UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

TRIANTAFYLLOS TAFAS, Plaintiff, **v.** **JON. W. DUDAS, *et al.*,** Defendants.	**1:07-cv-846 (JCC)**

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, *et al.*, Plaintiff, **v.** **JON. W. DUDAS, *et al.*,** Defendants.	**1:07-cv-1008 (JCC)**

MEMORANDUM OF *AMICUS CURIAE* RON D. KATZNELSON IN SUPPORT OF PLAINTIFFS MOTIONS FOR SUMMARY JUDGMENT

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1 INTEREST OF AMICUS CURIAE

I, Ron D. Katznelson of Encinitas, California, *pro se*, submits this brief as *amicus curiae* in support of the Tafas and GSK plaintiffs' motions for summary judgment. I am an engineer, an inventor, an independent entrepreneur and a user of the U.S. patent system for more than two (2) decades. As an inventor and co-inventor for 25 U.S. patents and pending applications, I depend on patents and on the patent application process for protecting my inventions. I will be directly harmed by these rules, as will many other small entities. My technology based business prospects depend in large degree on the ability to compete and exploit my own innovations under protection provided by the patent system. My abilities to profit from my own creations and ability to obtain investment capital to turn future inventions into useful products will be significantly compromised under these rules.

2 OVERVIEW

Plaintiff's are seeking to permanently enjoin or otherwise vacate the United States Patent and Trademark Office's ("USPTO") new rules on continuations and claims[1] ("New Rules"). This brief addresses only two aspects in support of Plaintiff's summary judgment motion. The first is the fundamental deficiencies of the USPTO's economic impact analysis of the New Rules and its improper certification under the Regulatory Flexibility Act ("RFA") that the New Rules under review in this case would have no significant economic impact on a substantial number of small entities.[2] The USPTO also published a study in support of its certification under the RFA ("RFA Study"). Unfortunately, the RFA Study and the new rules were not subject to public comment. The RFA Study is replete with errors and flawed analysis that renders the USPTO's certification invalid, thereby violating the RFA. In failing to correctly consider important aspects of its Rule's impact, the USPTO also violated the Administrative Procedure Act ("APA"). The second aspect discussed in this brief is the fact that alternatives to reduce USPTO workload were

[1] 72 *Fed. Reg.* 46716, (Aug 21, 2007).
[2] 5 U.S.C. § 605(b).

proposed but silently rejected by the USPTO without a cogent discussion in the Notice of Final Rulemaking. The APA requires that the USPTO study, evaluate and address during the rulemaking process and ***prior to*** promulgation of its rules, proposed alternatives to its rules for achieving its goal of reducing workload burdens. The USPTO failed to do so and therefore violated the APA

3 STATEMENT OF FACTS

I have submitted a supporting Declaration (Exhibit 1), hereinafter "Dr. Katznelson Decl." setting forth my interest in the case, as well as providing factual account of certain communications I had with USPTO officials and submissions to Office of Management and Budget ("OMB"). In the interest of brevity, I beg leave to incorporate the factual statements made in the appendices herein by reference, to the extent that any party should subsequently elect to challenge as "material" any of the factual matter contained therein.

4 DEFECTS IN THE ECONOMIC IMPACT ANALYSIS PROVIDED BY THE USPTO

The detailed analysis attached (Exhibit 1, Dr. Katznelson Decl. Appendix E) shows that the USPTO's impact analysis was woefully deficient. The economic impact analysis was provided in the USPTO's Regulatory Flexibility Act Study it published after the New Rules were issued, (the "RFA Study")[3]. The RFA Study grossly understated the number of small entities affected by the Claim Limit Rule (Appendix E §3.1) by asserting that only 1% would be impacted by this rule rather than 24% to 30% as plainly evident from the record. The RFA Study failed to identify fundamental factors that govern the costs of preparing the ESD and grossly underestimated these costs (Appendix E §3.2). It is shown that the RFA Study's method of annualizing ESD costs is fundamentally flawed because it assumes that small entities file only

[3] USPTO, *Certification Analysis Under The Regulatory Flexibility Act*, by ICF International, (A08270-A08306)
Only an August 28, 2007 version was published at
http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrcertificationanalysis.pdf.

one patent application per 20 years, when in fact small patenting entities file an estimated average of 1.2 applications per year (Appendix E §3.3). The RFA Study ignored the economic burdens of rebutting the presumption of patently indistinct claims and assumed that such costs are zero when in fact estimates show that the average cost per small entity application filed would be in excess of $4,200 (Appendix E §3.44).

