.) An agency's "'characterization of its [rule] as an exposition of its policy or interpretation of the standard [however] does not preclude [a court's] finding that it is something more."' Jerri's Ceramic Arts, Inc. v. CPSC, 874 F.2d 205, 207 (4th Cir. 1989) (citation omitted); Bragg v. Robertson, 54 F. Supp. 2d 653, 665-66 (S.D. W. Va. 1999). Indeed, courts owe no deference to an agency's resolution as to whether an agency action represents a "rule" and/or whether an agency is required to conduct rulemaking procedures pursuant to the standards set forth at 5 U.S.C. § 553(b). See Nat'l Family Planning and Reprod. Health Ass'n v. Sullivan, 979 F.2d 227, 230-31

(D.C. Cir. 1992) (*Chevron* deference is inapplicable in determining "whether [the agency] followed proper procedure in implementing" a regulatory change).

Moreover, Congress merely granted the USPTO limited authority to make rules to facilitate and expedite the processing of patent applications. Congress never delegated authority to the USPTO to make new law or policy by interpreting other provisions of the Patent Act to the exclusion of the federal courts. Appellants do not deserve any *Chevron* or *Skidmore* deference because the USPTO exceeded its statutory authority and entered the exclusive realm of Congress, the District Court, and the Federal Circuit. Fabil Mfg. Co. v. United States, 237 F.3d 1335, 1341 (Fed. Cir. 2001) (finding that Customs' ruling regarding burden of proof required no deference because such ruling was for Congress or the Courts). The USPTO has no special expertise in statutory construction that would warrant *Chevron* deference nor was the USPTO ever delegated with authority to act as an omnibus final interpreter of the Patent Act, which is instead the province of this Court. Id.

Even if *Chevron* deference was applicable to the USPTO's claim that the Final Rules are within the scope of its authority, no deference is due to the USPTO's assertion that the Final Rules are "not inconsistent with law." The preamble of Section 2(b)(2) of the Patent Act requires that regulations promulgated by the USPTO are "not inconsistent with law." 35 U.S.C. § 2(b)(2). To the extent

the Final Rules violate other provisions of law, the Final Rules cannot be given any deference, nor is the USPTO's interpretation of the interplay of Section 2 to other sections of the Patent Act entitled to deference.

As a hedge, the USPTO argues in the alternative that *Skidmore* deference applies because its Final Rules are "interpretative." *Skidmore* deference, however, is only given to agency interpretations to the extent they have the "power to persuade." Christensen v. Harris Cty., 529 U.S. 576, 587 (2000). Further, as Congress has not delegated interpretative authority to the USPTO, but rather to the judiciary, *Skidmore* deference is likewise inapplicable here. See, e.g., Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 161–62 (4th Cir. 1998); Sac & Fox Nation v. Norton, 240 F.3d 1250, 1265–66 (10th Cir. 2001) ("Because the Secretary lacked authority to interpret the term … we owe no deference to his interpretation").

A. Appellants Legal Authorities In Support of Application Of *Chevron* or *Skidmore* Deference Are Distinguishable

The cases that the USPTO cites to support its claim that the Federal Circuit precedent mandates *Chevron* deference be given the USPTO's exercise of its rulemaking authority under Section 2(b)(2) are unavailing.

First, three of the five cases relied upon by the USPTO in this regard are in the context of adjudications, not rulemaking. Bender v. Dudas, 490 F.3d 1361, 1364-65 (Fed. Cir. 2007) (a patent attorney refused to disclose to the USPTO a

conflict he had with an inventor and in response, the USPTO excluded the attorney from practicing before it. The Federal Circuit gave the USPTO's sanction deference because under the APA, an agency's choice of sanction is unlawful only if it is arbitrary and capricious); Lacavera, 441 F.3d 1380 (the plaintiff appealed the USPTO's decision denying her full registration and the Court held that the USPTO's decision was consistent with its regulations. No notice and comment rulemaking was at issue); Stevens, 366 F.3d at 1333 (the plaintiff appealed from a ruling entered by the USPTO in an interference proceeding, and the Court held that the rules the USPTO uses to govern interference proceedings were not unreasonable). There was no formal or informal rulemaking at issue in any of the above cases.

The other two cases the USPTO cites to support its claim that the Federal Circuit has consistently given *Chevron* deference to the USPTO's exercise of its rulemaking authority under Section 2(b)(2) are equally unavailing.

For example, in In re Sullivan, 362 F.3d 1324, 1328 (Fed. Cir. 2004), the regulation at issue was obviously a procedural rule that allowed conferences between the Administrative judge and parties to an interference proceeding. In Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1425-26 (Fed. Cir. 1988), no rulemaking had occurred, and the Court was simply giving deference to the USPTO's interpretation of a statute that set forth procedures for patent proceedings.

Considering that none of the cases the USPTO cites for its claim that the Court has consistently given deference to the USPTO's exercise of its rulemaking authority under Section 2(b)(2) actually involves rulemaking, these cases do little to further the USPTO's argument. More importantly, none of the cases relied upon by the USPTO support the notion that a court should blindly accept a proposed statutory interpretation by the USPTO that directly contravenes long established judicial interpretations of the Patent Act.

Likewise, the cases the USPTO cites for its claim that "[a]gencies are entitled to *Chevron* deference when the consistency of their regulations with the requirements of the governing statute is called into question" are equally ineffectual. (USPTO Br. 22.) The USPTO cites to only two cases. The first case, Nuclear Information Resource Serv. v. Nuclear Regulatory Comm'n, 969 F.2d 1169 (D.C. Cir. 1992), does not even involve the USPTO. The other case, Eli Lilly, 334 F.3d at 1269 n.1, deals only with an adjudication and the USPTO Board's interpretation of a regulation -- not rulemaking. To argue that an agency is entitled to *Chevron* deference when the consistency of its regulations with the requirements of the governing statute is called into question is akin to asking the Court to give the agency's interpretation unqualified deference, regardless of whether or not the agency's interpretation was a "reasonable interpretation" of the

governing statute. The USPTO's claim in this regard goes beyond asking for *Chevron* deference – the USPTO is asking for unqualified deference.

Citing just one case, Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Services, 545 U.S. 967 (2005) ("Brand X"), the USPTO argues that "an agency's interpretation of ambiguous statutory provisions is entitled to *Chevron* deference even if courts had previously arrived at a different construction without the benefit of the agency's views." (USPTO Br. 23.) This proposition does little to further the USPTO's claims because Brand X dealt with the FCC's interpretation of a single word in the statute, not rulemaking.

The USPTO cites Mississippi Power & Light Co. v. Mississippi ex rel. Moore, for the proposition that "the rule of deference applies even to an agency's interpretation of its own statutory authority or jurisdiction." 487 U.S. 354, 381 (1998) (Scalia, J., concurring). Justice Scalia reasoned that deference was due because "Congress would naturally expect that the agency would be reasonable, within broad limits, for resolving ambiguities in its statutory authority or jurisdiction." Id. at 382. Here, though, there is no ambiguity – Section 2(b)(2) of the Patent Act, pursuant to which the Final Rules are promulgated, is clear. Therefore, Justice Scalia's reasoning in Mississippi Power is inapplicable.

The USPTO argues that failing *Chevron* deference, at the very least, the Court should give *Skidmore* deference to the Final Rules. (USPTO Br. 23 fn. 3.)

The one case that the USPTO cites to support this claim, Cathedral Candle Co. v. USITC, 400 F.3d 1352 (Fed. Cir. 2005), is not analogous to the USPTO's promulgation of the Final Rules and offers little support. Cathedral Candle dealt with the U.S. Custom Service's interpretation of a statute, not rulemaking. Not only that, but the Court granted *Skidmore* deference on the basis that the agency's interpretation of the statute was a position the agency had adhered to consistently. Id. at 1367. Cathedral Candle is in stark contrast to the situation here, in which the Final Rules turn longstanding interpretations of the Patent Act upside down and retroactively deprive patent applicants of statutory rights. Moreover, it is apparent that the District Court carefully considered all the parties' respective arguments in the proceedings below and that USPTO's legal justifications proffered for the Final Rules simply had no power to persuade.

B. Even if *Chevron* or *Skidmore* Deference Were To Be Applied It Would Be Unavailing Because The Final Rules Are Not Based Upon A Permissible Construction of Section 2(b)(2)

Even if the Court were to apply the *Chevron* standard here, the USPTO's Final Rules would still fail the second step of the *Chevron* test, which is whether the USTPO's rulemaking is based on a permissible construction of the statute. Chevron, 467 U.S. at 843. In order to satisfy step two of the *Chevron* test, the USPTO must establish that the USPTO's interpretation was reasonable and one that Congress would have sanctioned. Id. at 845, citing U.S. v. Shimer, 367 U.S.

374, 382, 383 (1961). Here, Congress would never have sanctioned the Final Rules, because they are in conflict with numerous provisions of the Patent Act and affect the existing statutory rights of patent applicants. (JA. 3015-30.) Thus, even assuming *arguendo* that the District Court decision were to be reversed and remanded for further proceedings on the grounds that the Final Rules are within the scope of Section 2(b)(2) of the Patent Act, Tafas strongly believes that he will be able to demonstrate that the Final Rules are so in conflict with existing statutory law so that neither *Chevron* or *Skidmore* deference would be appropriate.