The USPTO failed to analyze or consider other "important aspects of the problem". It ignored the rapid rise of the fraction of applications that would be affected by the New Rules (Appendix E §3.5.1), the disproportionate adverse impact on small entities (Appendix E §3.52), the disproportionate adverse impact on emerging growth industry segments (Appendix E §3.5.3) and the disproportionate adverse impact on domestic inventors, negatively affecting U.S. competitiveness (Appendix E §3.5.4). All of these factors are important aspects of the problem to which the USPTO was alerted during the comment period.

An agency rule must be set aside if it is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A). The opinion in *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) indicated several categories that are considered arbitrary and capricious:

> "[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made. In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors... Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies: We may not supply a reasoned basis for the agency's action that the agency itself has not given.". (Citations and quotations omitted).

"Arbitrary and capricious" review is non-deferential when an agency has failed to "cogently explain why it has exercised its discretion in a given manner," failed to address alternatives, or failed to address all relevant factors. See *Id.*, 463 U.S. at 47, 48, 57.

5 THE USPTO PROVIDED MISLEADING, INCOMPLETE AND ERRONEOUS INFORMATION IN ITS CERTIFICATION UNDER THE REGULATORY FLEXIBILITY ACT.

5.1 The USPTO improperly certified its initially Proposed Rule under the RFA.

On November 25, 2005, the USPTO sent a letter to SBA Advocacy certifying under 5 U.S.C. § 605(b) of the Regulatory Flexibility Act ("RFA") that the proposed continuation rule subsequently published in the Continuations Notice of Proposed Rule Making[4] ("Continuations NPRM") would not have a "significant economic impact on a substantial number of small entities." The USPTO produced this letter in its Administrative Record, (A07325). In a related proceeding, the Examination of Claims Notice of Proposed Rulemaking was published on the same day[5] ("Claims NPRM"). However, for reasons it failed to explain, the USPTO did not produce in its Administrative Record a similar certification letter for the Claims NPRM, although the Federal Register notice indicates that such a letter was sent to SBA Advocacy.[6]

In the RFA section of the Claims NPRM[7], the USPTO stated what might have been presented to SBA Advocacy in such a letter. It stated that only 1.3% of small entities' patent applications contain more than 10 ***independent*** claims and arrives at its certification conclusion merely on the basis of its statistics on independent claims. But its proposed rule was ***not*** based only on the number of independent claims. Rather, it required applicants to designate 10 ***representative*** claims (independent and dependent) for examination in order to avoid submitting an ESD. Therefore, contrary to the USPTO RFA statements, under the Claims NPRM, every application submitted with more than 10 ***total*** claims would have required a submission of an ESD or

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[4] USPTO, Notice of Proposed Rule Making "*Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*", 71 *Fed. Reg.* 48, (January 3, 2006).
[5] USPTO, Notice of Proposed Rule Making, "*Changes to Practice for the Examination of Claims in Patent Applications*", 71 *Fed. Reg.* 61, (03 January 2006).
[6] Claims NPRM, at 66, Col, 2.
[7] Id.

cancellation of claims or investment in deciding which claims to designate as representative.

The USPTO failed to disclose that applications having more than 10 total claims contain an average of nearly 25 dependent claims from which to decide designation and that the top 20% of all applications have an average of 48 dependent claims from which to decide designation[8]. The USPTO misled SBA Advocacy onto a false statistical garden path of independent claims, when its RFA analysis should have disclosed that 80% of small entity applications have more than 10 total claims and therefore would be affected by the Claims NPRM.[9] The USPTO chose to focus only on independent claims, arbitrarily and capriciously concluding without any basis that the cancellation of dependent claims is somehow "economically insignificant" or that the designation decision time is insignificant[10]. Moreover, the Claims NPRM makes no mention of any statistical data pertaining to the number of dependent claims in applications or the decision of the USPTO to treat dependent claims as "economically insignificant" intellectual property assets. Consequently, it denied SBA Advocacy, OMB and the public the opportunity to scrutinize, analyze and comment on such critically relevant information and assumptions.

To the extent that the USPTO argues that its New Rules is a "logical outgrowth" of the Claims NPRM, it violated the RFA by withholding key information about the number of dependent claims in applications and by failing to disclose and explain its criteria holding dependent claims as having insignificant economic value.