V. ALL USPTO RULEMAKING IS SUBJECT TO NOTICE AND COMMENT UNDER SECTION 553 OF THE APA

Although not a basis for the District Court's summary judgment finding, the USPTO asks this Court to provide an advisory opinion as to whether Section 2(b)(2)(B) mandates that all USPTO rules are to be subject to notice and comment under the APA. While not material to the District Court's determination that the Final Rules are substantive, there is no merit to the USPTO's argument at all.

In its ruling, the District Court noted that "[w]hile Section 553 of the APA ordinarily requires notice and comment rulemaking only when an agency intends to promulgate a substantive rule, notice and comment must occur when required by statute." (JA. 12-13.) Noting that the "various provisions of Section 2(b)(2) are joined by an 'and,' and not an 'or,' the District Court found that the "USPTO may establish regulations, not inconsistent with law, that govern the proceedings in the

Office, *and* that the rules must be made in accordance with 5. U.S.C. § 553." (Id. (emphasis in original).) In short, the District Court found that "the USPTO must engage in notice and comment rulemaking when promulgating rules it is otherwise empowered to make – namely, procedural rules." (Id.) The USPTO, on the other hand, argues that Section 553 "expressly provides that notice and comment is not required for interpretive or procedural rules," and the "directive in Section 2(b)(2)(B) to issue rules 'in accordance with' Section 553 can only be understood to incorporate all of the provisions of Section 553, including the exceptions." (USPTO Br. 39– 40.)

The USPTO cites to Edelman v. Lynchburg College, 535 U.S. 106, 114 n.7 (2002), as providing support for its assertion that the language in Section 2(b)(2)(B) "issued in accordance with section 553 of Title 5" makes both the affirmative requirements and exceptions of section 553 applicable to rulemaking. Edelman is distinguishable, however, because it does not deal with such a statutory scheme, but instead with Section 713(a) of Title VII, which specifically provides the regulations be "in conformity with the standards and limitations" of the APA. Id. at 114 n.7 (emphasis added). Thus, it is not surprising that the Court looked at the exceptions of Section 553(b).

The linchpin of the USPTO's position is that Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) provides that not every rule issued by the

USPTO can be said to be subject to public notice and comment under Section 553 as such a read would vitiate the exceptions of Section 553. Tafas is aware that the Federal Circuit in Cooper adopts the reasoning of Animal Legal Defense Fund to find that a certain "interpretative rule" related to USPTO procedure as exempt from the formal notice-and-comment requirements of Section 553 of the APA. Cooper, 2008 WL 3842893, at *11. However, Tafas is also aware that the parties in Cooper did not fully brief the issue of 35 U.S.C. § 2(b)(2)(B), and respectfully urges the Court to revisit this issue in light of the legislative history (discussed below) surrounding the enactment of Section 2(b)(2)(B) of this provision.

The problem with the USPTO's argument invoking Animal Legal Defense Fund is that it involved a regulation issued by the USPTO under former statute 35 U.S.C. § 6, the predecessor statute to Section 2(b)(2). Section 6 did not include the specific limitation that the regulatory power provided by Section 2(b)(2) be "made in accordance with Section 553 of title 5." That is, 35 U.S.C. § 6 did not have the language "shall be made in accordance with section 553 of title 5" found at section 2(b)(2)(B). Section 2(b)(2)(B) was added when the rulemaking authority of the USPTO under 35 U.S.C. § 6 was moved to 35 U.S.C. § 2 by the American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4712, 113 Stat. 1501 (codified as amended in scattered sections of 35 U.S.C.).

Unlike the situation in International Brotherhood of Teamsters v. Pẽna, 17 F.3d 1478, 1486 (D.C. Cir. 1994), in which case similar language was found in both the amendment and the originally promulgated provision, the language of Section 2(b)(2)(B) was added by Congress to the rulemaking powers of former 35 U.S.C. § 6. Thus, the Court is bound to investigate the Congressional intent upon which such language was added.

It is a tenet of statutory interpretation that material added to a statute must have meaning. United States v. Bombardier Corp., 380 F.3d 488 (D.C. Cir. 2004) ("a cardinal principle of statutory construction [is] that a statute ought, upon the whole, to be so construed that if it can be prevented, no clause, sentence or word shall be superfluous, void or insignificant"), quoting Alaska Dep't of Envtl. Conservation v. EPA, 540 U.S. 4671 n.13 (2004). The Supreme Court has noted that "[w]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." Stone v. INS, 514 U.S. 386 (1995).