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[8] Calculations based on the detailed joint claim distribution in applications filed during FY 2004 (A03554) shows that the average number of dependent claims within applications having more than 10 total claims is 24.8 dependent claims and that 20% of all applications have more than 28 dependent claims wherein the average number of dependent claims over this top set is 47.7.

[9] USPTO's internal memorandum, (A04550) ("Of the 154.145 nonprovisional applications field in the first and second quarters of FY 2006, 121,905 (79%) have more than 10 total claims but only 1.664 (1.08%) have more than 10 independent [claims]".

[10] Had the USPTO acknowledged that 80% of all applications required applicants to perform legal work just for making the claim designation decision, it would have had to conclude that the proposed rule must be designated as "Economically Significant" under EO 12,866 – an obligation it evaded by this omission. Evidence that USPTO knew it falsely evaded the Economically Significant designation can be found in an internal memorandum (at A04552), where the USPTO acknowledged that the economic impact of just designating the 10 representative claims would exceed $100M.

5.2 USPTO's RFA Study failed to meet its own agency guidelines for RFA compliance and the Federal Information Quality Act.

The Department of Commerce, the USPTO's parent agency, has issued department-wide guidelines for compliance with the RFA.[11] Among other items, the guidelines direct the USPTO to compare the costs of compliance for small and large entities to determine whether any small entities are disproportionately affected. The guidelines state that:

> Disproportionality. Do the regulations place a substantial number of small entities at a significant competitive disadvantage to large entities? If the answer is "Yes," the rule ***should not be certified.*** (Emphasis added).

The RFA Study failed to make such comparison in every instant. The USPTO claims distribution data shows that small entities are 40% more likely than large entities to be impacted by the Claims Limit Rule by the USPTO's own impact criterion (Appendix E §3.52).

Relying on facially wrong analysis in virtually every aspect it addressed and not submitting it to peer review or public comment, the RFA Study violated the Federal Information Quality Act[12] and USPTO's own guidelines for Information Quality.[13]

5.3 The USPTO improperly certified its New Rules under the RFA.

From the previous section, it is clear that in essentially every category, the RFA Study understated the economic impact of the New Rules. The analysis in Appendix E show that

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[11] Department of Commerce, *Guidelines For Proper Consideration Of Small Entities In Agency Rulemaking*, available at http://www.ogc.doc.gov/ogc/legreg/zregs/guidelines.htm .

[12] Pub. L. 106-554, Section 515.

[13] USPTO, "Information Quality Guidelines," online at http://www.uspto.gov/web/offices/ac/ido/infoqualityguide.html . Note particularly the "Objectivity" section under the "Quality" heading. ("In a scientific, or statistical context, the original or supporting data shall be generated, and the ***analytical results shall be developed, using sound statistical and research methods.*** If the results have been subject to formal, independent, external peer review, the information can generally be considered of acceptable objectivity").

(a) The 5/25-Claim limit rule will have a significant economic impact on a substantial number of small patenting entities.

(b) The requirement to identify and rebut a presumption of patently-indistinct claims will have a significant economic impact on a substantial number of small patenting entities.

The RFA Study effort partakes of an artifice to feign good faith, statutory compliance. However, the USPTO did not comply with the statute and should not have certified the New Rules under Section 605(b) of the RFA. Nevertheless, on July 10, 2007, the USPTO sent a letter to SBA Advocacy certifying under 5 U.S.C. § 605(b) of the RFA that the New Rules would not have a "significant economic impact on a substantial number of small entities." The USPTO produced this letter in its Administrative Record, (A08307). The USPTO knew that it provided incomplete and misleading information in its RFA analysis of the Claims NPRM. Moreover, it was specifically aware of the fact that even a preliminary consideration of its available data on the number of total claims in applications would preclude it from an RFA certification and require it to perform the full economic regulatory impact analysis under the RFA. Based on the evidence in the record for the second certification, SBA Advocacy was unaware that 24%-30% of small entity applications have more than 5/25 claims. It was told that only 1% would be affected and had no other information that might have alerted it.

The RFA as amended in 1996 affords considerable discretion in formulating an appropriate remedy for the USPTO's failure to comply with the statute. In granting relief for a violation, a court may take corrective action which includes remanding the rule to the agency and deferring enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest. 5 U.S.C. § 611(a)(4).