The fact is, Congress felt it necessary to add Section 2(b)(2)(B) to the language of former 35 U.S.C. § 6, which had long been read by the courts to allow only for procedural rulemaking authority, and which section the USPTO had long maintained did not subject its rulemaking to the need for notice and comment under the APA. The addition of Section 2(b)(2)(B) cannot be read as simply a

recitation of the *status quo*. The District Court's studied reading of Section 2(b)(2)(B), as promulgated after the passage of the American Inventors' Protection Act, properly and persuasively interpreted all rulemaking under Section 2(b)(2) as subject to public notice and comment under Section 553 of the APA.

This interpretation is clearly supported by the legislative history of the American Inventors' Protection Act, which evidences a Congressional intent to require that the USPTO provide the public with a meaningful comment period regarding any proposed regulation. In the initial House Report of the American Inventors Protection Act of 1999, the language of Section 2(b)(2)(B) as introduced was to be that the USPTO may establish regulations which "shall be made after notice and opportunity for full participation by interested public and private parties." (H.R. Rep. No. 106-287, Reported in House, at http://thomas.loc.gov/cgi-bin/query/z?c106:H.R.1907:). This language was subsequently changed to "shall be made in accordance with Section 553 of Title 5" in H.R. Rep. No. 106-287, Engrossed as Agreed to or Passed By House, at http://thomas.loc.gov/cgi-bin/query/z?c106:H.R.1907:. There is nothing in the legislative history record to suggest Congress intended by such change to broaden the originally introduced language in any manner. This change was certainly made to provide the appropriate cite to the APA for notice and comment rulemaking. If Congress, had desired to extend the exceptions of Section 553 of Title 5 to such USPTO

rulemaking powers, it could easily have done so, for example, in specifically reciting that such limitations applied (as was the case of Edelman v. Lynchburg College, cited by the USPTO, and discussed *supra*).

The USPTO attempts to get around the language of Section 2(b)(2)(B) that further restricts its rulemaking power to notice and comment rulemaking, by urging the Court that the exceptions of Section 553 apply to any rulemaking under 35 U.S.C. § 2 including the exception for "agency procedure or practice." (USPTO Br. 39.) In effect, it suggests that if the USPTO is only permitted to make procedural rules, then all of its rules need not go through notice and comment as set forth in the exceptions of Section 553(b). Of course, this is sheer nonsense. As noted by Judge Cacheris, if "Congress … alter[s] fundamental details of a regulatory scheme – it does not … hide elephants in mouse holes." (JA. 13, citing Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 469 (2001).)

The USPTO's argument that Judge Cacheris's reading of Section 2(b)(2) would require a "Regulatory Flexibility Act analysis when it engages in a ministerial rulemaking to change its address and phone number" (USPTO Br. 40) is a red herring. First, the USPTO can always assert an exception to the Regulatory Flexibility Act, which undoubtedly would be on extremely sure ground with respect to a change in address and phone number. Second, 5 U.S.C. § 553(a) makes clear that the APA does not concern "a matter relating to agency

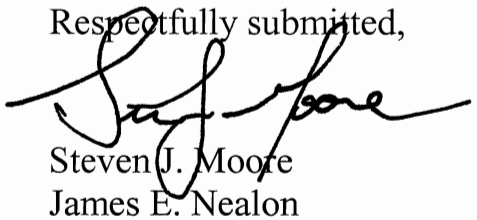
management or personnel or to public property, loans, grants, benefits or contracts." Clearly a phone number and address would relate to agency management. Further, the USPTO's argument that the "district court's conclusion is also at odds with 35 U.S.C. § 3(a)(2)(B), which requires the USPTO to consult with the Patent and Trademark Public Advisory Committees before changing or proposing to change regulations subject to § 553 notice and comment," is simply a non-sequitor. The mandate of 35 U.S.C. § 3(a)(2)(B) simply has no impact on the manner in which 35 U.S.C. § 2(b)(2)(B) should be read. The statement "subject to the requirement to provide notice and ... public comments under section 553 of title 5" modifies the whole clause before it. Clearly, "budgetary proposals" specified in such clause do not equate to rulemaking and would not be subject to Section 553 of Title 5. In short, the USPTO's argued "inconsistency" is simply not there.

For all the foregoing reasons, the USPTO is required to provide public notice and comment under the APA for its rulemaking under Section 2(b)(2) of the Patent Act.

VI. CONCLUSION

For the reasons discussed above, the District Court's grant of Plaintiff-Appellee Tafas's summary judgment motion was not in error, and should be affirmed.

Respectfully submitted,



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