6 A CREDIBLE AND EFFECTIVE ALTERNATIVE REGULATORY APPROACH WAS PROPOSED BUT SILENTLY REJECTED BY THE USPTO WITHOUT COGENT DISCUSSION IN THE FINAL NOTICE

The APA requires that the USPTO study, evaluate and address during the rulemaking process and ***prior to*** promulgation of its rules, proposed alternatives to its rules for reducing its workload burdens. The USPTO was aware of specific proposals that were neither frivolous nor out of bounds for reducing examination workload by a substantial factor and therefore had an obligation to consider them.[14] As a member of the Trilateral Patent Office, the USPTO was aware of procedures for *Examination-on-Request* or *Deferred Examination by Default* employed in foreign patent offices such as those in Europe and Japan. In the last decade, the USPTO participated in writing the Trilateral Patent Office's annual statistical reports. This report routinely publishes information showing that under such Examination-on-Request systems, the resulting examination rate is substantially lower than 100%. The report shows that under such examination system, 15% to 40% of applications are never examined.[15] This is due to applicants' voluntary abandonment of obsolete claims prior to examination.

In 2004, Congress provided specific authorization to the USPTO under the Consolidated Appropriations Act of 2004[16] to charge separately for application filing fees and examination fees, thereby enabling USPTO's implementation of *Examination-on-Request* procedures. In discussing Comment 340 in the Final Rules' text, the USPTO admitted that several parties have proposed during the comment period that the USPTO adopt Examination-on-Request or Deferred Examination system in order to reduce its workload. These parties suggested providing

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[14] *Chamber of Commerce of U.S. v. Securities and Exchange Com'n*, 412 F.3d 133, 145 (C.A.D.C.,2005) (concluding that agency's failure to consider an alternative that was neither frivolous nor out of bounds violated the APA).

[15] Trilateral Patent Offices, Trilateral Statistical Report 2005 Edition (2006), available at http://www.trilateral.net/tsr. The examination rate details are available in the top of table in the "Procedures" sheet in the web annex at http://www.trilateral.net/tsr/tsr_2005/web_annex/web_annex.xls (See the EPO and JPO examination rate and compare to the 100% shown for the USPTO).

[16] Pub. L. 108–447, 118 Stat. 2809 (2004). (Provides that 35 U.S.C. 41 shall be administered in a manner that separates user fees to permit deferred payment of examination and search fees).

for automatic deferral of examination, extending the period of deferral, allowing third party requests for examination of deferred applications, eliminating any negative impact on patent term adjustment resulting from deferral, adopting deferral of examination procedures used in other countries such as Japan and Canada, tying the period of deferral to the actual filing date of the application rather than the claimed benefit date, and establishing deferral fees based on the length of deferral.[17] In response, the USPTO only stated: "in view of the comments received on the deferral of examination procedure, the Office is studying whether changes (e.g., the maximum deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate".[18] Clearly, the USPTO ignored the fact that it must act on such suggestions ***prior*** to promulgating its rules. The statement that it would consider such proposal ***in the future*** is unavailing.

The Examination-On-Request alternative was neither frivolous nor out of bounds and the USPTO therefore had an obligation to consider it. *Cf. Laclede Gas Co. v. FERC*, 873 F.2d 1494, 1498 (D.C.Cir.1989) ("where a party raises facially reasonable alternatives ... the agency must either consider those alternatives or ***give some reason*** ... ***for declining to do so***") (emphases changed). The USPTO did neither in the public record.

There is evidence that strongly contradicts USPTO's statement above in its response to Comment 340. The USPTO had not only considered Deferred Examination in some detail (see USPTO presentation of Jay Lucas, A08960, slides 16-19; presentation of John Doll, A08980 pages, 24-25)[19]; but has also selectively sought and received inputs on it from special interest groups in several *Ex Parte* meetings (Dr. Katznelson's Decl. ¶¶ 3, 8-10, Appendix B). In addition, the potential benefits of an Examination-on-Request system were quantified in public comments filed by the undersigned during the second comment period associated with OMB's

[17] New Rules at 46829 Col. 2.
[18] *Id.*
[19] *See also* Jay Lucas' specific request for alternatives at A00253.

review of the New Rules (Dr. Katznelson's Decl., Appendix C).[20] OMB contemporaneously published these comments[21] and the USPTO had an obligation to consider them.

In his July 22, 2006 presentation (A08980), Commissioner John Doll listed the benefits of a Deferred Examination system as follows:

> "Expected Benefits
> - Non-deferred cases will be examined more quickly.
> - The upfront cost of filing will be reduced.
> - Delayed payment of certain fees will allow additional time for applicants to consider the commercial viability of inventions before further expenditure of funds.
> - The Office can devote its time and resources to applications deemed more pressing by applicants
> - ***Pendency will be reduced because some applications will not proceed to examination***".(Emphasis added).

The fact that the USPTO received *Ex Parte* responses to Deferred Examination proposals is corroborated by remarks made in the RFA Study as follows:[22].

> "The USPTO continues to study whether changes (e.g., an increased deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate, but notes that ***patent user groups*** have historically not favored increases in the deferral of examination. ***Therefore***, the final rule does not contain this alternative."

The USPTO admits in the statement above that it relied on undisclosed ***patent user group's*** inputs, which were withheld from the public, to decide that it would forgo an opportunity to reduce its workload. The potential reduction forgone would dwarf any illusory savings the USPTO purported to have from the New Rules. Nowhere in the public record can one find the reasons for the "patent user group" objections to deferred examination, or the reasons for the USPTO's ceding to such purported objections despite its own recognition of the workload reduction potentials, as indicated by Commissioner Doll's statements listed above.

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[20] Letter from R.D. Katznelson to Susan Dudley of June 29, 2007, at 20-22, available at http://www.whitehouse.gov/omb/oira/0651/comments/460.pdf on June 29, 2007,
[21] See OMB's web site at http://www.whitehouse.gov/omb/oira/0651/comments/460.html.
[22] RFA Study, note 3, at 31.

The reasons given to the undersigned by USPTO official Mr. Love and ex-official Mr. Spar for the "user group's" objections were concerns that deferral of examination would result in loss of legal work and reduced professional fees that these "patent user groups" would otherwise receive from their clients (Dr. Katznelson's Decl. ¶¶ 8,9). If so, USPTO's abandonment of such a proposal is perplexing because it should have gone forward with such a system ***precisely*** because the "patent user group" objected to the loss of legal work -- confirming that examiners would also see loss of burdens. Contrary to USPTO's representation in response to Comment 340[23], it withheld critical information related to its consideration and ***decision not to adopt*** an alternative procedure that goes to the heart of reducing examiner workload, authorized by Congress and proposed by several parties during the comment period. This amounts to rulemaking based on *Ex Parte* hidden influence of an interest group or due to other publicly unknown reasons. The evasive and disingenuous statement in the New Rules' text suggesting that the USPTO will consider Deferred Examination in the future makes no sense because it has already done so. *Chamber of Commerce of U.S. v. Securities and Exchange Com'n*, 412 F.3d 133, 145 (C.A.D.C.,2005) (concluding that agency's failure to consider an alternative that was neither frivolous nor out of bounds violated the APA).

To be sure, the USPTO was not required to consider "every alternative ... conceivable by the mind of man ... regardless of how uncommon or unknown that alternative" may be. *Motor Vehicle Mfrs. Ass'n, 463 U.S.* at 51, 103 S.Ct. 2856. Here, however, a specific examination workload reduction alternative was proposed and the USPTO's own statements supported its soundness, making it hard to see how that particular regulatory alternative was either "uncommon or unknown." The undocumented *Ex Parte* conduct in which Examination on Request ideas were presented only to certain interest groups and not to the public as a whole is a serious lapse in USPTO's responsibility to the public to address its workload problems as provided by law. Its failure to disclose that it had considered such measures and rejected them

[23] New Rules at 46829 Col. 2.

for unknown reasons and its obfuscation of the matter in its response to Comment 340 is a clear violation of the APA.

7 CONCLUSION

For the foregoing reasons, *amicus curiae* Ron D. Katznelson supports the issuance of a permanent injunction against the promulgation of the the New Rules.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of December 2007, I will cause a copy of the foregoing Brief of *Amicus Curiae* Dr. Ron D. Katznelson in Support of the Plaintiffs' Motions for Summary Judgment to be sent by electronic mail to the following:

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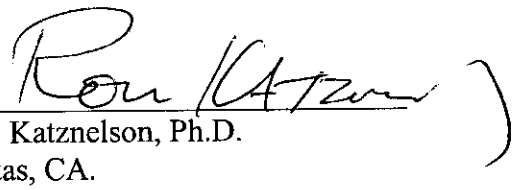
By: 

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